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Title

Understanding rapid infant weight gain prevention: A systematic review of quantitative and qualitative evidence

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Abstract

Background

Rapid infant weight gain is strongly related to childhood overweight and obesity, and prevention of rapid infant weight gain is an approach to early years obesity prevention. This systematic review aimed to explore effectiveness, deliverers' and recipients' experiences of involvement, and key intervention components and processes of such prevention activities.

Methods

Key databases and websites were searched systematically for quantitative and qualitative studies covering intervention effectiveness, experiences with intervention involvement, or process outcomes. After duplicate screening and quality assessment, papers were analysed through narrative synthesis, thematic synthesis and Intervention Component Analysis.

Results

Seven quantitative and seven qualitative studies were eligible for inclusion. Most intervention studies reported small, but significant results on infant weight gain. More significant results were measured on weight gain during the first compared to the second year of life. A weak evidence base made elaboration of the relationship between intervention effectiveness and content challenging. Home-delivered interventions may be more relevant for parents. Contextual factors, such as social norms, beliefs and professional identity should be considered during intervention development. Stakeholder involvement can be key to increase intervention acceptability and feasibility.

Conclusions

The field of rapid infant weight gain prevention is new and evolving, but more research is needed before further conclusions about intervention effectiveness and intervention content can be drawn. Future interventions should take parents, health professionals and other contextual needs into account in order to improve chances of success. More research on long-term effects on overweight and obesity is needed.

Keywords:

Infant, Weight Gain, Pediatric Obesity, Prevention, Systematic Review

Word count (excl. abstract, tables, figures and references): 5.000

Introduction

Rapid infant weight gain (RIWG), frequently defined in the literature as an increase of >0.67 in weight-for-age z-scores (WAZ) between two time points during the first two years of life (1), is associated with an increased risk of childhood overweight and obesity (COO) (1,2) and of having a higher body-fat percentage, greater waist circumference and lower insulin sensitivity in early adulthood (3). COO is an important public health concern as it may have a great impact on the physical and psychosocial health of individuals (4), and early years prevention is needed as weight problems often persist into adulthood (5). Development of effective early years prevention strategies is desirable (6), and preventing RIWG in the first place can be a promising strategy due to its strong and consistent association with COO (1,2).

Early years COO prevention undertaken via prevention of RIWG has received increasing interest over the last decade. Risk factors related to infant feeding have received particular attention (7–9), with a higher protein intake during infancy being causally related to both RIWG and COO (10,11). Increased risk of RIWG has also been associated with a range of other factors such as low birth weight (8), maternal smoking during pregnancy (12), gestational diabetes (12), infant day care attendance (13) and low socioeconomic position (SEP) (12,14). Despite growing interest for early years COO prevention, there is no published systematic review on RIWG prevention. Although finding some intervention effects of COO prevention for school-aged children (6), previous reviews considering evidence on COO prevention initiated at earlier ages have mainly identified small or no effect sizes (6,15), and there is little understanding as to why this is. Furthermore, an umbrella review on childhood obesity prevention has argued that most systematic reviews failed to provide clear recommendations for policymakers (16), making it difficult for decision makers and practitioners to know which interventions to implement (17). Thus, a comprehensive review of the existing RIWG evidence is necessary to identify and understand effective strategies.

We systematically reviewed evidence relating to RIWG prevention with the three following aims: *1) To explore intervention effectiveness, 2) To understand deliverers' and recipients' experiences of intervention involvement,* and *3) To identify key intervention components and processes.* Results from this systematic review will potentially enhance understanding of RIWG prevention activities, as well as support intervention

developers, policy makers and other relevant professionals in identifying effective RIWG prevention strategies that can strengthen early life COO prevention.

Methods

The protocol for this review was registered in the PROSPERO database of systematic reviews (https://www.crd.york.ac.uk/prospero/, ID: CRD42018076214). Quantitative and qualitative evidence was included in the review in order to address both intervention effectiveness and user experiences of involvement. The study is reported in accordance with PRISMA and ENTREQ guidelines (18,19). The review included published and unpublished quantitative and qualitative studies reporting on all types of interventions preventing RIWG in healthy term infants aged 0 to 2 years in high income countries. The restriction in age corresponds to the ages covered in the definition of RIWG presented in the introduction. Studies written in English, Spanish or Nordic languages were included. No restrictions were put on publication year.

Eligibility criteria for quantitative studies

Quantitative studies using differences in infant weight gain between two time points as primary or secondary outcomes were eligible for inclusion. Preferably, RIWG was defined as an increase of more than 0.67 standard deviations in WAZ measured between two time points during the first two years of life (1), but similar definitions using WAZ to capture rapid or excessive weight gain were additionally included. The review included primary experimental studies with randomised, non-randomised, quasi-experimental designs, before-and-after and observational studies reporting on relevant interventions. Eligible studies had to include a control group receiving standard care if appropriate in terms of the study design.

Eligibility criteria for qualitative studies

Eligible qualitative studies included information on intervention deliverers' or recipients' experiences with involvement in interventions that aimed to prevent rapid or excessive weight gain during infancy, or information on intervention development, implementation or evaluation processes of such interventions. All types of qualitative study designs were included.

Search strategy

An initial search in PubMed, MeSH database and CINAHL enabled identification of relevant index terms and text words used to develop the final search strategy that consisted of three blocks: 1) Study population (Infants), 2) The phenomenon of interest (Rapid infant weight gain), and 3) Study designs (Quantitative or qualitative) (Supplementary table S1). PubMed, EMBASE, CINAHL, PsycINFO, The Cochrane Library, Web of Science, and Scopus were searched using this strategy. Reference lists of all included studies were searched for additional studies. Qualitative search filters were used to identify qualitative studies (20). Searches for unpublished studies were conducted in http://www.opengrey.eu/, http://www.greylit.org/, https://clinicaltrials.gov/, https://www.isrctn.com/ and Research Gate using central keywords. A search for additional information related to relevant trials were conducted using http://www.google.com/. The searches for quantitative and qualitative evidence were conducted on the 31 October 2017 and the 13 February 2018, respectively. These searches were rerun on 31 May 2018 in order to identify any newly published research.

Study selection, quality appraisal and data extraction

The processes of study selection, critical appraisal and data extraction were conducted and crosschecked by two reviewers working in duplicate and independently. Bibliographic data from each database were imported into Excel, where duplicates were identified using the filter function. Titles and abstracts were initially screened based on relevance. Relevant records were then screened based on full-text where eligibility criteria decided final in- or exclusion. A third reviewer was included to solve disagreements between reviewers. Based on predefined data extraction forms, data on intervention characteristics, settings, outcomes denoting infant weight gain and adverse outcomes were extracted from quantitative papers, and entire result sections were extracted from qualitative papers. Data on process outcomes and informal evidence were extracted from all papers when identified. Quantitative and qualitative data extraction was performed using Excel and NVivo 10, respectively. Quality appraisal of quantitative studies was conducted parallel to data extraction using Cochrane risk of bias tool for RCTs (21) or the ROBINS-I (Risk Of Bias In Non-randomised Studies - of Interventions) (22), depending on study design. Assessment criteria applied by Rees et al. were used to evaluate quality reliability, trustworthiness and usefulness of qualitative study findings (23), as these are

suitable for appraisal of qualitative evidence comprising evaluations of intervention processes (23,24). Use of qualitative study findings in review analyses was weighted based on appraisal. No study was excluded based on poor quality.

Synthesis of included studies

Quantitative evidence on intervention effectiveness was presented in a narrative synthesis that included information on study quality, outcome measures, timing of measurements and effects. Qualitative data on end-users' and intervention deliverers' experiences of intervention involvement were analysed through thematic synthesis as described by Thomas and Harden (25). This was conducted due to a need for translation of concepts across occasionally thin descriptions (19,25). The process of analysis was carried out in NVivo 10 in three steps: *1) Identification of initial codes, 2) Development of descriptive themes, and 3) Development of analytical themes.* Identification of 37 initial codes led to the development of five descriptive themes and further elaboration enabled identification of three analytical themes (Supplementary figure S1). An intervention component analysis (ICA) integrated evidence from all included studies in order to describe and analyse key intervention features and implementation processes (17). Intervention features and processes were in each study identified through line-by-line coding and presented in a table, where each intervention or intervention arms were presented as individual cases. Thematic synthesis findings guided identification of relevant features and processes, but additional features were inductively identified in the coding process. Further elaboration of feature and process significance were conducted by integrating informal evidence, defined as authors' accounts and reflections on intervention content, components and processes found in discussion sections (17).

Results

Search results

1957 quantitative studies of which 689 were duplicates and 1036 qualitative studies of which 379 were duplicates were retrieved in the literature search. 67 quantitative studies including three RCTs were excluded after full-text screening for not comprising an intervention (n=47), not having published results at the time

(n=7), being trial doublets (n=6), not applying eligible outcomes (n=6), and being conducted in an underdeveloped country (n=1). 10 qualitative studies were excluded for not being related to any relevant intervention (n=5), not including qualitative data (n=4) and being a doublet of included work (n=1). Seven quantitative and seven qualitative studies, all published in English, were deemed eligible for inclusion (Figure 1). Study characteristics are presented in Table 1.

Narrative synthesis of quantitative evidence

Four individual behaviour change interventions (26–29) and three non-behaviourally focussed or mixed interventions (11,30,31) were identified. Three different outcomes denoting changes in infant weight gain were identified; mean change in WAZ (11,26,27,31), an increase in WAZ of >0.67 (26,27,30) and conditional weight gain (CWG) scores (28,29), as explained by Griffiths (32). All studies, except for *The TOTS Trial* (31), reported positive intervention effects on at least one outcome. Change in infant weight gain was most frequently measured around the age of 0 and 12 months (11,26–28,30). Two studies reported changes between 0 and 24 months (11,31) and three studies between 0 and 6 months (11,27,29). All studies measuring changes between 0 and 6 months reported significant intervention effects (11,27,29), while significant effects were reported in four of five studies measuring changes between 0 and 12 months (11,26,28,30) (Table 2).

None of the studies that measured changes between 0 and 24 months reported significant intervention effects. In the three-armed *SLIMTIME Pilot Study*, significant intervention effects were only observed for the sleep/soothe intervention group when compared to controls (28). The three out of seven studies reporting on possible adverse outcomes did not observe any adverse effects such as insufficient weight gain and downward centile crossing (26–28) (Supplementary table S2). The risk of bias in the included studies varied from low to moderate/high across studies (Table 1). Inadequate confounder control, deviations from intended intervention, bias in the selection of participants and in relation to missing data were the most common reasons for lower study quality (Supplementary table S3).

Thematic synthesis of qualitative evidence

Five qualitative studies were associated with three of the included intervention studies (33–37) (Table 1). One of these was a doctoral dissertation that included a process evaluation of *The NOURISH RCT* (36). Six studies were included in the thematic synthesis as they contained relevant data on end-users' and intervention deliverers' experiences in relation to intervention involvement (33,34,36–39). One study contained process-related quantitative data only and was thus not included in the thematic synthesis (35). Study quality varied from low/moderate to high across studies and study findings were weighted accordingly in the synthesis (Table 1). Most studies provided appropriate information on sampling strategy, study participants and method of analysis. However, common limitations were lack of transparency in how data supported study findings, lack of data collection tool piloting and lack of both breadth and depth in the presentation of study findings (Supplementary table S3).

1) Factors affecting parental acceptance and involvement

General misconceptions on infant feeding and growth were observed across studies. Common misconceptions include: all infancy weight gain equals health (33,34,37,39) and infants cannot be overfed or obese (34,39). These beliefs, together with the social environment (family, friends and health professionals), influence which parental practices are socially accepted and performed (37,39). Performance of parental practices that are less socially accepted or not seen as medical gold standard, e.g. bottle-feeding, could lead to parents being judged or stigmatised by their social environment (33). *"…it's like other parents looking down on you, that are breastfeeding, I found that that was a major thing. If I went to any baby groups, I'd try and make sure that she'd already had a bottle.*" (33 p. 4, Bottle-feeding mother). As such, it can be challenging for parents to accept and comply with RIWG interventions that promote practices that conflict with social norms, e.g. not always using feeding as the first response to infant crying, reducing formula-milk intake or preventing excess infant weight gain in general. Conversely, feeding formula can reduce parental anxiety, as parents are able to control the amount of formula given and, thus, better distinguish reasons for infant crying (39).

2) Factors affecting the intervention deliverer and recipient interaction

New parents' ability to participate in RIWG prevention can be reduced due to multiple commitments to family, work and other life events (36). Frustration of receiving conflicting and non-individualised information, guidance and support from different health professionals were also reported (33,34). This can indicate that parents value flexible and individually tailored interventions involving consistent messaging. Home visits can be an ideal delivery form, but it might be important for intervention acceptance that delivery agents are already familiar to the families (38,39). "*So I think that then when I said someone else would come in after me, some families were not keen to take part.*" (38, p. 8, Health professional). Furthermore, parents reported feeling guilty about bottle-feeding (33,34), which may be why parents involved in *The Baby Milk Trial* especially valued the non-judgmental support given by health professionals involved in the trial (33).

3) Factors affecting health professionals' acceptance and involvement

Health professionals often have time constraints and high workloads, which can challenge their opportunities of delivering RIWG interventions as intended (33,37,38). Effort should also be put on matching intervention activities with health professionals' identities and current practices, as failing to do to can result in compromised fidelity. *"You said to discuss one topic, we ended up discussing them all. Because all of those topics are covered in health visiting anyway, to me it didn't feel right that we talked about diet without exercise and feeding cues."* (38, p. 8, Health professional). Intervention delivery may also be complicated by health professionals' concerns regarding unintended consequences like introducing obesity risk communication too early and starving babies (38). Early life obesity prevention is also perceived as a sensitive topic, thus intervention delivery can be challenging. "*So yes, I feel that I would need more training, because this is such sensitive issues. How do you gently put it to them that they are overweight?(…)*" (37, p. 530, Health professional). Thus, some health professionals may need additional training and support to deliver early life obesity prevention. Additionally, this may apply for health professionals' use of growth charts, as they may be underutilised for checking upward percentile crossing and excessive weight gain (34,37). Some health care settings also lacked specific guidelines for carrying out early overweight risk identification (37), which indicate RIWG prevention being of low priority on higher organisational and political levels.

Intervention component analysis

All included studies were used to identify features and processes with importance for intervention success. Existence or absence of features was mapped across studies and intervention arms (Supplementary table S4). The following sections present further elaboration of relevant features and processes.

Intervention delivery

All studies reporting early effect-measures (≤6 months) presented positive intervention effects. Fewer studies reporting longer-term effect measures (between 0 to 12 months and 0 to 24 months) presented positive intervention results. Infancy is characterised by rapid developmental processes. As such, early initiation of prevention activities can be important for creating lasting changes in parental practices that target RIWG prevention before other practices are strongly embedded into everyday life (29,33). In line with this, early enrolment to The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was associated with lower risk of RIWG compared with infants of parents enrolled postpartum (30). Furthermore, a long time-lag between recruitment and initiation can give parents time to re-evaluate participation during the first months as new parents. This was suggested as an explanation for high attrition rates observed in *The NOURISH RCT* (36). Conversely, early initiation after recruitment may have secured the low attrition rates observed in *The INSIGHT Trial* (29). Moreover, few formal intervention contacts could have led to the high attrition rates observed in *The CHOP Study* (11).

All interventions were delivered individually at home, except from *The NOURISH RCT*, which was delivered through group sessions in a health care setting (26). The high attrition rates observed in this trial may be related to group delivery, as it restricts possibilities of personal tailoring compared with individually delivered interventions, which were identified as important by parents in thematic synthesis findings. Group delivery may also challenge parents need for flexibility, as they are required to travel and meet at a certain time and place.

Intervention content

Most interventions were multifaceted. Providing responsive parenting training was a recurrent component (26–29). Increasing parental responsiveness in feeding situations may be important, as parents, supported by peers and grandparents, could overattribute hunger as explanation for crying (39). Thus, some parents need to strengthen their ability to explore alternative explanations for infant distress as a means to prevent overfeeding and excessive weight gain. In two effective interventions, growth charts were used to communicate early life obesity risks (27,29). This strategy might be effective, as some parents have poor abilities to, and few concerns about, recognising and acknowledging their own child's obesity risk (39). Such risk communication should be combined with culturally relevant education and support on infant feeding and growth in order to have the most impact (37). However, thematic synthesis findings indicate that some health professionals would need additional training on how to use growth charts for such purposes. The variability in intervention components applied and how these are combined weaken the evidence base on effective component combinations, although most studies reported some positive intervention effects.

Intervention development

Higher attrition rates were observed in less educated, younger and single parents in several trials (11,26,28,29). These are population groups associated with the highest prevalence of RIWG (40), and attrition in high-risk groups contributes to existing uncertainties about how RIWG interventions actually work for groups with the greatest need for these initiatives. Low risk perception, lack of subject prioritisation, lack of time and resources needed to commit to interventions, and high expectations of negative experiences of participating have been suggested as reasons why there is low interest in intervention involvement in these groups (36).

Increasing interest may be achieved by involving deliverers and recipients in development processes. This was performed in *The Baby Milk Trial* (34,35), which resulted in trial communication messages focussing on healthy growth instead of obesity prevention, in addition to emphasis on delivery through a client-centered and non-judgmental communication style (35), and no socioeconomic differences were observed in trial attrition rates (27). Lack of stakeholder involvement may lead to development of interventions that mainly reflect researchers' perspectives, which can appear unfamiliar and meaningless for groups with other life

conditions (36). Consultancy work was also conducted in the formative phase in *The TOTS Trial* (31), which could have contributed to the high participation rates.

Intervention contextual factors

Having health professionals delivering interventions may itself initiate complex processes due to personal and relational factors. Accordingly, it can be important to consider the value parents place upon their health professional relation when designing interventions (39). Relational processes can influence intervention effectiveness and implementation, but they may be difficult to disentangle. For instance, some mothers in *The Baby Milk Trial* were possibly reluctant to tell health professionals that they bottle-fed due to worries of being judged, which could have challenged identification and recruitment of bottle-feeding mothers (33). Identification and recruitment of eligible parents may also be compromised by health professionals' own evaluation of parents' suitability and eligibility, as they may choose not to contact eligible parents if they judge them unsuitable for inclusion (38).

Only *The Baby Milk Trial* was explicitly informed by theory. While informed by social cognitive theory, the trial failed to produce longer term effects (27), and the authors suggest that their use of psychologically-oriented theory could have been inefficient for addressing problem complexity (33). Thus, application of theories with broader foci, such as socio-ecological models (41), may be needed in order to address the complex nature of RIWG. In line with socio-ecological thinking, Guell et al. suggest that changes should be made on higher level determinants defining social norms in order to help parents overcome stress of going against socially accepted practices when preventing RIWG (33). Creating supportive environments on several levels can be key in order to promote intervention effects. This is supported by informal evidence suggesting that future interventions should emphasise building constructive and enduring partnerships and collaborations between health care sectors, professionals and researchers (31,38).

Discussion

Key findings

The application of three different definitions of RIWG and several different timings of measurement challenged elaboration of intervention effectiveness across studies. Most intervention studies reported small but significant effects. All three studies measuring weight gain between 0 to 6 months of age reported at least one significant effect measure, and all but one study with similar measures between 0 to 12 months reported positive effects. Notably, no intervention effects were observed in the two studies measuring weight gain between 0 to 24 months (11,31). This may indicate that included intervention strategies target mechanisms that are of importance for infant weight gain during the first, but not the second year of life. Several of these strategies comprise early infant feeding factors, which may be less relevant for weight gain when infants grow older.

It is, however, unclear if and how short-term effects on weight gain affect later risk of developing COO. Long-term effects on COO risk have been explored for *The CHOP Study* (10) and *The NOURISH RCT* (42,43), where only *The CHOP Study* reported a significantly lower risk of obesity. Interestingly, this study reported significant changes in infant weight gain between 0 to 6 and 0 to 12 months, but not between 0 to 24 months (11), followed by significant lower mean BMI and lower risks of obesity at age 6 years (10). These findings could indicate that provision of formula with reduced protein content, a structural rather than a behavioural strategy, is effective in preventing both increased weight gain in early infancy and obesity in childhood.

Findings from synthesising qualitative evidence showed that parents ideally request tailored, but consistent, support, information and guidance delivered flexibly in a non-judgmentally manner by known relations. Findings from the ICA support the use of home delivery in order to meet these parental needs. A preceding concept paper suggests that home visiting structures can be ideal for obesity prevention delivery due to their potential of being cost-effective and sustainable, as well as reaching low-income infants and families with high-risk of COO (44). These groups can be hard to reach and retain in intervention studies, as shown by social differences in attrition rates across studies delivered at home and in health care settings in the current

review. Exploration and integration of recipient views and requests on intervention delivery resulted in emphasis on a non-judgmental communication style in *The Baby Milk Trial*. This trial showed no social differences in attrition rates, which could suggest that broad involvement of participants in intervention development processes can be essential for keeping different types of participants interested in continued intervention engagement.

The effects of an intervention can potentially be moderated by different contextual factors (45). The great variability in components applied and combinations thereof made it impossible to draw conclusions on how specific intervention features and content were related to effectiveness. However, review results identified some social and contextual factors that could influence intervention effectiveness and implementation processes. Some beliefs and social norms tended to support infant weight gain in general, and a professional focus on promoting sufficient weight gain may overshadow any importance of preventing RIWG. This could work against professional's and parental acceptability of delivering and receiving RIWG prevention activities. Additionally, early life obesity prevention was evaluated as a sensitive topic by some health professionals and this can complicate RIWG prevention delivery. Some health professionals may be anxious about bringing up the topic with parents and thus some may need additional training and support prior to doing so. These challenges indicate that using health professionals as intervention deliverers adds an additional dimension of complexity that should be considered when planning and evaluating such interventions. In general, consideration of social, institutional and community factors should identify barriers that need to be addressed to create environments supportive of RIWG prevention activities. This is essential for intervention effectiveness.

Strength and limitations

Some limitations of the review should be acknowledged. It is possible that relevant results have been missed despite the comprehensiveness of the search. No indexed keywords existed for rapid infant weight gain and using only text words to identify this phenomenon may have compromised the precision of the search. However, using a three-stepped search strategy involving identification of words used in current literature led to identification of a range of relevant text words. Additionally, a search of grey literature enabled

identification of ongoing trials, and relevant trials were tracked during the review process, so the review included the latest research. Nevertheless, the coverage of the search for grey literature may have been insufficient, as few relevant citations were identified and only one of these was eligible for inclusion in the review (36).

The risk of bias varied across intervention studies and were generally higher in community-based interventions (30,31), which could reflect a challenge of reducing bias when intervening in more complex settings. Thus, the evidence on the effect of community-based interventions is weak compared to the evidence on behaviourally focussed interventions. Due to the nature of the interventions, *The CHOP Study* was the only double-blinded intervention (11), however, outcome assessors were blinded in most trials. Attrition bias may compromise the ability to generalise review results onto groups with low SEP. Most interventions were carried out in the US and the UK, and thus generalisability may be restricted to similar contexts. Application of these review findings should be refined and adjusted to the context in which interventions are delivered in order to enhance the probability of intervention success (45,46).

The quality of the qualitative evidence was generally high, but some studies included data of low quality, such as data collected from open-ended questionnaires (36) or data with less transparent audit trails (35). No studies were excluded due to poor quality in order to consolidate as much knowledge as possible on this new and evolving field. Nevertheless, the qualitative evidence was analysed with regard to the critical appraisal in order to enhance the validity of the review findings. Furthermore, validated appraisal tools do not exist for informal evidence which limits our ability to judge the validity of such information. The lack of formal process evaluations of included trials may, however, justify the use of informal evidence, as this type of information may then represent current best evidence (17).

Implications

Several context and process factors were identified as potentially influential on intervention success, such as the significance of early intervention initiation after recruitment for preventing attrition. However, the low number of relevant interventions and the heterogeneity between them leaves uncertainties on how

effectiveness relates to intervention content, components and timing. Most included interventions were initiated after birth, but earlier initiation during pregnancy could have additional value as it widens the window for intervening. Prenatal provision of support and guidance can be important for reducing RIWG risk, as observed in the study of timing of enrolment to WIC (30). Here, infants of mothers enrolled prenatally to WIC, compared to postnatally, were associated with lower RIWG risk. A previous review identified anticipatory guidance as an important strategy for amending early life parental behaviours preventive of COO, such as breastfeeding and timing of introduction to solid foods (47). More research on timing for intervention initiation and intervention content and components are needed to explore how these findings relate to RIWG prevention. An important focus for further research is also to identify the long-term effects of RIWG prevention on COO in order to clarify the value of these prevention strategies as means of early life obesity prevention. Follow-up on recent and on-going trials will hopefully provide such long-term results.

Review findings also indicate a need for understanding the context of intervention delivery and its actors. Certain beliefs and social norms regarding infant weight gain can result in low levels of readiness and acceptability of RIWG prevention activities in both deliverers and recipients. Increasing readiness and acceptability in these key stakeholders can be an important next step to accelerate early life obesity prevention through a focus on preventing RIWG. More research is needed on exploring professionals' needs in terms of additional education, training and support, so the right support can be provided. Furthermore, parental, professionals and organisational values and views should be considered during intervention development processes. This can be accomplished through stakeholder involvement in order to support development of RIWG prevention activities that are meaningful and feasible on multiple levels. Most included studies embraced psychologically-oriented behaviour change theories, thus potentially ignoring the importance of environmental factors. More substantive use of ecological theories during these processes may potentially support identification of important contextual and environmental factors. Applying an ecological lens on RIWG as a problem also implies a focus on undertaking non-agentic and environmental level changes that support lower-level changes (41). As such, more RIWG prevention research should emphasise non-behavioural interventions or public health policy changes.

Conclusion

Prevention of RIWG as a part of early life obesity prevention is a new and evolving research field. The existing evidence base on RIWG prevention is generally weak, though most interventions produced small, but significant changes in infant weight gain. More interventions reported significant results on change in infant weight gain during the first year, compared to the second year of life. Future intervention programs may advantageously offer parents non-judgmental support delivered in a flexible manner by trusted relations, be initiated quickly after recruitment, take into account the norms, values and beliefs operating in the delivery context, and provide a sufficient amount of resources to intervention deliverers, such as time, training and support. Effort should be spent on reaching and sustaining participation of groups in lack of resources. More knowledge on how RIWG prevention affects long-term COO risk is although needed.

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Conflict of interest

None declared

Key points

- Prevention of rapid infant weight gain as a means for early life obesity prevention is a new and evolving field
- Intervention strategies tend to be more effective on infant weight gain during the first year, compared to the second year of life
- Social norms and beliefs about infant weight gain can challenge intervention acceptance
- Parents request tailoring, flexibility and consistency in intervention activities, thus home delivery can be key
- Health professionals' identity and everyday practices should be considered during intervention development if they are used as intervention deliverers

Authors contribution

TAR, GJMT, CO, AMBH and HB and developed the conceptional design of the study and search strategy. TAR conducted the systematic search, supported by an information specialist from Aalborg University Library. The quantitative studies were screened by TAR and KP and the qualitative studies by TAR and GJMT. TAR, KP and JHN performed data extraction and critical appraisal. TAR carried out the analyses with support from GJMT and AMBH. TAR wrote the first draft of the paper, and all authors contributed to the interpretation of data and critical revision of the manuscript. Furthermore, all authors have read and approved the final version and are accountable for all aspects of the work.

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Table 1. Characteristics of included papers

Narrative synthesis and intervention component analysis (ICA)					
Authors, year, country, trial name, study design	**N of participants (% of original sample)**	**Study population, setting and intervention duration**	**Outcome definition and timing**	**Intervention content and delivery agent**	**Risk of bias[a]**
Daniels et al., 2012, Australia, The NOURISH RCT, RCT (26)	N=541 (77.5%)	First-time, generally affluent mothers with mean age of 30 y. Health care. 3 months	WAZ[b] change and >0.67 change in WAZ (binary 1/0) between 0 and 14 mo.	Behaviourally focussed intervention promoting healthy feeding strategies when introducing solids foods. Delivered by dietitians and psychologists	Low to moderate risk
Edmunds et al. 2014, The US, WIC[c], Observational study (30)	N=157.590 (-)	Low income mothers with mean age of 26.6 y. Health care and community. 5 years	>0.67 change in WAZ (binary 1/0) between 0 and 12 mo.	Behaviourally focussed and community-based intervention providing nutritious supplemental foods, breastfeeding support, nutrition education, and medical and social referrals. Delivered by health professionals	Moderate risk
Karanja et al. 2010, The US, The TOTS Trial, Two-armed separate sample pretest–posttest study (31)	N=177 (86.3%)	Mothers from a native population with a mean age of 25 y. Home and community. No information on duration	WAZ change between 0 and 24 mo.	Behaviourally focussed and community-based intervention promoting breastfeeding and reducing sugar-sweetened beverages. Delivered by community workers	Moderate to high risk
Koletzko et al. 2009, Belgium, Germany, Italy, Poland, and Spain, The CHOP Study, RCT (11)	N=635 (55.8%)	General population of mothers with a mean age of 30 y. Home. 12 months	WAZ change between 0 and 3, 6, 12 and 24 mo.	Non-behaviourally focussed intervention providing low or high protein content formulas. Delivered by researchers	Low risk
Lakshman et al. 2018, The UK, The Baby Milk Trial, RCT (27)	N=586 (87.6%)	General healthy formula feeding mothers. Home and health care. 6 months.	WAZ and >0.67 change in WAZ (binary 1/0) between 0 and 6 and 12 mo.	Behaviourally focussed intervention reducing formula-milk intake, promoting responsive feeding, and monitor growth. Delivered by health professionals	Low risk
Paul et al. 2011, The US, The SLIMTIME Pilot Study, RCT (28)	N=110 (68.8%)	First-time, generally affluent mothers with mean age of 27 y. Home. 6 months.	CWG[d] between 0 and 12 mo.	Behaviourally focussed intervention promoting healthy practices in terms of 1) infant sleep and/or 2) introduction to solid foods. Delivered by health professionals	Moderate to high risk
Savage et al. 2016, The US, The INSIGHT Trial, RCT (29)	N=250 (85.9%)	First-time, generally affluent mothers with mean age of 29 y. Home. 10 months	CWG between 0 and 6 mo.	Behaviourally focussed intervention promoting responsive parenting focusing on infant emotional regulation, feeding, active social play, sleep and growth chart education. Delivered by health professionals	Low to moderate risk
Thematic synthesis and ICA					

Authors, year of publication, country	Relation to included trial	Study aim	Informants and data collection	Method of analysis	Weighting of study findings[a]
Guell et al. 2018. The UK (33)	*The Baby Milk Trial*	To explain some of the underlying mechanisms that might have been at play when implementing and participating in the Baby-Milk Trial and shaped its outcome	10 intervention and 9 control mothers and 3 health professionals contributed in 22 individual interviews	Thematic analysis	High
Lakshman et al. 2012. The UK. (34)	*The Baby Milk Trial*	To explore the views of healthcare professionals and bottle-feeding mothers on: 1) the Programme for Healthy Growth and Nutrition during infancy; 2) the trial design for the planned Baby Milk trial and 3) two draft leaflets	10 mothers contributed in 3 focus groups discussions and 8 health professionals and one mother contributed in 9 individual interviews	Hierarchical thematic framework	Moderate to high
Redsell et al. 2010. The UK. (39)	No	To explore UK parents' beliefs on infant's size, growth and feeding behaviour and parental receptiveness to early intervention aimed at reducing the risk of childhood obesity	38 parents contributed in six focus groups	Thematic analysis	Moderate to high
Redsell et al. 2017. The UK. (38)	No	To assess the feasibility and acceptability of using digital technology for Proactive Assessment of Obesity Risk during Infancy (ProAsk) with the UK health visitors and parents	12 parents and 15 health professionals contributed in 27 individual interviews	Thematic content analysis	Moderate to high
Thébaud et al. 2015. Australia (36)	*The NOURISH RCT*	To develop and apply an evaluation framework based on pre-existing effect and process data collected as part of the NOURISH RCT, an obesity prevention research programme starting early in infancy	344 mothers responded to questionnaires that included open-ended questions and health professionals ratings of 293 intervention sessions	Thematic content analysis	Low to moderate
Valencia et al. 2016. The US (37)	Indirectly (WIC population)	To conduct a formative assessment among the WIC population in Southern Arizona, a group with a high percentage of Latino families, to evaluate mothers' perceptions of infants' growth/weight change in early life	34 mothers and 19 caregivers contributed in 7 focus groups and 6 individual interviews were conducted with health professionals	Grounded theory	Moderate
ICA only					
Authors, year of publication, country	**Related to included trial**	**Study aim**	**Informants and data collection**	**Method of analysis**	**Weighting of study findings[a]**
Lakshman et al. 2014. The UK. (35)	*The Baby Milk Trial*	To describe the experience of using the 2008 Medical Research Council's framework to develop and evaluate a theory-based, behavioural infant feeding intervention aimed at preventing childhood obesity, including	Different health professionals and stakeholder-mothers were interviewed using both	Not specified in paper	Low

	benefits and challenges of using this framework	individual and focus group interviews in order to inform intervention development

[a]Based on quality appraisal, [b]WAZ=Weight-for-age z-scores, [c]WIC= The Special Supplemental Nutrition Program for Women, Infants, and Children, [d]CWG=Conditional weight gain

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Table 2. Intervention effectiveness across infant weight gain outcomes	
Mean change in weight-for-age z-score (WAZ)	
Daniels et al. 2012 The NOURISH RCT (26)	Between 0 and 12 months of age: ↓ mean change in intervention (0.06 ± 1.06) compared to control infants (0.22 ± 1.06), p=0.05
Karanja et al. 2010 The TOTS Trial (31)	Between 0 and 24 months of age: No significant intervention effects when comparing Tribe B and C receiving community and family intervention (0.89 ± 1.46) to Tribe A receiving community intervention only (1.57 ± 1.64), p=0.17
Koletzko et al. 2009 The CHOP Study (11)	Between 0 and 6 months of age: ↓ mean change in lower compared to higher protein group (p <0.01, no exact effect estimate provided) Between 0 and 12 months of age: ↓ mean change in lower compared to higher protein group (p <0.01, no exact effect estimate provided) Between 0 and 24 months of age: No intervention effects (0.12, 95%CI [-0.11 to 0.25], p=0.072)
Lakshman et al. 2018 The Baby Milk Trial (27)	Between 0 and 6 months of age: ↓ mean change in intervention compared to control infants (−0.08 95%CI [-0.17 to -0.004]) Between 0 and 12 months of age: No intervention effects (−0.04 95%CI [-0.14 to 0.07])
Risk of >0.67 SD WAZ	
Daniels et al. 2012 The NOURISH RCT (26)	Between 0 and 12 months of age: ↑ risk in control compared to intervention infants (Odds ratio (OR) 1.6, 95%CI [1.1 to 2.4], p=0.008)
Edmunds et al. 2014 WIC (30)	Between 0 and 12 months of age: ↓ risks in infants enrolled to WIC during first trimester (OR 0.76, 95%CI [0.74 to 0.79]), second trimester (OR 0.81, 95%CI [0.78 to 0.84]) and third trimester (OR 0.85, 95%CI [0.82 to 0.89]) compared to infants enrolled postpartum
Lakshman et al. 2018 The Baby Milk Trial (27)	Between 0 and 6 months of age: No intervention effects (OR 0.74 95%CI [0.51 to 1.07]) Between 0 and 12 months of age: No intervention effects (OR 0.84 95%CI [0.59 to 1.17])
Conditional weight gain (CWG) scores	
Paul et al. 2011 The *SLIMTIME Pilot Study* (28)	Between 0 and 12 months of age: ↓ scores in intervention infants receiving sleep/soothe component (-0.394) compared to controls (0.08), p=0.02. No intervention effects of solid food component alone or both components combined compared to controls
Savage et al. 2016 *The INSIGHT Trial* (29)	Between 0 and 6 months of age: ↓ scores in intervention infants (−0.18 95%CI [−0.36 to 0]) compared to controls (0.18 95%CI [0.02 to 0.34]), p=0.004

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Supplementary table S1. Quantitative and qualitative search strategy used in PubMed. Search words in same cell are combined by "OR" and cells are combined by "AND".

Infant	Rapid infant weight gain	Study design
"Infant"[Mesh] Infant [tw] Infants [tw] Newborn [tw] Baby [tw] Babies [tw]	"Rapid infant weight gain"[tw] "Rapid infancy weight gain"[tw] "Rapid weight gain"[tw] "Rapid infant growth"[tw] "Catch up growth"[tw] "Catch up weight gain"[tw] "Accelerated weight gain"[tw] "Accelerated growth"[tw] "Excess Weight Gain"[tw] "Rapid Growth"[tw]	<u>1) In quantitative search strategy:</u> "Clinical Trial" [Publication Type] "Comparative Study" [Publication Type] "Cross-Over Studies" [Mesh] "Evaluation Studies" [Publication Type] "Intervention study"[tw] "Clinical Trial"[tw] "Randomized Controlled Trial"[tw] "Randomised Controlled Trial"[tw] "RCT"[tw] "Comparative study"[tw] "Comparison study"[tw] "Cross-over study"[tw] "Evaluation study"[tw] "Pre-post intervention" [tw] "Before and after study"[tw] "Quasi experimental study"[tw] "Non-randomized"[tw] "Non-randomised"[tw] <u>2) In qualitative search strategy:</u> Interview* [Title/Abstract] Interviews [MeSH:noexp] Experience* [Text Word] Qualitative [Title/Abstract]

Supplementary table S2. Information presented on potential adverse intervention effects.

Paper and trial/project	**Reporting of adverse outcomes**
The NOURISH RCT *Daniels et al. 2012* (26)	*Only 3% (n=15) showed slow weight gain defined as a change in WAZ from baseline to follow-up <- 0.67 with no group effect (P=0.12). There were no differences in length between the groups and the prevalence of slow weight gain was very low (3%) and similar in both groups, indicating no adverse intervention effects on overall growth.* *Overall, our trial adds substantially to this evidence. With a much larger sample our results also indicate that feeding interventions commencing in infancy may have positive effects on anthropometric indicators of future obesity risk with no evidence of adverse effects on growth*.
Timing of enrolment to WIC *Edmunds et al. 2014* (30)	No information
The TOTS Trial *Karanja et al. 2010* (31)	No information
The CHOP Study *Koletzko et al. 2009* (10)	*Whereas adverse effects of higher protein intakes were not of major concern, worries about the deleterious effects of too low an intake of protein (34) prevailed. Considering that the protein content of human milk varies and tends to have a higher biological value than cow milk protein (19), the protein composition of infant formula was designed to always meet the assumed minimum requirements of protein and indispensable amino acids of infants.* *Consumption of the lower-protein formula supported normal length growth, and parental reports did not indicate any untoward effects. Given that the supply of total protein and essential amino acids with the lower protein formula is clearly higher than reference intakes for infants that are regarded as safe (19, 35, 36), one would not expect any untoward effects on growth or functional outcomes, such as neurologic development or immune response. However, further follow-up of the study cohort up to school age is planned to document neurologic and other outcomes.*
The Baby Milk Trial *Lakshman et al. 2018* (27)	*There were no differences in infant safety outcomes between the groups; percentage of infants who crossed centile lines downwards (-0.67SDS) from baseline, change in length (cm) from baseline, change in head circumference SDS from baseline.*
The SLIMTIME Pilot Study *Paul et al. 2011* (28)	*In assessing the safety of the interventions on weight status in terms of sufficiency of weight gain, nine (8.2%) participants had weight-for-age <5th percentile at age 1 year, and 16 (14.6%) had downward crossing of two major percentile lines (Table 4). No significant differences were detected among treatment groups for either definition of insufficient weight gain.*
The INSIGHT Trial *Savage et al. 2016* (29)	No information

Supplementary table S3. Detailed information on quality appraisal of included studies

Qualitative studies								
Assessment criteria		**Redsell et al. 2010** (39)	**Valencia et al. 2015** (37)	**Redsell et al. 2017** (38)	**Lakshman et al. 2014** (35)	**Lakshman et al. 2012** (34)	**Guell et al. 2018** (33)	**Thébaud et al. 2015** (36)
1) Were steps taken to increase rigour in the sampling? **Consider whether:**	*The sampling strategy was appropriate to the questions posed in the study*	Yes, relevant sampling strategy as included settings comprise children with increased risk	Yes, relevant sampling strategy. Latino mothers approached through WIC.	Yes, sampling strategy match the research questions	Unclear	Yes, relevant sampling strategy recruiting formula feeding mothers	Yes, participants recruited from Baby Milk trial	Yes, participants recruited from NOURISH trial
	Attempts were made to obtain a diverse sample of the population in question	Yes, participants are recruited from different centres, but there is a lack of male informant and varying SEP status	Yes, there is some diversity in the sample as women are recruited form two different clinics, although in the same state.	Yes, there seems to be diversity, but health professionals only included the ones themselfs though were "interested"	Unclear	Uncertain, and lacks somehow a broad population (mainly older, white mothers and health professionals)	Yes, intervention mothers, control mothers and facilitators were recruited. However, participants were limited to those recruited by trial originally and from the most recent wave	Yes, attempts were made to follow up everyone who consented to follow up
	Characteristics of the sample critical to the understanding of the study context and findings were presented	Yes, presented in table 3-4	Yes, inclusion is described, and characteristics are presented in tables	No, not explicitly over the qualitative sample, but yes, over all the informants	Unclear	Yes, basic socio-demographics presented	Not presented	Yes, presented in detail (Table 4-6)
2) Were steps taken to increase rigour in the data collected? **Consider whether:**	*Data collection tools were piloted/(and if quantitative) validated*	No information, but the focus group topic guide was revised after each group	Unclear	Unclear	Unclear	No information	No information	No information
	Data collection was comprehensive, flexible and/or sensitive enough to provide a complete and/or vivid and rich description of people's method of data collection used	Yes, assumedly. The groups were not too big or too small, and they were encouraged to express and discuss all views	Yes, the use of focus groups and grounded theory supported this	Hard to evaluate due to the little information given, but the method seems appropriate in related to the questions that parents are asked	Unclear, but a variety of people have contributed	Yes, to some extent as the approach was semi-structured for comprehensiveness but flexible with room for discussions of issues of interest	Yes, assumedly, as the interviews were semi-structured for balance between comprehensiveness and flexibility	Comprehensive but more structured than flexible, only a few open-ended questions
	Steps were taken to ensure that all participants were able and	Yes, information was given, and informed	Yes, they provided dual language focus groups	Yes, informed consent were collected, but some	Unclear	Yes, consent discussed. But no mention of language	Not described	No information

	willing to contribute	consent were collected	and gave gift cards	language barriers occurred		barriers or power relations		
3) Were steps taken to increase rigour in the analysis of the data? **Consider whether:**	*Data analysis methods were systematic*	Yes, methods of analysis are thoroughly described	Yes, both quantitative and qualitative methods for analysis were described	Yes, data analysis methods were described and used systematically	Unclear	Yes, tools were provided in supplementary materials	Yes, thematic analysis, double coded transcripts, developed coding tree	Yes. Thoroughly described in Appendix 10
	Diversity in perspective was explored	Yes, there is diversity, but it could have been better described	Unclear	Little information is given, but the combination of quantitative and qualitative perspectives seems to create diversity in perspectives	Unclear, but a variety of people contributed	Yes, as they looked within and between cases. They also identified outliers which did not fit with the majority view for a certain theme or subtheme.	Yes, constant comparison between cases and on negative cases were performed to ensure rigor in the analysis	To some degree. Differences between consenters, non-consenters and those who could and could not be reached were assessed
	The analysis was balanced in the extent to which it was guided by preconceptions or by the data	No, the analysis was guided by data and not preconceptions in line with its explorative aim	Only guided by data	Somehow unclear, but it tended to only be guided by data	Unclear	Yes, as key themes were identified based on the topic guide and a final list of key themes was achieved through discussion between researchers	Yes, but the analysis was deliberately not based on trial's theoretical framing, but on social practice theory. Codes were developed iteratively	No information
	The analysis sought to rule out alternative explanations for findings	Unclear due to no information	Little effort is performed to rule out alternative explanations	No, not explicitly	Unclear	Yes, outliers were identified, and two researchers read the transcripts and subsequently discussed it	Yes, findings were identified by several reviewers and used constant comparison. Negative cases were sought. Interventions and controls were compared.	No
4) Were the findings of the study grounded in/supported by the data? **Consider whether:**	*Enough data are presented to show how the authors arrived at their findings*	Yes, a suitable amount of data/quotes were presented to support the findings	No, not enough data were presented in order to understand how authors arrived at their findings	Yes, but few quotes were presented	Unclear	Yes, but few quotes were presented	Yes, many quotes were presented	No. Data were only presented quantitatively in the result section but as quotes in appendices
	The data presented fit the interpretation/ support claims about	Yes, data and interpretations tend to fit together	Yes, there is a good fit, but few quotes are presented	Yes, there seems to a good fit	Unclear due to lack of information presented	Yes, quotes support this	Yes, quotes support patterns	Yes, but this is only presented in the appendix

	patterns in data							
	The data presented illuminate/illustrate the findings	Yes, data illustrate the results sufficiently	Yes, the few presented quotes illustrates the findings	Yes, the presented quotes illustrate the findings nicely	Unclear	Yes, quotes support this	Yes, quotes support illustrate findings	Yes, but this is only presented in the appendix
	Quotes are numbered or otherwise identified and the reader can see that they don't just come from one or two people	Yes, informants are numbered and it seems to be a variability of informants represented	No, so there is no way of tracing informants' quotes	Yes, citations are numbered and there seems to be variation in informants that represented	Unclear	Yes, but there are several quotes from mum 04	No, they are only labelled as intervention or control	Yes
5) Please rate the findings of the study in terms of their breadth and depth. **Consider whether:**	*A range of issues are covered*	Yes, topic guide confirms this	Yes, and the findings are presented in a socio-ecological model which illustrates this	Yes, a broad variety of topics concerning acceptability and feasibility are covered	Unclear	Yes, about the program, leaflet and process	Yes, about reasons for and experiences with formula feeding, experiences with participating	The questions are quite narrowly focussed on some topics concerning their evaluation of the intervention
	The perspectives of participants are fully explored in terms of breadth and depth;	There exists some lack of contrast between perspectives, but insight into perspectives are presented	The is a lack of contrasts and insight in the presentation of perspectives	There lacks a bit of breath and depth in the analysis, as the results sometimes appears to be at the descriptive level	Unclear, but tend to be descriptive	Lacks some contrast between and insight into perspectives	Yes, multiple quotes shown under each theme, showing similarities and differences	Hard to evaluate, as the transparency of analysis is low
	Richness and complexity has been portrayed	The findings lack some richness and complexity, as there lacks contrast between perspectives, but literature is strongly integrated	No, results presented are quite superficial	Lacks some richness and complexity as findings are a bit descriptive and could have included more variation	Unclear	Lacks some richness as few quotes and little data are presented	Yes, a rich and comprehensive analysis is presented	Limited richness and complexity in the presentation of findings is mainly descriptive
	There has been theoretical/conceptual development	Yes, as findings are recognised and extends existing literature	Yes, there is some development as new perspectives and needs are identified	Limited	Yes, findings support intervention development	Limited	Yes, as perspectives support the understanding of intervention mechanisms	No
6) To what extent does the study privilege the perspectives and experiences? **Consider:**	*Whether there was a balance between open-ended and fixed response options*	Use of semi-structures focus groups supported a strong focus on open ended questions	Unclear, but there seems to be several open questions	Unclear	Unclear due to lack of information	Yes, semi-structured with room for discussion of other topics. All questions were open-ended	Yes, semi structured questions, open ended	Mostly fixed response options
	Whether informants were involved	No	No	Unclear, but no	Yes, in the overall picture	No information	No information	No information

	in designing the research							
	Whether there was a balance between the use of an a priori coding framework and induction in the analysis	Focus on inductive coding	Mainly focus on induction due to the use of grounded theory	Analysis only guided by content	Unclear due to lack of information	Yes, both use of an a priori coding framework (topic guide) and induction	A balance between induction and social practice theory	Codes were compared to existing list of non-attendance reasons and items from Q8 (appendix 10)
	The position of the researchers	Unclear	No information on researchers' position	Unclear	Unclear due to lack of information	No information	No information	No information
	Whether steps were taken to assure confidentiality and put informants at ease	Unclear due to lack of information	Unclear	Unclear	Unclear due to lack of information	Yes, confidentiality was discussed prior to data collection	No information	No information
7) Overall, what weight would you assign to this study in terms of the reliability/trustworthiness of its findings? **Think (mainly) about the answers you have given to questions 1 to 4 above.**		Moderate to high	Moderate	Moderate to high	Low	Moderate to high	Moderate to high	Low
8) What weight would you assign to this study in terms of the usefulness of its findings for this review? **Think (mainly) about the answers you have given to questions 5 and 6 above and consider:**	*The match between the study aims and findings and the aims and purpose of the synthesis*	High	High	High	Moderate	High	High	Low to moderate
	Its conceptual depth/explanatory power	Moderate	Moderate	Moderate	Low	Moderate	High	Moderate
Overall <u>weighting</u> of study findings		<u>Moderate to high</u>. The reliability of the study findings is evaluated as high, as the analysis is transparently performed with high quality. There is some lack of contrast and	<u>Moderate.</u> The usefulness of study findings is high. However, limited presentation of data/quotes to support findings reduces study	<u>Moderate to high</u>. The reliability and usefulness of study findings seems to be generally high, but there is some lack of depth in the analysis as findings	<u>Low</u>. The study describes authors experiences with using the MRC-framework, and little focus is placed on presenting traditional methodical consideratio	<u>Moderate to high</u>. Overall good quality study producing reliable and important findings, but they are not necessarily generalisable to a wider population	<u>High</u>. Rigorously performed study that produces trustworthy findings useful for understanding participants experiences. But the sample is not	<u>Low to moderate</u>. High quality process evaluation comprehensively performed involving some open-ended questions. However, mostly focused on

	variety in presentations of some of the themes	reliability and trustworthiness.	appear purely descriptive at times	ns on the qualitative findings. However, the usefulness of the few findings presented are high		well described.	quantitative data and lacks transparency of the qualitative data analysis.

Quantitative studies (RCTs)

	Daniels et al. 2012 (26)	**Koletzko et al. 2009** (10)	**Lakshman et al. 2018** (27)	**Paul et al. 2011** (28)	**Savage et al. 2016** (29)
Selection bias: Random sequence generation	A statistician external to the study performed random allocation. A block schedule (four from each assessment clinic) was used to minimise design or cluster effects related to socioeconomic similarities Low risk of bias	Randomisation for each country were stratified by sex and randomly selected based on blocks of 8. No significant differences were seen on background characteristics of intervention groups and controls after randomisations. Low risk of bias	Central telephone randomisation was based on a computer-generated randomisation list. Little information on randomisation. Inclusion of an independent statistician decreases risk of bias. Safe method. Low risk of bias	Randomisation included stratification for maternal pre-pregnancy BMI with two groups, BMI <25 and BMI ≥25. Unclear how this was done. Lacks more detailed information Moderate risk of bias	A research nurse randomised the groups by telephone. Permuted blocks of 6 were used and were stratified on birth weight for gestational age and intended feeding mode. There seems to be some differences between the randomised groups on background characteristics Moderate risk of bias
Selection bias: Allocation concealment	A statistician external to the study allocated individual dyads randomly to the intervention or control group. Low risk of bias	Colour coding only known by the statisticians labelled lower and higher protein formula. Randomisation numbers were drawn from an internet-based platform. The formulas were identically packaged and labelled. Low risk of bias	Central telephone randomisation was based on a computer-generated randomisation list. Little information on randomisation. Inclusion of an independent statistician. Safe method. Low risk of bias	No information provided on this, thus uncertainties. Moderate risk of bias	The research nurse(s) completed randomisation during a telephone call 10 to 14 days post-partum. It is uncertain what this means in practice. Moderate risk of bias
Performance bias: Blinding of participants and personnel. Assessments should be made for each main outcome (or class of outcomes).	The nature of the intervention does not allow blinding of participants and personnel. Moderate risk of bias	All investigators and participating families were blinded. Low risk of bias	The nature of the intervention does not allow blinding of participants and personnel. Moderate risk of bias	The nature of the intervention does not allow blinding of participants and personnel. Moderate risk of bias	The nature of the intervention does not allow blinding of participants and personnel. Moderate risk of bias
Detection bias: Blinding of outcome assessment. Assessments should be made for each main outcome (or class of outcomes).	Staff that collected data were blinded. Low risk of bias	The colour codes were only disclosed to the statisticians performing the final analysis. Low risk of bias	Outcome assessors were blinded for group allocation and trained in not discussing this with parents. Parents were also told not to discuss group allocation with program staff. Low risk of bias	Outcome assessors were not blinded High risk of bias	Staff that collected data were blinded. Low risk of bias
Attrition bias: Incomplete outcome data. Assessments should be made for each	Intention to treat analysis performed. Reasons for non-participation were	Reasons for attrition provided. More low educated parents and	Relatively low levels of attrition. Intention-to-treat analyses conducted.	Some attrition and differences in attrition by study group were	Reasons for attrition were not presented. Imputed analyses

main outcome (or class of outcomes).	reported. Higher attrition in intervention compared to control group. Consenting and non-consenting/completers and non-completing mothers differed in terms of age at deliver, education and civil status. Moderate risk of bias	smokers were lost to follow-up creating some risk for attrition bias. Moderate risk of bias	No differences in baseline characteristics among participants who completed the trial and those who were randomised. Reasons for attrition provided in flow-diagram. Low risk of bias	observed. No report of reasons for drop out, but own suggestions for why was presented. Small sample size makes the study results sensitive to bias by attrition. The attrition rate affects the interpretation of the findings as most dropouts was in the dual intervention group. High risk of bias	performed. Relatively high retention rate, but mothers of infants who withdrew from the study were significantly younger, more likely to be single, had lower education levels and lower annual household incomes compared to those completing the study. Moderate risk of bias
Reporting bias: Selective reporting	Not all outcomes described in the protocol are reported in study Moderate risk of bias	All outcomes are well reported. Low risk of bias	The reported trial outcomes reflect the outcomes stated in the trial protocol. Low risk of bias	No protocol for this trial exists. Relevant outcomes are provided. However, they tend to have collected more data than they actually report on. High risk of bias	Authors only report on certain outcomes listed in the protocol. However, other outcomes are reported in other studies. They report outcomes relevant for this review. Low risk of bias
Other bias: Other sources of bias		They excluded 169 non-compliant children that could have been included in order to perform a proper intention-to-treat analysis. However, exclusion was already fixed in the study protocol.			
The overall judgment	Low to moderate risk of bias	Low risk of bias	Low risk of bias	Moderate to high risk of bias	Low to moderate risk of bias

Quantitative studies (Non-randomised studies)

Assessment criteria Abbreviations: Y = Yes, PY = Probably yes, PN = Probably no, N = No, NI = No information, NA = Not applicable	**Edmunds et al. 2014** (30)	**Karanja et al. 2010** (31)
1. Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? If Y/PY to 1.1, go to question 1.2	PY: Somewhat self-selected groups enrolling in various trimesters/postpartum	PY: "Control group" is artificial and collected two years previously
1.2. Determine whether there is a need to assess time-varying confounding: Was the analysis based on splitting participants' follow up time according to intervention received? If N/PN, answer questions relating to baseline confounding (1.4 to 1.6). If Y/PY, go to question 1.3.	N	PY: "Control group" is artificial and collected two years previously
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? If N/PN, answer questions relating to baseline confounding (1.4 to 1.6). If Y/PY, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)	NA	NI: But probably yes, like socioeconomic status
1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	PY: They adjusted for important covariates like race, age, smoking, pregnancy weight gain, infant sex, gestational age	PN: They do not adjust for covariates in the results, but they adjust for baseline value in z-score
1.5. If Y/PY to 1.4: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	P: Standard demographic factors, but information comes from administrative registries	NI, hard to evaluate

1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	Y: Breastfeeding is included as covariate)	NI
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding?	NA	NA
1.8. If Y/PY to 1.7: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	NA	NA
Bias due to confounding: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Moderate	Moderate/High
2. Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? If N/PN to 2.1: go to 2.4	N: Selection to study based on intervention	Y- pregnancy
2.2. If Y/PY to 2.1: Were the post-intervention variables that influenced selection likely to be associated with intervention?		N
2.3 If Y/PY to 2.2: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?		N
2.4. Do start of follow-up and start of intervention coincide for most participants?	Y: Enrolment to study and intervention were the same	PN: Exposure to intervention differed in relation to type of intervention, as exposure to community intervention started when initiatives were initiated, but individual interventions were only initiated during pregnancy
2.5. If Y/PY to 2.2 and 2.3, or N/PN to 2.4: Were adjustment techniques used that are likely to correct for the presence of selection biases?	PY: Factors between enrolment points assessed and controlled for	N: No information is provided on how infants were recruited. However, they managed to recruit 75% of all babies born during the recruitment year, and 86% of these completed the study. No information given on the pre-test sample in terms of recruitment, so it is uncertain how the applied adjustment techniques corrected for selection bias
Bias in selection of participants into the study: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Moderate	Moderate
3. Bias in classification of interventions:		
3.1 Were intervention groups clearly defined?	Y: Timing of enrolment to WIC	Y: Being part of one of the intervention tribes
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	Y: Time	Y: Tribes
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	N: Enrolment in standard government program	N: Cluster intervention
Bias in classification of interventions: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Low	Low
4. ***Bias due to deviations from intended interventions***		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	NI, but nothing of note	PY: Many more participants in tribe B did not receive all home visits
4.2. If Y/PY to 4.1: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	NA	PY
4.3. Were important co-interventions balanced across intervention groups?	NI, but PN (early enrolment may lead to receiving more or other public services)	NI
4.4. Was the intervention implemented successfully for most participants?	NI	PY: Besides the lower rate of home visits in tribe B. However, reach is a bit compromised in accordance to table 3
4.5. Did study participants adhere to the assigned intervention regimen?	NI	PY: Besides the lower rate of home visits in tribe B
4.6. If N/PN to 4.3, 4.4 or 4.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?	NA	NA
Bias due to deviations from intended interventions: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	NI	Moderate
5. Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?	PN-33% dropout rate (similar to NY WIC program)	Y: 86%
5.2 Were participants excluded due to missing data on intervention status?	N	PN: Cluster intervention

5.3 Were participants excluded due to missing data on other variables needed for the analysis?	NI	NI
5.4 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across interventions?	NI	NI
5.5 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Is there evidence that results were robust to the presence of missing data?	PY: The high number of missing data may have helped to increase robustness, but it is uncertain if there are skewness in missing data across intervention/exposure groups	NI
Bias due to missing data: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Low/Moderate	Moderate/high
6. Bias in measurement of outcomes		
6.1 Could the outcome measures have been influenced by knowledge of the intervention received?	PN: Standard measures, standard program	PN: Standard anthropometric measures. However, the outcome assessors might have known about the project and have favourably measured some children
6.2 Were outcome assessors aware of the intervention received by study participants?	PN: Standard measures, standard program	PY: Community clusters
6.3 Were the methods of outcome assessment comparable across intervention groups?	Y: Same measures applied, standard program	Y: Same measures applied
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	PN: None stated and unlikely	PN: None stated and unlikely
Bias in measurement of outcomes: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Low	Moderate
7. Bias in selection of the reported result		
7.1 Is the reported effect estimate likely to be selected, on the basis of the results, from multiple outcome measurements within the outcome domain?	PN: Outcome defined previously, and the definition is used in other research)	N: All anthropometric measures presented
7.2 Is the reported effect estimate likely to be selected, on the basis of the results, from multiple analyses of the intervention-outcome relationship?	PN: 3 models presented, uncertain if any others used	N: All anthropometric measures presented
7.3 Is the reported effect estimate likely to be selected, on the basis of the results, from different subgroups?	PN	N: Community clusters presented
Bias in selection of the reported result: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	Low	Moderate
Overall bias: **Risk of bias judgement** Low / Moderate / Serious / Critical / NI	**Moderate risk of bias**	**Moderate to high risk of bias**

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Supplementary table S4. Overview of intervention features and processes. Intervention cases are presented according to outcome measurement timing, presenting studies with earliest outcome measurement to the left.

	The CHOP Study (10)	*The Baby Milk Trial* (27)	*The INS-IGHT Trial* (29)	*The NOUR-ISH RCT* (26)	*The SLIM-TIME Pilot Study (Com-bined)* (28)	*The SLIM-TIME Pilot Study (Sleep)* (28)	*The SLIM-TIME Pilot Study (Solid food)* (28)	*Timing of enrol-ment to WIC* (30)	*The TOTS Trial (Com-bined)* (31)	*The TOTS Trial (Com-munity only)* (31)
Intervention effectiveness in relation to timing of outcome measurement										
Between 0-6 months	+	+	+							
Between 0-12 months	+	–		+	+	–	–	+		
Between 0-24 months	–								–	–
Theme 1: Factors affecting parental acceptance and involvement										
Intervention aim to reduce infant food intake		✓								
Intervention aim to prevent excess weight gain		✓	✓							
Intervention aim to prevent use of feeding as only first response to fussiness			✓		✓	✓				
Theme 2: Factors affecting the intervention deliverer and recipient interaction										
Home visits		✓	✓		✓	✓	✓		✓	
Health care setting		✓		✓				✓		
Community setting								✓	✓	✓
Group sessions				✓						
Delivered by HP[a]		✓	✓	✓	✓	✓	✓	✓	✓	
Attrition (%)	44.2	12.4	14.1	22.5	31.3	31.3	31.3	-	13.7	13.7
SEP[b] differences in attrition	✓		✓	✓	✓	✓	✓	NA[c]	NI[d]	NI
Theme 3: Factors affecting health professionals' acceptance and involvement										
Training of HP	NA	✓	✓	✓				✓	✓	NA
Other potentially important intervention features										
Initiation (mo.)	0-2	2.3	1	4-6	0.5	0.5	0.5	Prenatal	Prenatal	Prenatal
Duration	12 mo.	6 mo.	10 mo.	3 mo.	6 mo.	6 mo.	6 mo.	>5 y	NI	NI
N of contacts	NA	5	4	6	2	2	2	Differ	7 to 21	NA
Focus on healthy growth[e]		✓	✓	✓						
Involvement of deliverers		✓								
Involvement of end-users		✓								
Involvement of community									✓	✓
Individual behaviour change		✓	✓	✓	✓	✓	✓	✓	✓	
Environmental change	✓							✓	✓	✓
Explicit theory of change		✓								
Risk of bias	Low	Low	Low/ mod.	Low/ mod.	Mod./ high	Mod./ high	Mod./ high	Mod.	Mod./ high	Mod./ high
Level of intervention										
Infant	✓									
Mother/family		✓	✓	✓	✓	✓	✓	✓	✓	✓
Institutional								✓		
Com./policy								✓	✓	✓
Intervention focus										
Responsive feeding		✓	✓	✓	✓	✓	✓			
Introduction to solid foods		✓	✓	✓	✓		✓	✓		
SSB[f]			✓					✓	✓	✓
Breastfeeding								✓	✓	✓
Reducing protein intake	✓									
Provision of free foods	✓				✓		✓	✓		
Physical activity			✓							
Growth monitoring		✓	✓							
Sleep			✓		✓	✓				

[a]HP = Health professionals, [b]SEP = Socioeconomic position, [c]NA = Not applicable, [d]NI = No information reported in paper, [e]Explicit focus on healthy growth, not obesity prevention, [f]SSB = Sugar sweetened beverages