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Supplementary feeding for improving the health of disadvantaged infants and young children

A systematic review

June 2016

Systematic Review 15

Health

International Initiative for Impact Evaluation

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Supplementary feeding for improving the health of disadvantaged infants and young children: a systematic review

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Summary

Background

Recent figures indicate that 842 million people globally were chronically undernourished between 2011 and 2013; the vast majority of them (827 million) in low and middle income countries (LMIC). Many of those who are undernourished are children and undernutrition is especially devastating for them. Undernutrition contributed to the deaths of more than three million children in 2011. It contributes to higher risk of infection, poorer intellectual and school performance, chronic disease in adulthood, and death. Evidence about the effectiveness of nutrition interventions for young children is therefore of vital importance, not only for governments, funding agencies and nongovernmental organisations, but also for the children themselves.

Objectives

1. To assess the effectiveness of supplementary feeding interventions, alone or with co-intervention, for improving the physical and psychosocial health of disadvantaged children aged three months to five years.
2. To elucidate the programme theory and to understand which factors in the context and implementation had an impact on success or failure of the programmes
3. To determine whether there are any adverse effects of the supplementary feedin
4. To assess the potential of such programmes to reduce socio-economic inequalities in undernutrition.

Methods

We undertook a mixed methods review using rigorous Cochrane and realist review methodologies. We searched nine electronic databases up the end of January 2014; we also searched reference lists of included articles and other reviews. In the systematic review of effects, we included experimental or quasi-experimental studies that focused on supplemental food interventions for disadvantaged children to improve their health. To be included, studies had to target children aged three months to five years, be experimental (Randomized Control studies (RCTs)), quasi-experimental (Controlled Before and After Studies (CBAs) or Interrupted Time Series) or use regression based methods to control for self-selection. The realist review used all included and excluded studies, 'sister studies' and other studies that provided information on conceptual issues or process factors.

For the Cochrane review, two or more review authors independently reviewed searches, selected studies for inclusion or exclusion, extracted data, and assessed risk of bias. We conducted meta-analyses for continuous data using the mean difference (MD) or the standardised mean difference (SMD) with a 95% confidence interval (CI), correcting for clustering if necessary. We analysed studies from lower middle-income countries (LMIC) and from high-income countries (HIC) separately, and RCTs separately from CBAs. We conducted a process evaluation to understand which factors impact on effectiveness.

For the realist review, three people independently reviewed all included and excluded studies from the systematic review. Two authors extracted data on context, mechanisms and outcomes

from the intervention studies, process evaluations and discussion papers. Differences between researchers were resolved by discussion. Candidate theories were developed and explored, looking particularly for disconfirming cases (i.e. examples of studies where the theory appeared not to hold), leading to either rejection or iterative refinement of the theory.

In the final stage, we integrated the syntheses from both reviews, thus allowing us a fuller picture of both effectiveness and factors that contributed to success (or failure).

Results

The search strategy identified 32,983 articles. Use of our inclusion/exclusion criteria, resulted in the inclusion of 34 (21 RCTs, 11 CBAs and 2 other quasi-experimental) studies, while 15 were excluded. Twenty-six studies (16 RCTs and 10 CBAs) were included in meta-analyses.

The 34 included studies and 15 excluded studies were included in the realist review; we also included 12 other papers that involved discussion of theoretical or methodological issues.

We found that providing supplementary food to young children in LMIC had significant positive effects on weight and height gain, but they were small (0.12 kg for weight and 0.27 cm. for height over six months in the most rigorous trials). Supplementary feeding resulted in positive changes in HAZ, WHZ and haemoglobin.

Psychosocial outcomes. Eight RCTs in LMIC assessed psychosocial outcomes. Our meta-analysis of two studies showed moderate positive effects of feeding on psychomotor development; children who were given feeding gained nearly half a standard deviation more on psychomotor test than controls. We found mixed, but generally negative evidence of effects on cognitive development.

Our subgroup analyses found that providing supplementary food was more effective for children under two years of age, for those who were poorer or less well-nourished, or both. Studies that were better implemented (well-supervised and provided a greater proportion of the recommended daily allowance for energy) were generally more effective. We also found substantial leakage. When the supplementary food was home-delivered or take-home, children took in an average of 36% of the total energy. However, when the food was given in preschool or day cares, on average, children took in 85% of the energy in the supplement.

The realist review indicated that prerequisites for programme success included the quality and quantity of the supplement and a reliable supply chain. These factors interacted with mechanisms in the child, caregiver and programme staff. First, the supplement had to match the child's needs; second, measures had to be in place to ensure that the child received and consumed the supplement as well as their usual diet; third, the caregiver had to be capable of learning and changing in response to any intervention; fourth, the caregiver had to be receptive and responsive to the particular intervention offered; and finally, programme staff had to be motivated and capable of maintaining the supply chain, supporting caregivers to deliver the supplement and adapting their efforts in the light of local progress data.

Conclusions and Recommendations

Supplementary feeding had a small effect on growth and small to medium effect on psychosocial outcomes. Results for growth were lower than would be expected. A number of factors seem to be important determinants of success: child age and nutritional need, caregiver capacity, supervision (at all points in the supply chain to prevent leakage), provision of adequate energy and energy dense, palatable food, giving the family additional rations, multiple intervention design, and family and community context. We believe that better implementation would result in better outcomes for children. Our findings lead us to suggest that:

- Supplementary feeding should begin early in a child's life
- The poorest children or areas should be targeted
- The distribution and intake of the supplementary food should be closely supervised
- In general, a moderate to high proportion of the dietary reference intake (DRI) for energy is desirable.
- Food should be palatable and culturally acceptable to children and their parents.
- Foods with a high energy density for their volume are generally desirable.
- Supplementary feeding programs should build family capacity

We also found that more research is needed on psychosocial effects of feeding, effects on gender equity and on the impact of large scale feeding programs.

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1. Introduction

1.1 Background

Undernutrition is the single biggest cause of the global burden of disease [1]. The most recent figures indicate that 868 million people globally were chronically undernourished between 2010 and 2012, the vast majority of them (852 million) in low- and middle-income countries. [2] Throughout the lifecycle, undernutrition contributes to increased risk of infection, poorer cognitive performance, chronic disease in adulthood, and mortality [3]. The consequences of undernutrition in early childhood are particularly severe; both physical and intellectual development may be affected. [4] [5]

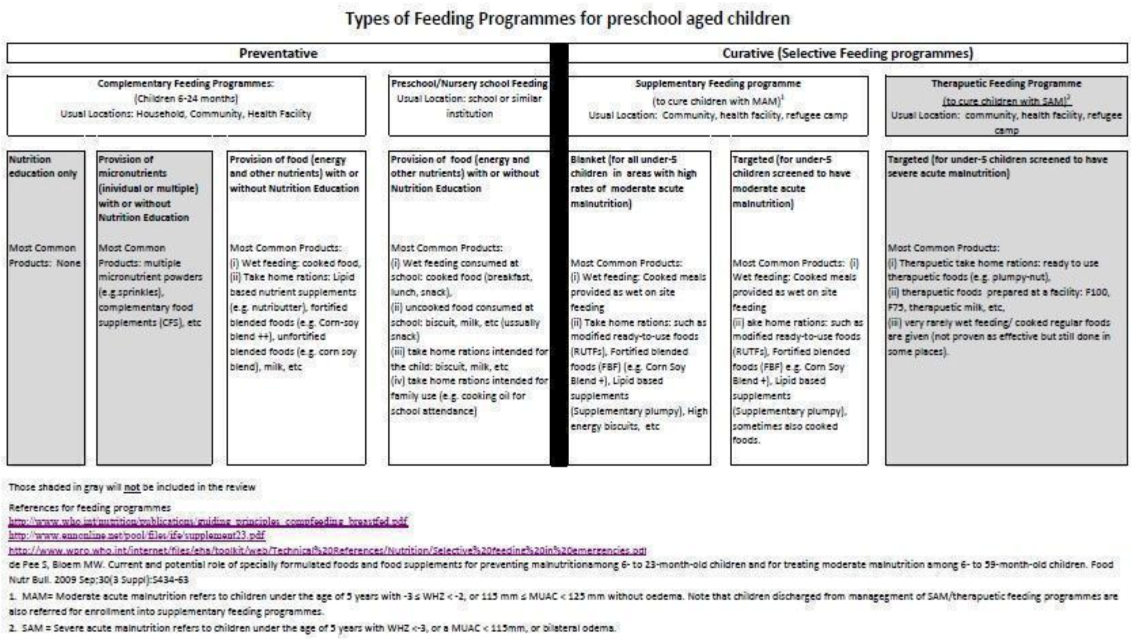
Undernutrition is responsible for about 35% of child deaths under 5 years of age and for an additional 35% of child morbidity.[6] Early and persistent undernutrition may cause permanent changes in physiology, metabolism, and endocrine function [7] [8] and has been increasingly linked to chronic diseases including obesity, hypertension, diabetes, stroke, and coronary heart disease. [7] [8] [9] [10] [11] [12]

Although it is sometimes difficult to disentangle the effects of undernutrition from other deprivations to which children living in poverty are exposed, early undernutrition is linked to lowered cognitive functioning and poorer school performance. [13] [14] [15] [16] [17] It is possible that some of the effects of undernutrition on cognition are produced through decreased interpersonal interaction and lower motivation; animal studies show that malnutrition leads to changes in motivation, emotionality, and anxiety. [18] [19] These effects may limit a child's capacity to interact with his/her environment and to learn from these interactions. [19] [20] [21] Chronic malnutrition in early childhood may result in partially irreversible structural and functional brain changes. [22] Maternal, fetal, and early childhood undernutrition is also linked to lower educational attainment and lower economic productivity in later life. [17] [23]

1.2 Description of the intervention

Supplementary feeding involves provision of energy (with nutrients or micronutrients or both) through food (meals/snacks) or beverage to children to ameliorate or prevent undernutrition. This may be given in preschool, day care, or community settings; take-home or home-delivered rations are also included. Programme goals generally include one or more of the following: improved survival, prevention or amelioration of growth failure, lowered morbidity, and promotion of normal cognitive and behavioural development. [20] Figure 1 provides an overview of the interventions eligible for inclusion in this review.

Figure 1. Types of Feeding programmes for Preschool aged children



1.3 How the intervention might work

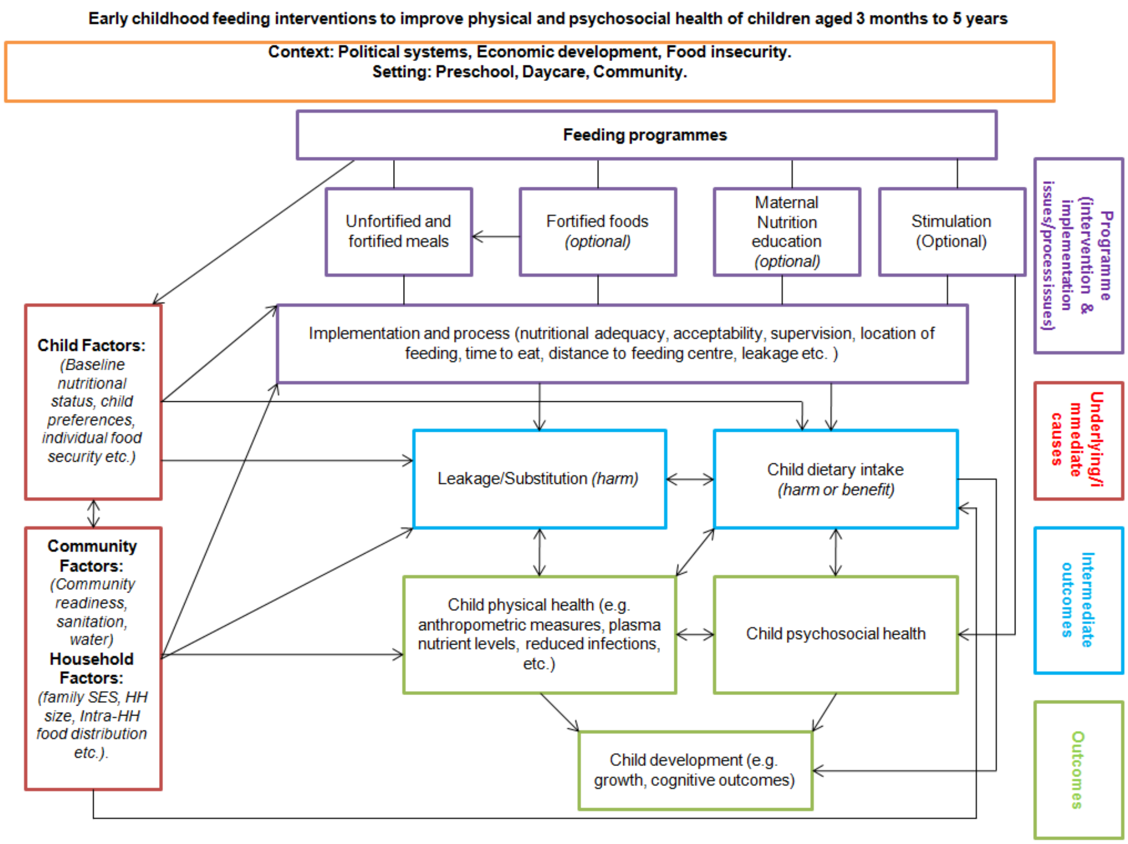
It is important to intervene in early childhood to maximize developmental potential and lifelong health. [24, 25] Food supplementation for disadvantaged young children is designed to accomplish this. According to Beaton and Ghassemi, [26] these programmes are usually planned to meet 40% to 70% of the estimated energy gap and should exist alongside usual meals consumed at home. The food/beverage given may improve growth and micronutrient status through providing additional energy, macronutrient, and micronutrients; it may also boost immune status and reduce risk of infection. [7, 8, 13]

The energy, nutrients, and micronutrients given may also improve motivation and psychosocial health, including cognitive functions such as intelligence, attention, psychomotor skills, language, visuo-spatial skills, and memory. Feeding-related cognitive benefits may be achieved through both neurological and behavioural mechanisms. Nutrition can influence the development and function of a young child's brain through several mechanisms: development of brain structure, including increased brain volume [4], myelination, and neurotransmitter operation. [15, 27] Feeding may also improve social behaviour through increased interaction, improved emotional state, and lowered anxiety. [28]. Increased social interaction may, in turn, enhance cognitive functioning and learning. Better nutrition in the first two years of life is associated with achieving a higher level of schooling.

Several factors may affect the success of supplementary feeding. The amount of energy given and the macronutrient and micronutrient composition of the food are critical for achieving adequate growth and meeting physiological needs. [26, 30, 31, 32] The child's age is also important; effects on growth, particularly linear growth, may be most pronounced for children two years of age and under [33, 34]. Substitution and ration sharing within the family are common, potentially reducing the impact of an intervention.

Our conceptual model (Figure 2) provides details of the hypothesized causal pathways and factors that impact on effectiveness.

Figure 2. Conceptual model



1.4 Why it is important to do this review

Child undernutrition is one of the most important global health issues today. And yet, distressingly, 'Nutrition is a desperately neglected aspect of maternal, newborn, and child health' (p 179[35]). In order to effectively intervene to improve child health, we need good evidence on which interventions work. It is equally important to understand how context and implementation impact on effectiveness. Systematic reviews on supplemental feeding for preschool-aged children are especially timely at a time when governments and leading international organizations are placing increasing emphasis on evidence-based strategies to improve the health of the poor.

Yet, thus far, syntheses of this evidence are limited. There have been earlier reviews[26 20] of supplementary feeding programmes for young children, one systematic review of the effectiveness of complementary feeding interventions for children aged six months to two years in LMIC, [34] a systematic review of Randomized Control Trials of supplementary feeding in LMIC and a review by Bhutta [36] of interventions that affect maternal and child undernutrition.

The current review went beyond existing reviews in several ways. First, it included quasi-experimental studies and regression based designs in addition to RCTs. Second, we performed a quantitative process evaluation within the systematic review as well as a realist review to elucidate pertinent information on factors that impacted on effectiveness. In doing so, we applied the reporting guidelines for realist review developed by the RAMESES (Realist and Meta-narrative Evidence Synthesis Evolving Standards) international collaboration. [37] Finally, we assessed the effect of the intervention on a range of outcomes, including psychosocial and physical development. Thus our review helped to address one of the evidence gaps identified by Bhutta [6]: the lack of evidence about whether adverse effects of undernutrition on cognition and infectious disease may be ameliorated.

1.5 Objectives

To assess the effectiveness of supplementary feeding interventions, alone or with co-intervention, for improving the physical and psychosocial health of disadvantaged children aged three months to five years.

To elucidate the programme theory and to understand which factors in the context and implementation had an impact on success or failure of the programmes

To determine whether there are any adverse effects of the supplementary feeding

To assess the potential of such programmes to reduce socio-economic inequalities in undernutrition.

2. Study Eligibility

2.1 Effectiveness review

Studies were included if they were experimental, quasi-experimental or used regression based methods to control for self-selection. We also accepted RCTs with stepped wedge designs (treatments began at different times for different groups of participants). In these cases, our baseline was the time at which the 'treated group' (longest treatment) began treatment and our endpoint was the point that the 'control group' began treatment. We excluded all other study types.

To be included, the interventions had to provide energy, nutrients and micronutrients through food or drink to children aged three months to five years. The supplementary food could be delivered at preschool, daycare, feeding centre or to the home. Controls had to be untreated or receive a very low calorie placebo.

Included studies also had to report one of the following outcomes: Growth, psychomotor development, cognitive or mental development, attention, language, memory or adverse effects.

2.2 Realist review

We included all included and excluded studies from the Cochrane review, additional papers describing relevant qualitative studies and relevant theoretical or methodological papers. Each paper was assessed against two criteria: 1) relevance; is the study relevant to our research question 2) rigour: is the study, or aspects of the study we wish to draw upon, sufficiently rigorous for us to be able to trust the findings? In making our final selection of studies to include, we prioritised those that offered rich descriptions of the interventions and programmes, thereby allowing us to identify mechanisms and make informed judgments about the interaction between context, mechanism and outcome.

3. Methods

3.1 Searches

We searched the following databases for all available years up to January 2014: Cochrane Central Register of Controlled Trials (CENTRAL), Ovid MEDLINE, PsycINFO, ERIC, Social Sciences Citation Index, Conference Proceedings Citation Index, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE) and Proquest Dissertations and Theses. We also searched ClinicalTrials.gov, and the reference lists of relevant articles and reviews. Finally, we performed hand-searches of reference lists of included articles and other reviews.

The realist review drew from results of the searches described above; we also searched reference lists of included and excluded studies and used citation tracking in Google Scholar to identify relevant papers.

3.2 Summary of data extraction, management and analyses

Effectiveness review. At least two review authors, working independently, scanned all titles and abstracts of articles retrieved by the searches. Two review authors reviewed the full text of all retrieved studies against the inclusion and exclusion criteria, with disagreements settled by a third author. The team comprised review authors fluent in Portuguese, Spanish, French, and English, and therefore, we were able to assess articles written in these languages.

Four people extracted data, working in pairs. They compared their work and resolved discrepancies. We pilot-tested the data extraction form on two studies.

Two authors independently rated study quality. We used the Cochrane Collaboration's 'Risk of bias' tool [38]to assess risk of bias in RCTs and c-RCTs; there were no CCTs. Most items are scored as 'high risk', 'low risk' or 'unclear risk'. We gave component ratings, but did not give an overall rating. For CBAs, we used the 'Risk of bias' tool from the Cochrane EPOC group.[39] In addition to the domains covered by the Cochrane Collaboration's 'Risk of bias' tool, it includes similarity of baseline outcome measurement, similarity of baseline characteristics, and protection against contamination.

Quantitative data on intervention effects was synthesized by using weighted random effects meta-analysis of change data reported in studies, correcting for clustered allocation if necessary. We analysed studies from low and middle-income countries (LMIC) and from high-income countries (HIC) separately, and RCTs separately from CBAs.

We used subgroup analyses to understand the impact of various equity and implementation factors. In total, we performed subgroup analyses across seven categories.

1. Age: three to 12 months, one to two years, and two years and older for RCTs.
2. Sex: male versus female.

3. Socio-economically disadvantaged: poor versus less poor or undernourished versus well nourished.
4. Nutritional adequacy: percentage of daily requirements (RDI) for energy provided by the supplement (low (0% to 29%), moderate (30% to 59%), and high (60% +)).
5. Location of feeding: take-home rations versus feeding centre or day care or preschool or both.
6. Level of supervision (i.e. monitoring): low supervision versus moderate supervision versus strict supervision.
7. Single versus multiple interventions.

We constructed 'Summary of Findings' tables and rated the quality of evidence using GRADE.

Realist review. Three authors extracted further relevant data independently. This data included the theory of change proposed by study authors, why they felt the intervention was needed and what they thought it would achieve, authors' conclusions about why the intervention had worked or not worked; differences in subgroups and any explanations for these differences; additional mechanisms proposed by authors (or hypothesized by reviewer on the basis of study findings). The spreadsheets were compared and differences resolved by checking the original paper and discussion.

Full details of our review methods are presented in Appendix 2.

4. Results

4.1 Results of literature search and description of studies

The literature search identified 32,983 articles. We retrieved 301 papers for the quantitative review; each was read in full. After carefully going through the inclusion/exclusion criteria, we included 34 studies: 21 RCTs, 11 CBAs and 2 which used propensity score matching. 26 of these (16 RCTs and 10 CBAs) were used in meta-analyses. With the exception of Meller[40], all included studies were found in published data. Twenty-six studies had some data that could be included in meta-analyses. Eight of the thirty-four studies [41 42 43 44 40 45 46 47] could not be included in meta-analyses due to lack of suitable data. They were summarised narratively. Fourteen studies did not meet inclusion criteria, but were close enough in design and purpose that they were detailed in the excluded studies table (Table 2).

For the realist review, we included the 34 included studies from the Cochrane review (including 'sister' papers from these studies that described process evaluations, [48 49 50 51 52 53 54 55 55 56 57 58 59 60 61 62] 14 studies that had been considered for the Cochrane review but not included[63 64 65 66 67 68 69 70 71 72 73 30 74 75] and 12 additional papers describing qualitative studies, theories or methodological issues. [76 36 77 78 79 80 81 82 83 84 85]

Our study flow diagram is shown in Figure 3. Characteristics of the included studies are summarized in Table 1.Thirty-one of the included studies were from low and middle-income countries (LMIC); three were from high-income countries (HIC). Within LMIC, six were performed in India, three in Malawi, two in Bangladesh, Jamaica, Indonesia, Columbia, Mexico and Ecuador, and one in each in Niger, Nigeria, Kenya, Peru, South Africa, Vietnam, Thailand, Brazil, Haiti and Mexico. One study was performed in four countries: Bolivia, Caledonia, Congo, and Senegal. All were conducted in poorer settings; such as slums and poor rural areas. Of the three high-income country studies, one was implemented in Australia with Aboriginal children, one in Canada and one in the United States.

The participants were all 3 month to 5-year-old children. In most studies, a high proportion of children had low WAZ or HAZ; however, very few children were severely malnourished or ill. Many children came from low-income areas and from low-income families. The number of participants per study ranged from 30 [45] to 3166.[86]

All interventions comprised supplementary food or drink, with or without added micronutrients. The supplementary foods comprised Ready to Use Therapeutic food, milk, locally produced food or cereal mixtures. As seen in Table 4, the % DRI for energy ranged from 8% to 136%.

In sixteen of the programmes in LMIC [44 41 87 88 89 90-92 93 61 94 42 95 96 86 97] and two programmes in HIC ,[98 99] supplementary feeding was the only difference between experimental and control groups. Thirteen studies in Low and Middle Income countries provided adjunctive interventions. Seven programmes [100 41 51 47 101 102] provided additional rations for the family to reduce redistribution of the child's supplement.The Progresa programme in Mexico [103] provided cash transfers to families as well if they complied with healthcare requirements. Three programmes [104 47 51] provided stimulation as well as supplementation; [51] also had a supplementation-only group. Four [105 106 33 107] provided health education programmes in addition to supplementation.

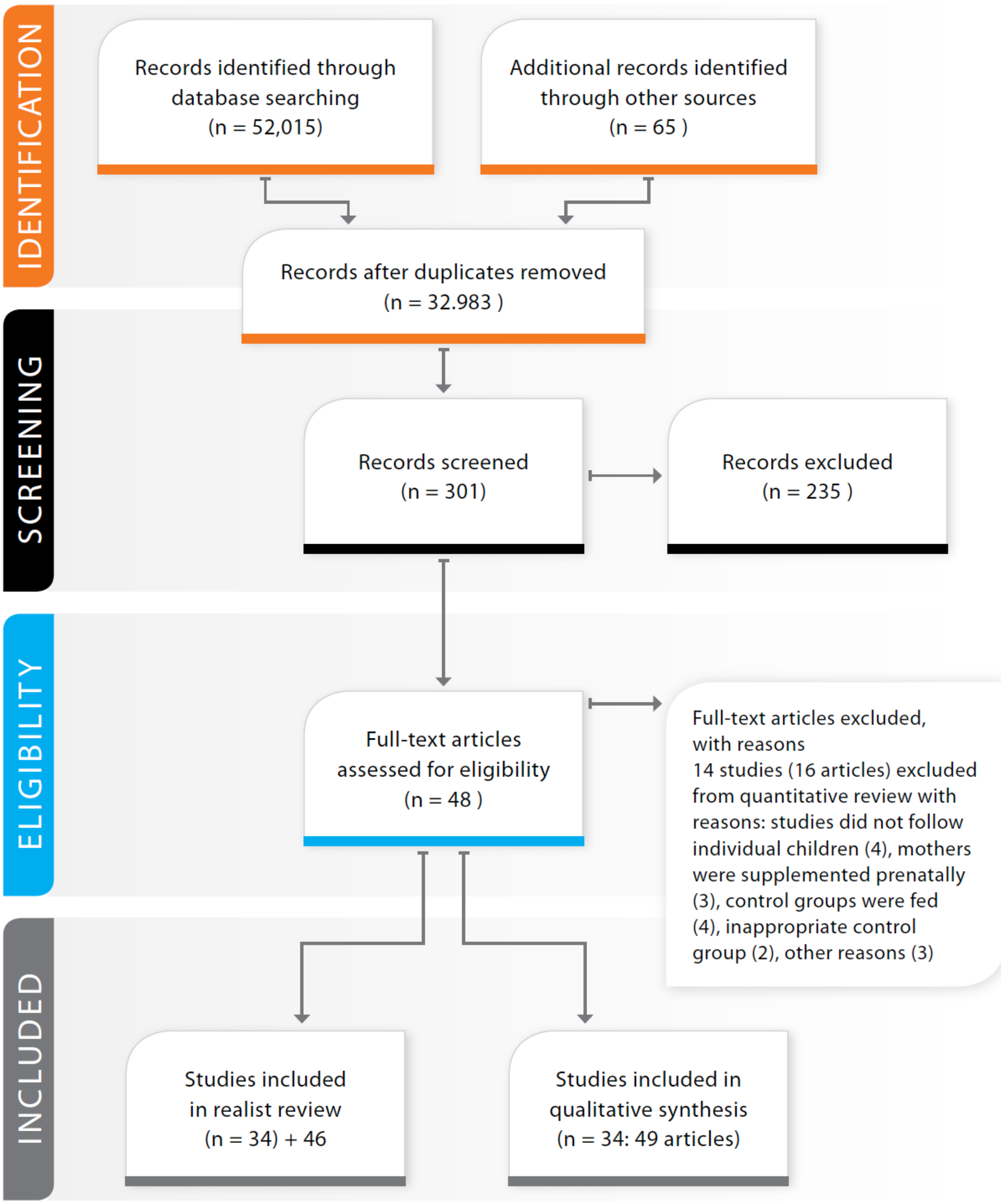
One study. Schroeder [33] provided nutrition education, health care, and supplementation. Roy[46] compared children who received supplementation + maternal education to children who received maternal education alone and to controls who received no treatment.

In the Coyne study (HIC) [108] the children who received supplementation were in day care; the controls were not.

Nine studies in LMIC delivered the supplement at day-care or feeding centres. One study in HIC provided meals in day-care. The remaining studies involved home delivered food. In LMIC, thirteen studies provided strict monitoring of the supplementary feeding, thirteen studies provided moderate monitoring and five studies provided little monitoring. One study in HIC provided strict monitoring and the two other HIC studies provided moderate monitoring.

Table 4 shows the percentage (%) of the dietary reference intake (DRI) provided by the supplement in each study for different age groups. The % DRI for energy ranged from a low of 7.9 [42] to 111.7. [102]

Figure 3. Study Flow diagram



4.2 Allocation/clustering

Sixteen studies were allocated by cluster; these clusters included regions, neighbourhoods, or day cares. Sixteen studies were allocated by cluster (regions, neighbourhoods, or day cares). Of these 16, six [46 86 107 103 101 102] adjusted for clustering appropriately in some or all analyses. We performed this adjustment for eight studies [88 108 105 106 107 104 33] and for the weight analyses in Pollitt. [56] We did not adjust for clustering in the following studies, [44 41 42 56] as appropriate data were not available. Table 3 provides a summary of the clustered studies.

Intervention lengths ranged from three months [94 88]; [95 86 46,93 61] to 32 months. [47] The average was 10 months and the median was 9 months.

Risk of bias in included studies

Details of the ROB assessments are summarized in Figure 4. Thakwalakwa[61] was the only RCT to receive ratings of low risk in all categories. Most of the other RCTs in LMIC received three 'low risk' ratings, while the other ratings were unclear, and a few were high risk. Half were judged to have low risk for incomplete outcome data.

The number of 'unclear' judgments is particularly notable across all categories; often the primary studies did not provide enough information to make judgments

Among the CBAs, Coyne, Tomedi and Gershoff [108 107 102] had the best study designs. All received judgments of low risk for five or six out of six categories (excluding allocation concealment and random sequence generation). Blinding of outcome assessment was rarely reported.

Excluded studies

Fourteen studies were excluded from the review. Table 2 gives details of the excluded studies and reasons for their exclusion.

Figure 4. Risk of Bias in included Studies

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Baseline outcome measurements	Baseline characteristics	Incomplete outcome data (attrition bias)	Blinding of outcome assessment (detection bias)	Blinding of participants and personnel (performance bias)	Protection from contamination	Selective reporting (reporting bias)	Other bias
Bhandari 2001	?	?	+	?	+	?	−	?	?	
Coyne 1980	−	−	+	−	+	?	−	+	?	
De Romana 2000	?	?	?	?	?	?	−	?	?	
Devadas 1971	−	−	+	+	?	?	−	+	?	
Fauveau 1992	+	?	?	?	+	?	−	?	?	
Gershoff 1988	−	−	?	?	?	?	−	+	?	
Gopalan 1973	−	−	+	?	?	?	−	+	?	
Grantham-McGregor 1991	?	?	+	?	+	?	−	?	?	
Heikens 1989	?	?	?	?	+	?	−	?	?	
Husaini 1991	+	?	?	?	−	?	−	?	?	
Iannotti 2014	+	+	+	?	+	?	−	?	?	
Isanaka 2009	+	?	?	+	+	?	−	?	?	
Joshi 1988	−	−	+	?	?	?	−	−	?	
Kuusipalo 2006	+	?	+	?	+	+	−	?	?	
Lutter 2008	−	−	+	+	+	?	−	+	?	
Mangani 2014	+	+	?	?	+	?	−	?	?	
Manjrekar 1986	−	−	+	?	−	?	−	+	?	
McKay 1978	?	?	+	?	+	+	−	?	?	
Mittal 1980	−	−	+	−	−	?	−	?	?	
Obatolu 2003	+	?	+	?	?	?	−	?	?	
Oelofse 2003	?	?	?	?	?	?	−	?	?	
Pollitt 2000a	+	?	?	?	?	?	+	?	?	
Rivera 2004	?	?	+	?	+	?	−	?	?	−
Roy 2005	+	?	?	?	?	?	−	?	?	
Santos 2005	−	−	+	+	+	−	−	−	?	
Schroeder 2002	−	−	−	+	?	?	−	?	?	
Simondon 1996	+	+	+	?	−	?	−	?	?	
Thakwalakwa 2010	+	+	+	?	+	+	−	?	?	
Tomedi 2012	−	−	+	+	+	?	−	+	?	
Waber 1981	?	?	?	?	?	?	−	?	?	
Yeung 2000	?	?	+	?	?	+	−	?	?	
Ziegler 2009	?	?	?	?	−	?	−	?	?	

4.3 Impacts on Physical Growth

4.3.1 Weight gain

Lower income countries. We included nine RCTs with 1057 participants in a meta-analysis for weight. There was a small, but significant impact of supplementation; children who were given supplementary food gained 0.12 kg more over six months than those who were not supplemented. Obatolu [45] (n = 60) found significant effects of 14 months of feeding on weight for boys (4.21 kg.) and girls (3.91 kg.). Finally, one study (n = 48) [41] found no effect.

Our meta-analysis of seven CBAs in LMIC (1784 participants) showed a small, significant effect of feeding; children who were given supplementary food gained an average of 0.24 kg more over a year than those who were not supplemented. Leroy and colleagues [43] found no significant overall impact of the Mexican Opportunidades program on weight, but there were significant impacts for the youngest children and for those in the lowest third in the income distribution.

Higher Income Countries. Coyne [108] conducted a study with 116 Aboriginal children and found that the children who received supplementary food at day-care gained 0.95 kg more in four months than those who were not in day-cares. In contrast, one RCT in higher income countries [99] found that children who received no supplementation gained more than children who received an iron fortified cereal.

4.3.2 Growth in length/height

LMIC. Nine RCTS with 1463 participants contributed to this meta-analysis. The average period of supplementation was six months. This analysis demonstrated that children who were given supplementation grew an average of 0.27 cm. more (sig.) than those who were not supplemented.

Results of a regression analysis in Pollitt's tea plantation study in Indonesia [48] showed that feeding had no overall effects on height but that there was a significant effect in the younger (12-month old) cohort. The fourteen month Obatulo [45] study (n = 60) found a large and significant effect of feeding on growth for both boys (difference = 5.12 cm) and girls (difference = 6.95 cm.).

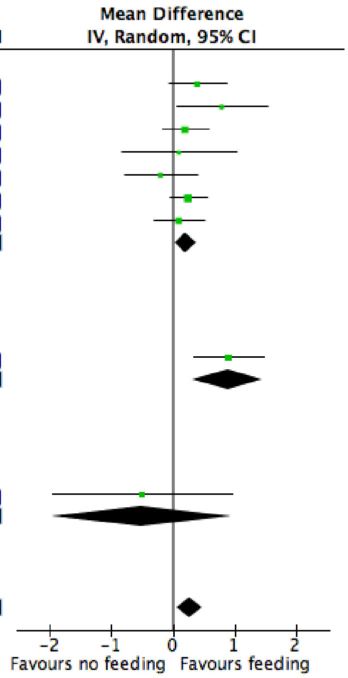
Seven CBAs with 1782 participants contributed to a meta-analysis for height, which showed no significant effects. Similarly, Leroy [43] found an overall non-significant impact on height, however, there was a significant effect for the youngest children.

Higher-Income Countries. Two studies: an RCT [99] and a CBA [108] did not find any significant effects of supplementary feeding on height.

The GRADE summary of findings table for growth among the RCTS can be seen in Table 5 while the summary of findings tables for the CBAs is in Table 6

Figure 5. Meta-Analysis of RCTS: Height

Study or Subgroup	Feeding Mean	Feeding SD	Feeding Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
1.2.1 Subgroup analysis by age: < 12 months								
Bhandari 2001	10.3	1.6	87	9.9	1.6	93	13.2%	0.40 [−0.07, 0.87]
Kuusipalo 2006	2.5	0.93	18	1.7	1.3	18	6.6%	0.80 [0.06, 1.54]
Mangani 2014	13.2	1.7	188	13	2	185	17.3%	0.20 [−0.18, 0.58]
Oelofse 2003	10	0.79	16	9.9	1.63	14	4.3%	0.10 [−0.84, 1.04]
Rivera 2004	14.3	3.34	261	14.5	3	185	9.4%	−0.20 [−0.79, 0.39]
Simondon 1996	4.89	0.83	65	4.64	0.9	62	21.8%	0.25 [−0.05, 0.55]
Thakwalakwa 2010	3.4	1.1	66	3.3	1.2	58	15.8%	0.10 [−0.31, 0.51]
Subtotal (95% CI)			**701**			**615**	**88.3%**	**0.22 [0.05, 0.39]**
Heterogeneity: Tau² = 0.00; Chi² = 5.31, df = 6 (P = 0.50); I² = 0%								
Test for overall effect: Z = 2.54 (P = 0.01)								
1.2.2 Subgroup analysis by age: 1 – 2 years								
Grantham-McGregor 1991	11.6	1.25	32	10.7	1.1	33	9.9%	0.90 [0.33, 1.47]
Subtotal (95% CI)			**32**			**33**	**9.9%**	**0.90 [0.33, 1.47]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.08 (P = 0.002)								
1.2.3 Subgroup analysis by age: > 2 years								
Heikens 1989	2.7	3.4	39	3.2	3.4	43	1.9%	−0.50 [−1.97, 0.97]
Subtotal (95% CI)			**39**			**43**	**1.9%**	**−0.50 [−1.97, 0.97]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.67 (P = 0.51)								
Total (95% CI)			**772**			**691**	**100.0%**	**0.27 [0.07, 0.48]**
Heterogeneity: Tau² = 0.03; Chi² = 11.33, df = 8 (P = 0.18); I² = 29%								
Test for overall effect: Z = 2.60 (P = 0.009)								
Test for subgroup differences: Chi² = 6.01, df = 2 (P = 0.05), I² = 66.7%								



4.3.3 *Change in Weight for age z-scores*

Lower income countries. Eight RCTs (total sample of 1565 children) were included in this meta-analysis, which demonstrated small but significant positive differences (0.15 gain in WAZ) between the supplemented and non-supplemented groups. In a cluster RCT with 282 children, Roy [46] found that children who received both supplementation and maternal education gained 0.71 more in WAZ than the children who received no treatment (P < 0.001) and 0.26 more than the children who received maternal nutrition education only (not significant).

Our meta-analysis of four CBAS with 999 participants showed a positive, but non-significant significant difference in WAZ between children who received supplementation and those who did not.

4.3.4 Change in Height-for-age z-scores

Lower income countries. Nine RCTs (4544) children were included in the meta-analysis, which showed a significant effect of supplementation; over six months, the supplemented group gained 0.15 more in HAZ than the control group.

Our meta-analysis of four CBAs (999 children) showed little effect of supplementation on HAZ score. Leroy [43] also found no effect overall, but did find a significant effect for children who were younger at study onset.

4.4 Impacts on Psychosocial Development

4.4.1 Psychomotor Development: LMIC

Four RCTs in LMIC assessed the effect of supplementary feeding on psychomotor development. Our meta-analysis of two studies [88] [51] found that children who received supplementary feeding had significantly greater improvement on tests of psychomotor development than children who did not receive any supplementary food. This improvement was equal to .41 of a standard deviation.

Waber [47] reported that children who received 2.5 years of supplementation (n= 60) beginning at six months of age had better overall scores at the end of the study on the Griffiths Mental Development Scales (GMDS) than those who received no supplementation (n = 54), but significance was not given.

Pollitt [109] reported no main effect of supplementary feeding on children's psychomotor performance in a Repeated Measures ANOVA, but did find significant differences in change over time contrasts.

None of the CBAs in LMIC or the RCTs and CBAs in HIC assessed psychomotor development.

Motor milestones

Findings concerning the effect of supplementation on achievement of motor milestones are equivocal. Pollitt [109] found that significantly more of the supplemented children walked by 18 months. Iannotti [96] and Mangani [97]found no significant effects.

4.4.2 Cognitive Development

Three RCTs [88] [104] [109] in LMIC assessed change in cognitive development. The outcome measures in these studies were too different conceptually to be included in a meta-analysis.

For the McKay study, our analysis (n = 99) found that the cognitive abilities of children who had been supplemented for 21 months improved more than the children who were not yet supplemented; the difference was moderate and equal to more than half of a standard deviation in the overall score on a battery of cognitive tests.

Our analysis of Husaini (n = 113) found a non-significant difference in change on the Bailey Scales of Mental Development (BSMD).

Pollitt and his colleagues [109] found no main effects of supplementation on the BSMD. They reported significant positive effects in a contrast over time for the younger cohort but not for the older cohort.

4.4.3 Follow-up of Cognitive Functioning

Grantham-McGregor [110] followed up 97% (n = 127) of the original cohort of stunted children (n = 129) in the Jamaican study after four years and tested them on a battery of cognitive and perceptual tests. A multiple regression found effects on perceptual motor tasks, but not on general cognition or memory. Interestingly, stimulation had a significant effect on later perceptual motor skills for all children ($P < 0.05$), but supplementation only had a significant effect for children whose mothers had higher scores on a test of verbal intelligence.($P < 0.05$). They also found that the supplemented children had higher average scores than the controls on 14 out of 15 cognitive tests (P value = 0.02).

Seven years after the Husaini study was completed, Pollitt and his colleagues [59] found no differences between the experimental and control groups in the Peabody Picture Vocabulary Test, emotionality, and math. They did find small, (15-second difference) positive effects of supplementation on working memory performance, although these are unlikely to be clinically significant.

4.4.4 General development

Low- and middle-Income countries: RCTs
Oelofse [91] (n = 60) found no significant differences on the Denver Developmental Screening Test (DDST) between the group of South African infants (aged six months at baseline) given a micronutrient-fortified supplement for six months and control infants.

None of the CBAs in low- and middle-income countries or RCTs and CBAs in high-income countries assessed general development.

Table 7 shows the GRADE Summary of Findings table for psychosocial development.

4.5 Adverse effects

4.5.1 Substitution or leakage

We were able to calculate the net benefit from supplementary feeding for seven studies that provided home-delivered rations [51 103 100 107 101 102] and three of the day-care/feeding centre studies. [88 109 105] We found important differences in the number of calories provided by the supplementary food and the number of extra calories that the children actually consumed in addition to their regular food; this was especially problematic in studies which gave take home food. In the take-home studies, we found that the net benefit to children was only 36% of the extra calories provided by the supplement. In the day-care and feeding centres, the net benefit was 85% of the extra calories provided by the supplement.

4.6 Secondary outcomes: Physical Health

4.6.1 Heamoglobin

LMIC. Five RCTs with 300 children were included in our meta-analysis for haemoglobin. We found that children who were supplemented showed positive change in haemoglobin status compared to controls; this change was equal to half of a standard deviation (0.49).

Lutter [107] (CBA) reported that children who were supplemented had a 42% lower risk of being anaemic than those who were not supplemented; this was significant (P = 0.003). Similarly, Lopez [44] reported that while the prevalence of anaemia decreased by 27% in the intervention group, it decreased by only 13% in the control group.

4.6.2 Physical Activity

Two studies [51] [109] had conflicting results. Jahari and colleagues (part of Pollitt [109]) found that children who received a high energy supplement showed significantly greater increases in high energy activities compared to controls. They also displayed significantly greater increases in motor activity that began at 16 months of age and continued to the end of the study. In contrast, Meeks-Gardner (part of Grantham-McGregor [51]) reported that no significant effect of supplementation alone or supplementation with stimulation on changes in motor activity in children.

4.6.3 Morbidity

Three RCTs [100] [96] [86] and two CBAS [87] [102] found few differences between the supplemented group and the control group in the prevalence of morbidity. Roy [46] (reported mixed results; the prevalence of diarrhoea and fever was higher in the children who received supplementation (n = 99), while the prevalence of respiratory infection was higher in the control group (n = 90).

4.6.4 Mortality

Using a regression discontinuity design, Meller and his colleagues[40] found a significant reduction in child mortality (from 2.5% to 1% or 1.5%) during the eight months of exposure to Ecuador's PANN program of supplementary feeding and health care checks. This represents a 40 to 60% decrease in mortality. In contrast, Isanaka [86] found no difference in mortality between children were supplemented and those who were unsupplemented.

5. Factors that can impact on success

In this section, we report results of the subgroup analyses from the effectiveness review as well as findings from the realist analysis.

5.1 Characteristics of the child

5.1.1 Age

We conducted subgroup analyses to explore the possible impact of age on effectiveness for weight and height. For the RCTs, we compared the following age groups: < 12 months, one to two years, and > 2 years. The age groups for the CBAs were: < 1 year, 1 year, 2 years and > 2 years.

Weight

We found no significant differences by age group in either the subgroup analysis of nine RCTs (9 studies: 1057 children) or that of seven CBAs (7 studies: 1784 children).

Height

The subgroup analysis for the RCTS showed significant subgroup differences: supplementary feeding was effective for increasing height among the youngest age groups (< than 12 months: 7 trials, n = 1316; and 1 to 2 years, 1 trial, 65 children), while the height gains in the oldest age group (> two years old: 1 trial, n = 82) were non-significant.

Seven CBAs (n = 1782) in LMIC contributed to a subgroup analysis for age and height. There were no significant differences among subgroups.

Leroy [43] reported a significant impact on weight, height and WHZ for children who began the program when they were under 6 months of age. These children gained 1.53 cm in height relative to controls.

Psychomotor and mental development. The Pollitt [109] [53] study showed that supplementation was more effective in improving mental and motor development for the younger (12 months) cohort.

5.1.2 Sex

Our subgroup analyses to explore effectiveness by sex comprised two CBAs from LMIC [106] [90] and 840 children. There were no significant subgroup differences in either the analysis for weight or height.

In the study of Aboriginal children in Australia, Coyne [108] reported that the only statistically significant differences between those who were fed and the control group in weight gain were found among girls. The tea plantation study [109] [53] found stronger effects on weight and height for girls than for boys, however, the interaction was significant only at the 0.10 level.

5.1.3 Poverty/Child's Initial Nutritional Status

Our analysis of an RCT with 192 children [61] found that supplemented children who were more undernourished/ poorer gained significantly more weight than controls, but that feeding was ineffective for children with normal weights. One CBA [87] also found that children with low baseline WAZ gained more weight than controls while those whose WAZ was higher did not (n = 293). The Jamaican study [51] reported greater gains in mid-upper arm circumference for those who were undernourished. Two other studies: 1 RCT and 1 CBA (888 children) [33, 103] found a three-way interaction with age; undernourished children grew more (WAZ, HAZ, height) in response to feeding than better nourished children, but only if they were in the younger age group.

In contrast, two studies (an RCT and a CBA: 647 children) [88, 106] found no difference in effectiveness between children who were undernourished and those who were better nourished. Finally, Joshi (247 children) [42] found that children living in slums did not respond as well to feeding as those from families of moderate socioeconomic status. He suggested that poor environmental conditions might have reduced effectiveness.

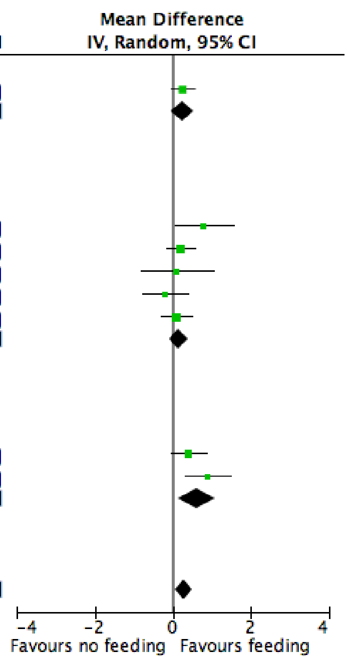
5.2 Implementation

5.2.1 Nutritional Adequacy

The subgroup analyses of the RCTs for weight and height were not significant (see figure 6).

Figure 6. Subgroup analysis of height and nutritional adequacy: RCTs

	Feeding			Control				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
10.4.1 Low nutritional adequacy (0 – 29% energy)								
Simondon 1996	4.89	0.83	65	4.64	0.9	62	22.2%	0.25 [−0.05, 0.55]
Subtotal (95% CI)			**65**			**62**	**22.2%**	**0.25 [−0.05, 0.55]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.63 (P = 0.10)								
10.4.2 Moderate nutritional adequacy (30 – 59% energy)								
Kuusipalo 2006	2.5	0.93	18	1.7	1.3	18	6.7%	0.80 [0.06, 1.54]
Mangani 2014	13.2	1.7	188	13	2	185	17.6%	0.20 [−0.18, 0.58]
Oelofse 2003	10	0.79	16	9.9	1.63	14	4.4%	0.10 [−0.84, 1.04]
Rivera 2004	14.3	3.34	261	14.5	3	185	9.6%	−0.20 [−0.79, 0.39]
Thakwalakwa 2010	3.4	1.1	66	3.3	1.2	58	16.1%	0.10 [−0.31, 0.51]
Subtotal (95% CI)			**549**			**460**	**54.3%**	**0.16 [−0.09, 0.41]**
Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 4.45$, df = 4 (P = 0.35); $I^2 = 10\%$								
Test for overall effect: Z = 1.28 (P = 0.20)								
10.4.3 High nutritional adequacy (60% or higher energy)								
Bhandari 2001	10.3	1.6	87	9.9	1.6	93	13.4%	0.40 [−0.07, 0.87]
Grantham-McGregor 1991	11.6	1.25	32	10.7	1.1	33	10.1%	0.90 [0.33, 1.47]
Subtotal (95% CI)			**119**			**126**	**23.5%**	**0.62 [0.13, 1.11]**
Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 1.76$, df = 1 (P = 0.19); $I^2 = 43\%$								
Test for overall effect: Z = 2.50 (P = 0.01)								
Total (95% CI)			**733**			**648**	**100.0%**	**0.29 [0.08, 0.50]**
Heterogeneity: $Tau^2 = 0.03$; $Chi^2 = 10.28$, df = 7 (P = 0.17); $I^2 = 32\%$								
Test for overall effect: Z = 2.72 (P = 0.007)								
Test for subgroup differences: $Chi^2 = 2.72$, df = 2 (P = 0.26), $I^2 = 26.4\%$								



5.2.2 Location of Feeding (Day-care/preschool/feeding centre versus home)

There was not enough data to fully test this in the RCTs as most studies provided home-delivered supplements. Among the CBAS, we found no significant subgroup differences for weight or height.

5.2.3 Leakage and Substitution

We calculated the net benefit (actual contribution of the supplement to the diet) for seven studies providing take home rations [100] [51] [44] [107] [103] [101] [102] and three of the day-care/feeding centre studies. [105] [88] [109] We found that when rations were delivered at home, the net benefit to children was only 36% of the extra calories provided by the supplement. In the day-care and feeding centres, the net benefit was 85% of the extra calories provided by the supplement.

5.2.4 Supervision

We classified studies according to the amount of monitoring they provided. There were three groups in LMIC:

1. Strict supervision: foods provided at day care centers [106] [88] [58] or feeding centres [105] [87] [42] [104] [89] [33] OR take home rations with strict monitoring [100] [94] [91] [93,107]
2. Moderate: take home rations with moderate monitoring [51] [95] [44] [103] [101] [61] [102]
3. Low: take home rations with little to monitoring [41] [45] [46] [47]

We found no significant subgroup effects of supervision in the subgroup analysis for weight in the RCTs.

Among the CBAs, five studies were strictly supervised, [105] [87] [106] [107] [89] one was moderately supervised[90] and one provided little supervision. [101] The subgroup analyses for weight and height were non-significant.

5.2.5 Single Food intervention versus multiple interventions

Weight and height. Neither the subgroup analyses for the RCTs nor those for the CBAs were significant.

Psychomotor development. Grantham McGregor [51] found that when supplementation was combined with stimulation, effects on psychomotor development were even stronger than with supplementation alone. Their analyses showed that 32 children who were supplemented and stimulated gained 13.4 points (more than 33 controls on the Griffiths Developmental Quotient (GDQ). The 32 children who were supplemented without stimulation gained 6.5 points more than the controls on the GDQ.

5.3 Realist analysis

Successful programmes appear to be characterized by five key mechanisms: close match between the supplement and nutritional need, agentic mechanisms in the child (that is, ways in which the child comes to consume the supplement), general agentic mechanisms in the caregiver (capability to learn and change in response to *any* intervention), programme-specific agentic mechanisms in the caregiver (the caregiver's likelihood of changing behaviour as a result of *this particular* intervention), and agentic mechanisms in programme staff (willingness and capacity to provide the supplement consistently to caregivers and support them in administering it to the child).

The biological mechanisms are not the main focus of this review and are covered in detail elsewhere (see sources referenced below). The following mechanisms are postulated:

- Supplemental foods correct an energy, protein or micronutrient deficiency, producing skeletal and brain maturation and growth in height and/or weight. [111]
- Supplementary food and micronutrients [91] [98] [99] have a specific effect on brain development perhaps only during a critical age window [52] although the latter has not been proven. [47]
- Supplements stabilise the diet by protecting against seasonal food shortages. [63] [85] [84]
- Micronutrients may help the child resist and recover from infections and infestations.[63]
- Micronutrients may increase appetite. [86]
- Well-nourished girls grow into well-nourished and adequately-grown women who are able to sustain a healthy pregnancy and whose offspring are more likely to be born well-nourished, thereby creating a positive intergenerational cycle of nutrition.[43]

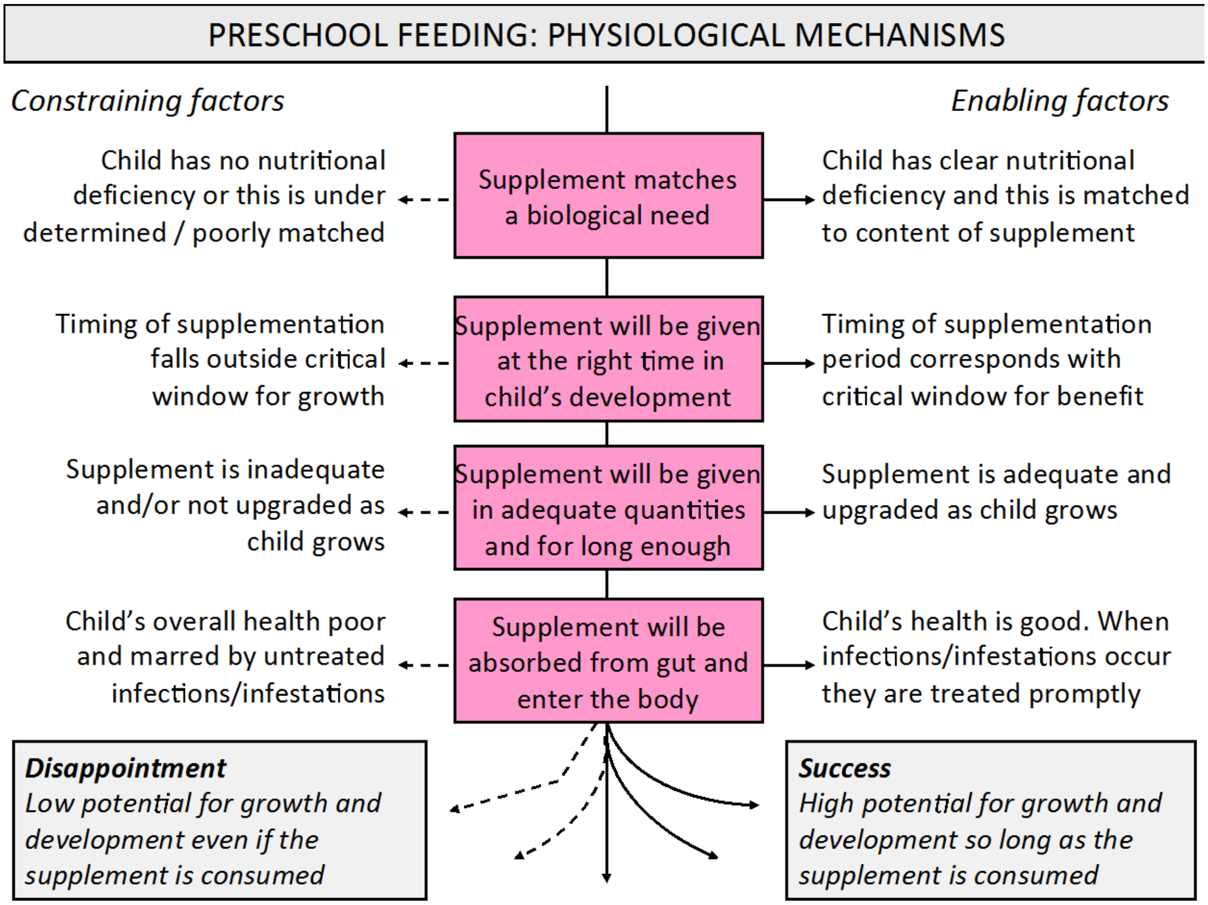
5.2.6 Physiological mechanisms linking the supplement to growth and development

The identified physiological mechanisms and their interactions with contextual influences are summarized in Figure 7. First, programmes where the supplement was designed to redress a clear nutritional need tended to be more successful than those where nutritional need was defined in vague terms and not explicitly measured. [106] Several studies with little or no impact were characterized by limited assessment of nutritional need or by absent or weak match between the identified need and composition and volume of the supplement. [105] [93] [103] [103] [61] [41]

Relatedly, as mentioned previously our nutritional analyses showed that the percentage of the Recommended Daily Intake (RDI) for energy in the supplementary feeding varied widely: from 8% to 100%. [111] Furthermore, the % RDI was quite low in several studies and often was not increased sufficiently as the child grew. Indeed, only a minority of studies in our sample increased the amount of the supplementary food as the child got older. [100] [93] [101]

Finally, authors of one study [49] suggested that effects on growth were not stronger because the supplement led to greater physical activity, hence burned off some of the additional calories.

Figure 7. Summary of physiological mechanisms



5.3.1 *Agentic mechanisms in the child*

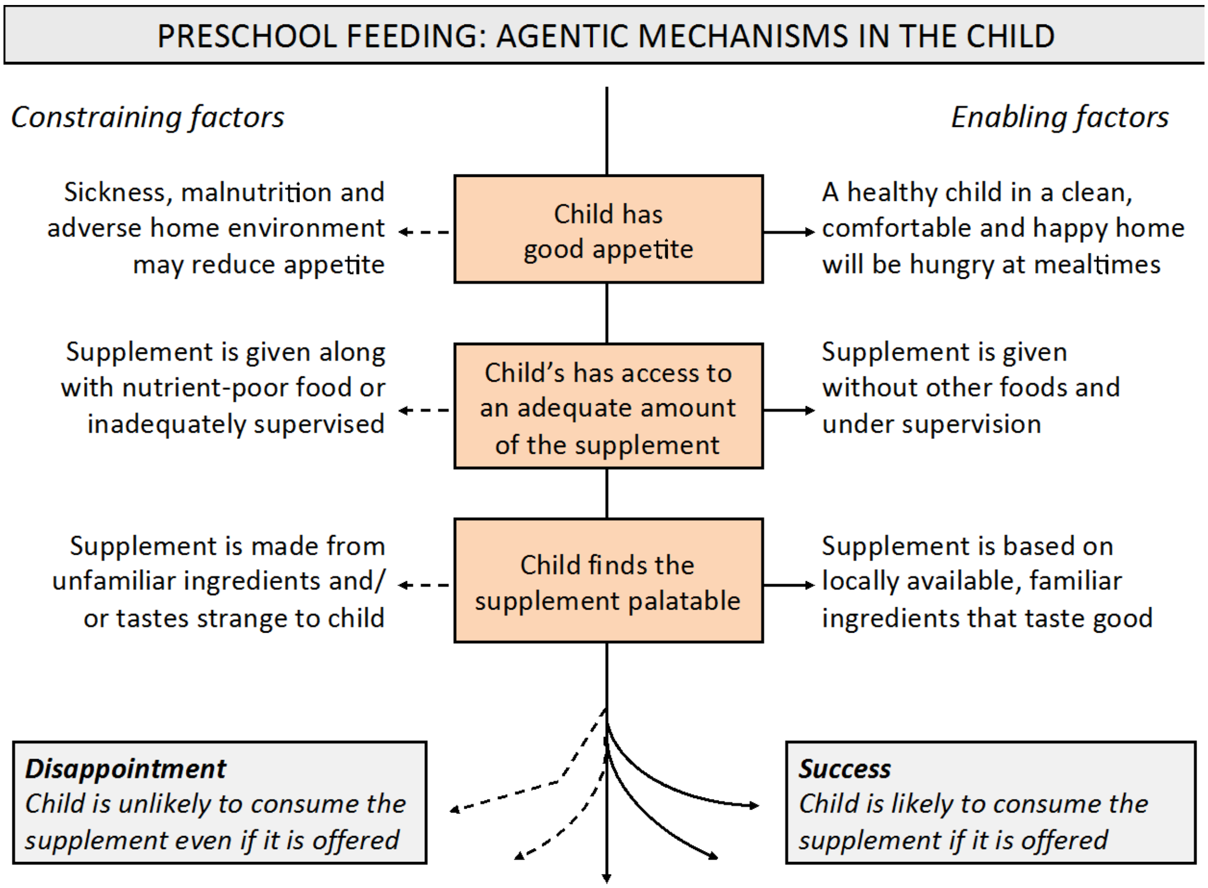
Even given that a food supplement that is matched to nutritional need, impact on growth and development requires that the supplement be provided and consumed consistently. Figure 8 summarizes three main mechanisms by which a child may come to consume the supplement (or not) when it is offered.

First, a child with a normal appetite is more likely to eat or drink the supplement than one with a reduced appetite. [100] A number of contextual influences appeared to influence the child's appetite: prior nutritional status, concurrent illness and adverse home environment. [36 94] While our review excluded studies with children who were overtly sick, subclinical illness may have been common in some deprived communities and may have reduced some children's appetites. [43] Failure to gain weight despite adequate supplementation was sometimes attributed to profound malnutrition affecting both bioavailability of food and appetite. [56]

Second it is important to provide the supplement in a sufficiently dense physical form. [81] Young preschool children have small gastric capacity and thus, it is possible that children may be physically unable to consume the entire supplement. [87]

Third, the child must find the supplement palatable. [106] Studies in this review suggested that this would be more likely if the supplement was based on locally based ingredients which he or she already found palatable. [63 106 33 102 44] Another proposed contributor to palatability was a high fat/protein content[106] though this was not tested in any study.

Figure 8. Summary of agentic mechanisms in the child



5.3.2 Agentic mechanisms in caregiver (general)

In order for the supplement to be offered to the child consistently, the caregiver must be receptive to supplementation and/or health-related education or support *in general* (this section, Figure 9); they must also actually receive and respond to the *specific* education or support offered in the programme (next section, Figure 10). The studies in our sample suggest that a number of preconditions influence caregivers' capability to respond to a nutritional intervention.

First, a caregiver living in abject poverty will be less capable of responding to any intervention. Some trials with disappointing impact of a supplementary feeding programme attributed this finding at least in part to the limited ability of caregivers to engage with the intervention because of profound levels of poverty. [100 101 43 56]

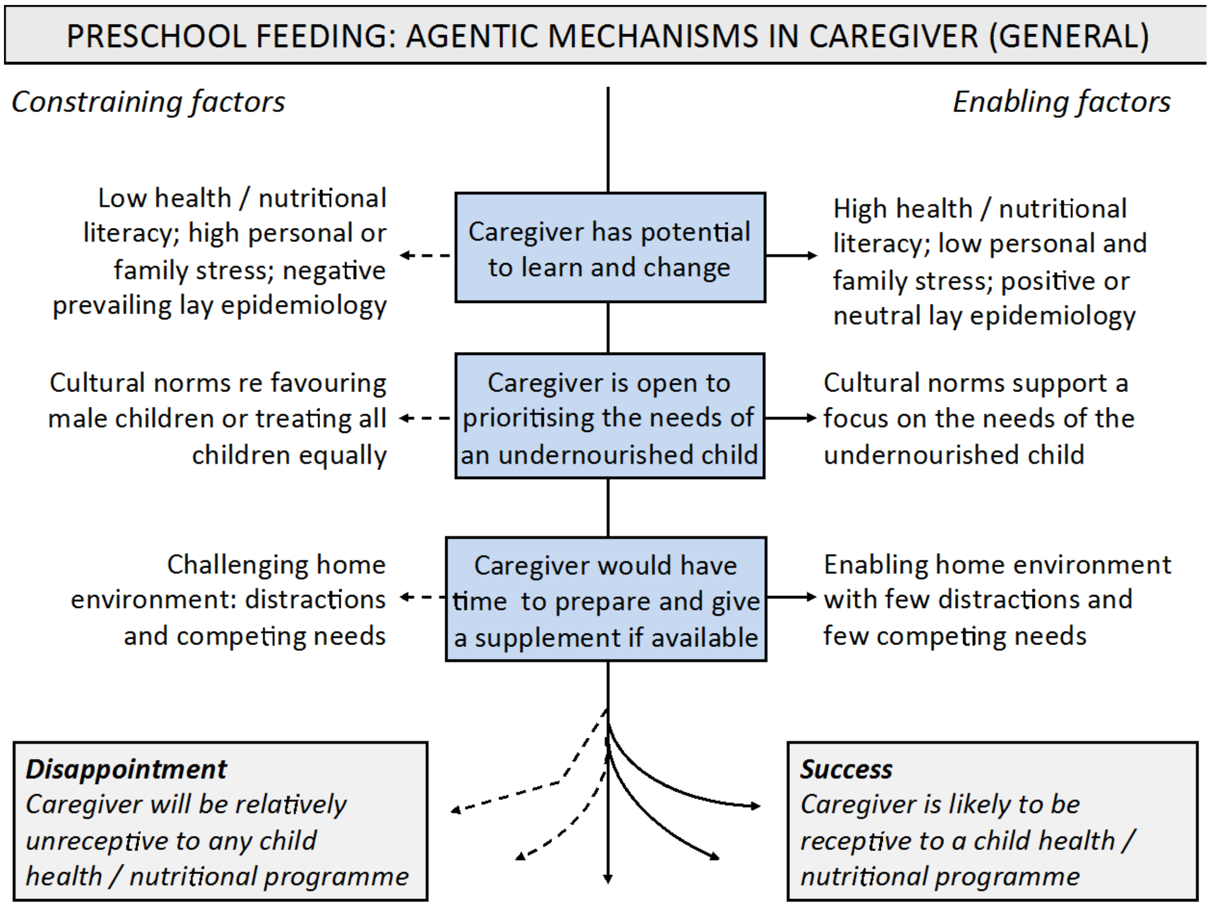
Feeding programmes tended to be more effective when the caregiver had sufficient time and resources to prepare and administer the supplement as intended. A home environment with sufficient space, clean water and few distractions was a more enabling context than one with a challenging home environment, distractions and competing demands on caregiver time. [56] For children in day care, lack of sufficient staff (and, more generally, a poor quality day care environment) sometimes led to insufficient time and resources to feed the children adequately.[56 70]

Often, the wider home and community environment lacked resources (e.g. extreme poverty, poor sanitation, lack of clean water) and was a source of stress[56 42] Adverse environments can be partially overcome by supplements, but growth does not increase as much as it would have occurred had the environment been more supportive. [63]

Second, the caregiver's health and nutritional literacy will make them more or less receptive to supplementary feeding for their child and to education and support in this regard. [65] In Bangladesh, the program of supplementary feeding with nutrition education was based on the premise that 'bad' habits' and poor nutritional knowledge were responsible for child undernutrition. [75] Thus, in this study as in others, [75 51 105 41 33 40 43 44 104 103 93 102], [46 107]caregivers were given nutritional counseling. In some studies where supplementation had limited impact, levels of health and nutritional literacy in the local community were extremely low, hence programmes began from a low base and sometimes had to counter prevailing folk myths and 'lay epidemiology'.[43] Authors of the Bangladesh study attributed poor results, in part, to the fact that they hadn't reached out to other members of the family (father, mother-in-law) who made nutritional decisions. [75]

Third, the caregiver must be open to the suggestion that an undernourished child may need to be treated differently and 'favoured' over other children in the family. This is difficult to achieve. One qualitative study, for example, explored the deeply held maternal views about *not* favouring one particular child over the others, even when that child had greater nutritional needs. Our sample included a number of studies where the supplemental food ration was diverted within the family, [72 43 65] particularly to adult wage earners[103 43] or siblings; sometimes this was related to gender. [65 83] In one study, [43] only 32.5% of the participating children received the full ration. Substitution also occurred (i.e. the supplemented child was given less food at other times). [100 91]

Figure 9. Summary of agentic mechanisms in caregiver capability



5.3.3 Agentic mechanisms in caregiver (programme-specific)

Several aspects of the programme context are important for the caregiver to benefit maximally from the specific package of education and support offered with the supplement as part of a complex intervention (Figure 10).

First, the level of trust between the caregiver and the programme appears to be crucial. In our sample of studies, contextual influences that tended to engender trust in a programme included a history of similar programmes with positive experiences in that locality, high cultural synergy (e.g. local staff preparing and delivering local food), a perception of accountability to the local community and a general sense that the programme is well-organized, efficient and responsive. Conversely, a history of negatively received programmes, a perception that the programme was top-down and inflexible, or the absence of a previous working relationship with the community made trust more difficult to establish. In some studies with limited impact, supplements appeared to have been viewed negatively within the community. In contrast, in other studies, the supplement was seen as a ‘prestige food’ or ‘health boost’. Thus, caregivers were interested in it and motivated to co-operate with the programme[63]. In one study where a programme had limited impact on outcomes across a range of low-income settings, for example, the evaluators commented:

"The program is run in a very top-down fashion, with all the implementational inefficiencies and rigidities that such an approach entails, and workers are not accountable to the communities they serve. Also, the heavy focus of the [policymakers] on nutritional supplementation leads to the relative neglect of other more cost-effective approaches to improving nutrition outcomes. This would include efforts to improve environmental hygiene and domestic health management practices, so that children are less exposed to disease and its consequent toll on child growth" (page 4-5[64]).

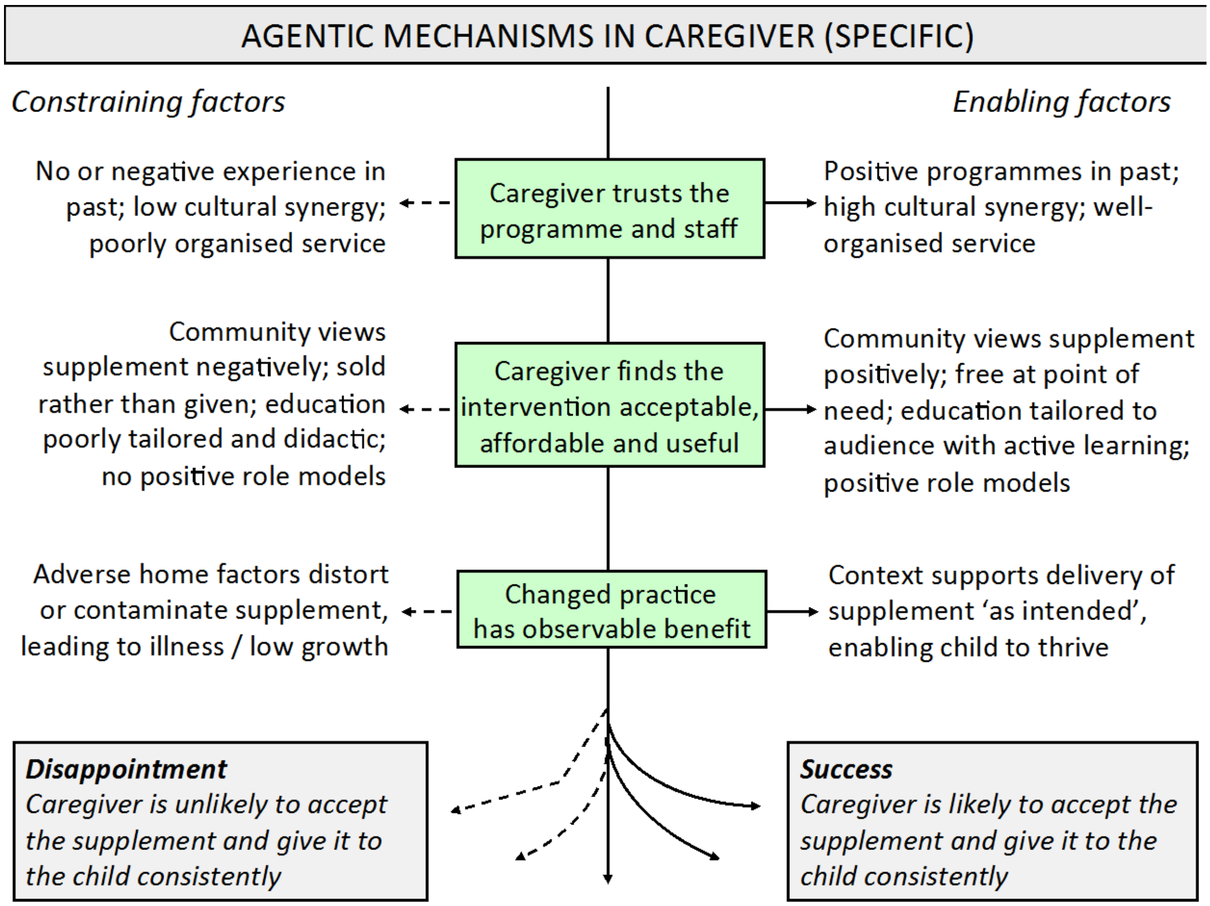
Second, the caregiver must find the supplement acceptable, affordable and useful. Few programmes in our sample involved a cost to participants, but subsequent rollout after a trial was often dependent on continuing to provide the service free. Relatedly, distance from home to distribution centre may be important. One study found that the distance of feeding centre to child's home was proportional to the dropout rate [89] and another study was designed to ensure that no caregiver had to walk more than 1.5 km to collect supplements [103]. Other aspects of the education/support package that appeared to increase its acceptability and usefulness to caregivers included careful tailoring to the knowledge needs and learning styles of the target group and the use of active, hands-on teaching methods [66 104 104] and wider advice on child nutrition (e.g. breast feeding, complementary feeding) [36] .

Third, the changed feeding practice must produce an observable and positive change in the child's health status. In some studies, the supplement was sometimes discontinued when the child became ill with fever or diarrhoea. [100 80] One author explained illness in terms of poor food preparation techniques (e.g. failure to boil water for milk powder). [100] Another problem is that sometimes mothers with low nutritional literacy may discontinue breastfeeding their children who receive supplementary feeding. [107] Three studies in our review examined this issue with contradictory results. In Ecuador, supplemental feeding did not interfere with breastfeeding practices. [107] In Indonesia, this was only true for male children [50]. However, Bhandari and colleagues[100] found that the proportion of mothers who breastfed their children was lower in the supplemented group.

A particular theory of change identified in this regard is *positive deviance*, defined as follows:

"Positive deviance (PD) refers to a phenomenon that exists in many resource-poor communities, that is, the finding that a few individuals and families employ uncommon, beneficial practices that allow them and their children to have better health as compared to their similarly impoverished neighbors. These PD behaviors are likely to be affordable, acceptable, and sustainable by the wider community because their peers are already practicing them." (Page 3 [54])

Figure 10. Summary of agentic mechanisms in caregiver (specific)



5.3.4 *Agentic mechanisms in programme staff*

The front-line staff who deliver a supplementary feeding programme are crucial to its success. They must draw creatively on the programme's resources and available infrastructure to 'make it work' in different local settings. Our data suggest three key mechanisms are involved: staff capability and motivation, whether and how they engage with caregivers and promote active learning and whether and how they monitor the programme's success and adapt their efforts in the light of process data. Figure 13 summarizes the mechanisms through which the programme staff can influence effectiveness.

Breakdown in the supply chain can severely limit effectiveness. In one study, 50% of the caregivers reported 'gaps in delivery''; 36% reported that these gaps occurred more than twice. [101] One of the studies that did not meet the eligibility criteria for the Cochrane review (but which provided important data for wider theory-building) reported that in India, supplies failed to reach those who delivered the programme 20-30% of the time. [64] In low-resource settings, trained staff may be in short supply. Much effort may need to be put into a training programme to ensure that all team members understand the intervention and are capable and willing to deliver it according to protocol.

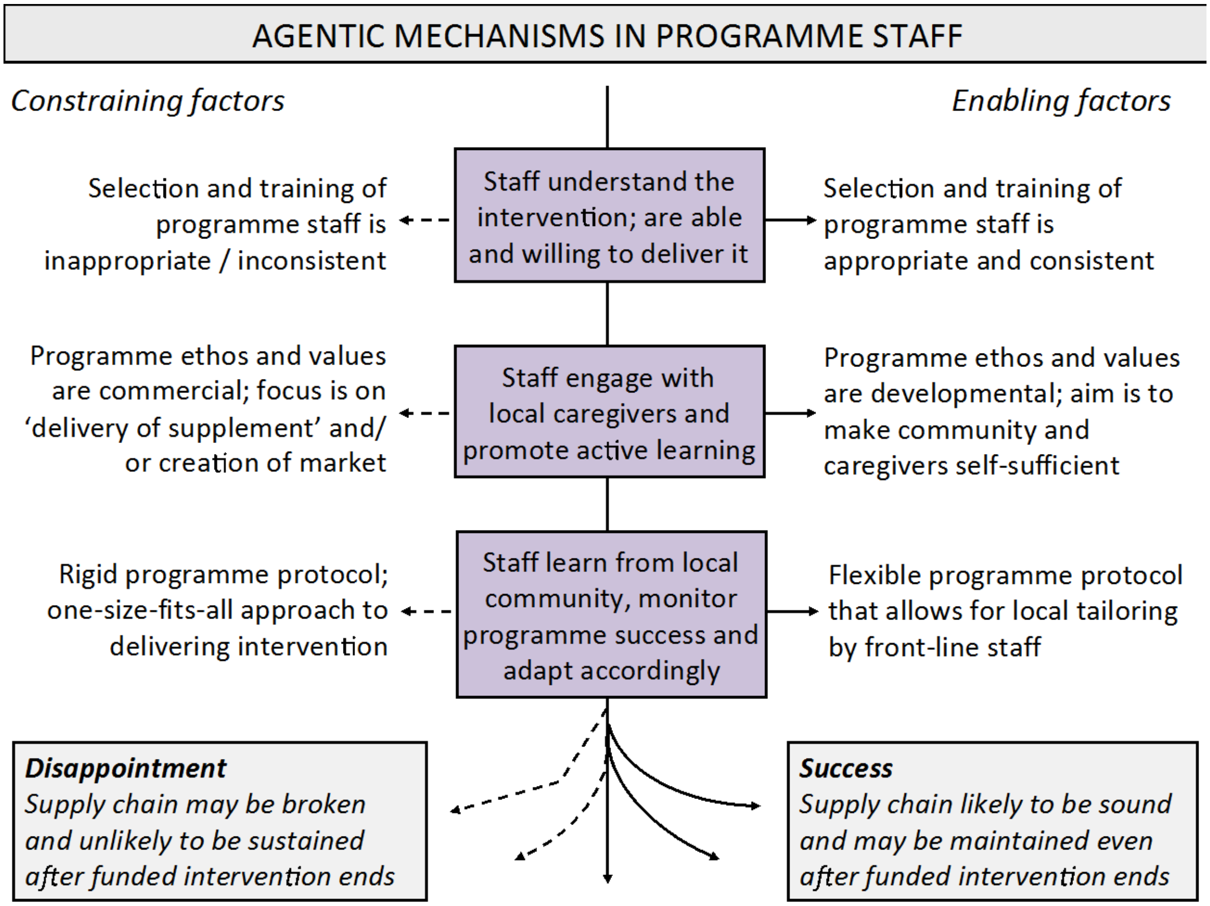
As the previous section emphasized, the final pathway for delivering the supplement is the caregiver (and the child). An essential element of most feeding programmes (if they are to be sustainable) is promotion of active learning in the caregiver. To achieve this, programme staff must engage closely with caregivers, understand their background and learning styles, take account of contextual barriers to learning, and promote active learning. Whilst the principles of 'educating for capability' are near-universal[112] , the precise ingredients for success will differ substantially between settings (and indeed, between caregivers within any setting).

One study, for example, provided a take-home ration and the health worker went to the participant's home twice a day and helped to prepare and administer the food, thus achieving both supervised intake and caregiver active education.[93] Four studies providing take-home rations included intensive input from programme staff, such as delivering and preparing the supplements twice a day, 7 days a week [93] ; twice weekly visits to collect empty and partly used wrappers; [100] weekly visits to the home [107] or random visits to check container contents. [43] Through repeated visits, a relationship was built between health worker and caregiver, allowing development of trust and ongoing, active education.

In some studies in our sample, however, the ethos of the programme did not emphasize educating for capability. As noted above, spot feeding was one way to get around the issue of caregiver incapacity, but this would not lead to a sustainable way of feeding the child effectively after the end of the programme. Another solution to low caregiver capacity was that a number of studies, often sponsored by manufacturers of commercial food supplements, provided pre-cooked and ready to mix food, or pastes (typically based on a regional staple such as peanuts) that could be consumed from the packet or as a spread. [86] [93] [91] [103] [107] Such 'ready to use therapeutic food' (RUTF) formulations, overcame (at least temporarily) the practicalities and challenges of food preparation, the limited capability of caregivers, the problem of portion size measurement and some limitations of the home environment (e.g. lack of fuel). [100] [72] In addition, RUTF was produced in a very energy-dense ('thick food') formulation, allowing the child to obtain high energy from low volumes, reducing the likelihood of displacing other food (or breast milk) from the diet, and – according to one group of authors – reducing the risk of redistribution within the family. [61] Interestingly, the trade-off between this instant commercial solution and a more locally embedded one based on local ingredients and linked to caregiver education, especially in relation to long-term sustainability, was not empirically tested in any study.

A third mechanism by which programme staff deliver effective feeding programmes is adapting their efforts in light of process data. In one study, caregivers' use of the supplement and the optimal amounts to be fed were reviewed every month; if the mother reported non-acceptability, the child was fed in the mother's presence to demonstrate that he or she could consume the recommended amounts, and additional packets were given for the other siblings if requested. [100]

Figure 11. Summary of agentic mechanisms in programme staff



6. Discussion

Feeding interventions for young children are complex interventions; studying them requires consideration of a number of factors within the context, the family, and the children. Below, we summarize the major effectiveness findings from the review. Then, we discuss factors that may impact on effectiveness, integrating results from the Cochrane and realist reviews.

Supplementary feeding young children has a small effect on gain in weight and weight-for-age z-scores (WAZ) in low- and middle-income countries

Meta-analyses of weight gain and WAZ gain in RCTs showed increases for children who were supplemented compared to those who were unsupplemented. However, these differences were small (0.12 kg for weight and 0.15 for WAZ over a period of six months).

Results from high-income countries were mixed. An American study of infants from predominantly middle-class families found no effects. However, large gains of 0.95 kg. relative to controls over four months were realized in a study among 116 Aboriginal children in remote Australian communities; if a similar trajectory were maintained for a year, the children who were fed would have gained 2.85 kg. This may be because the Aboriginal children were less well nourished at baseline than those in the American study. In Australia, Aboriginal families are more likely to suffer food insecurity than non-Aboriginal families (24% compared to 5%). [113]

Supplementary feeding young children has a small effect on gain in height and height-for-age z-scores (WAZ) in low- and middle-income countries

The meta-analysis of nine RCTs revealed that those who received supplementary food grew 0.27 cm more than controls over an average of six months. Results for height-for-age z-scores (HAZ) in the RCTs also revealed a small impact: over five months children who received food supplementation gained 0.15 more than controls.

Psychosocial development

While nearly all of the studies assessed growth, only eight assessed psychosocial outcomes in response to supplementary feeding.

Supplementary feeding may have a moderate positive effect on psychomotor development in low- and middle-income countries

Our meta-analysis of two RCTs in low- and middle-income countries found greater gains in psychomotor development for children who were supplemented. Two other RCTs reported equivocal results.

The evidence on attainment of motor milestones is equivocal. Two studies revealed that supplemented children reached motor milestones earlier, but the effects in one of them disappeared after maternal education was entered into the equation. Another study found no differences.

The evidence of effects on cognitive development in low- and middle-income countries is sparse and mixed

Our meta-analysis of two RCTs in low- and middle-income countries (178 children) found greater gains in psychomotor development for children who were supplemented. Two other RCTs reported equivocal results.

There is sparse evidence that feeding may result in long-term gains in intelligence or cognition in low- and middle-income countries

One RCT found long-term effects of supplementation and stimulation on perceptual motor skills. The effects of supplementation alone were limited to those children whose mothers had high scores on verbal intelligence at baseline while the effects of supplementation AND stimulation extended to all children. This suggests that supplementary feeding may be most effective if mothers have higher capacity to feed and stimulate their children. Another study found that supplementation had very small long-term positive impacts on working memory but not on reaction time or math performance.

Supplementary feeding results in increased haemoglobin and lowered anaemia in low- and middle-income countries

Evidence from five RCTS revealed a positive effect of supplementary feeding on haemoglobin that was equal to half of a standard deviation. Furthermore, evidence from two controlled before-and-after studies (CBAs) found that supplementary feeding reduced the risk of anaemia.

Factors that can impact on effectiveness

Our process analyses (subgroup and realist) identified several factors that impacted on effectiveness. Below, our findings from the quantitative and qualitative components of our review are integrated and summarized.

Biological mechanisms/Mechanisms in the child

Child's age

The notion of a critical age window for provision of supplementary feeding is long-standing. Results from subgroup analyses are somewhat mixed, but generally found that children who were younger at the start of the studies grew more in response to the supplemental food than those who were older (over 2 years of age). Our findings are consistent with those of Beaton and Ghasemmi[26] and Dewey [34] who concluded that feeding interventions have maximum impact on linear growth if they are started in infancy as the period between 6 months and 24 months is one of rapid growth. [34] However, it is important to note that feeding can also have an impact on linear growth in older children. [26] In fact, our earlier review of school meals found that linear growth in school aged children was increased by 0.25 to 1.47 cm. per year when adequate nutritional supplementation was given. [111 114]

The relationship between age and supplementation is less clear for psychosocial development. In one study, younger children benefitted more, but several studies in our review were performed with older children and showed benefits. One study directly tested, and refuted, the hypothesis that there is a critical age window for supplementation and mental development. [47]

Although in our view, the physiological mechanisms have not been thoroughly drawn out, [33 93 52 104 88 53 62] most evidence does suggest that supplementary feeding should probably start when children are below 2 years of age.

Gender

Gender equity is an important consideration in LMIC. In some contexts, there appears to be a cultural preference for favouring male adults and children in the distribution of food within the family. This was found in a qualitative study in Guatemala [115], in surveys in Bangladesh and the Philippines [116] and reported in one of our included studies. [46] Thus, the question of whether males and females benefit equally from feeding interventions is quite important.

However, the evidence is sparse and mixed. Our subgroup analyses of two CBAS found no difference in effectiveness by sex. However, two other CBAs reported stronger effects on growth for girls than for boys. This latter finding is consistent with analyses from the longitudinal Guatemala study [115], which showed that girls benefited more in terms of growth and cognition from supplementation. We believe that this should be explored further, both quantitatively and qualitatively.

Poverty/Child's Nutritional Need

The realist review found that programs were more likely to succeed when they filled a nutritional need. Supporting this, our analysis of one study found greater effectiveness for weight gain if children were undernourished at baseline. Analyses within two primary studies also found greater effectiveness for undernourished children: one for weight and another for skinfold thickness. Two other studies found that young undernourished children had greater height and WAZ gain in response to feeding, but that older undernourished children did not. Relatedly, the one HIC study that showed effectiveness for growth was performed among Aboriginal children. This may be because the Aboriginal children were less well nourished at baseline than those in the other high-income country studies. In Australia, aboriginal families are more likely to suffer food insecurity than non-Aboriginal families (24% compared to 5%).[117]

It makes biological sense that the children who are more undernourished would benefit more from supplementary feeding. Our findings concur with those of Beaton and Ghassemi [26] and Kennedy.[81] They also have important implications for targeting interventions, if targeting is necessary. [81]

However, as mentioned above, two studies found no effects of nutritional need and one primary study found that children living in very poor socio-economic conditions did not respond as well to supplementation as those living in better socio-economic conditions did. We suggest that poorer children are more likely to benefit from feeding, but that feeding may not be all that is needed to overcome the effects of deprived environments.

It is important to point out that we were not able to assess whether or not the food actually reached those children who were most in need. Beaton [26] and Rondo [118] both noted that feeding programmes in developing countries often fail to do this.

Caregiver capacity

Our realist review found that caregiver capacity is an important factor in success of supplementary feeding. Furthermore, authors of the Jamaican study reported that supplementation only had long-term effects IF the mothers had high vocabulary scores at baseline (and thus, presumably greater capability). Our findings concur with Wachs, [27] who noted that maternal education and health literacy are important contributors to infants' dietary intake and nutritional status.

In resource poor environments, caregivers may lack nutritional knowledge and/or the energy to prepare and distribute the supplements adequately. They may also have to overcome traditions of favoring male children or, alternately, the tendency to feed every child equal amounts of food. To circumvent these problems, seven programs gave the family extra rations to reduce sharing of the target child's supplement; some supervised and monitored intake when rations were home-delivered. Other programs fed 'on-the-spot', at daycare, preschool and feeding centres. This latter method of delivery did seem to ensure that the child consumed more of the supplement, and there was some indication that gains in growth were larger when feeding was delivered at day-care or preschool.

However, the final pathway for delivering the supplement is the caregiver (and the child). An essential element of most feeding programmes (and of sustainability) is therefore promotion of active learning in the caregiver. To achieve this, programme staff must engage closely with caregivers, understand their background and learning styles, take account of contextual barriers to learning, and promote active learning. Whilst the principles of 'educating for capability' are near-universal [112]; the precise ingredients for success will differ substantially between settings and caregivers.

Implementation

Energy provided and nutrient density of the supplement

Supplementary food should provide enough energy to meet biological needs, and yet, we found that several studies did not provide sufficient energy.

Our hypothesis that higher nutritional adequacy would result in better outcomes was partially supported. Among the RCTs, there was little evidence of subgroup differences but weight, but for height, the studies that provided high nutritional adequacy were the only group which found positive effects for feeding; the differences between high and low and between high and moderate nutritional adequacy subgroups were 0.37 cm and 0.46 cm respectively. We believe that this subgroup analysis may have been non-significant due to a dearth of trials in the high adequacy group.

Among the CBAs, there were no significant subgroup differences, but programmes that provided moderate nutritional adequacy (four trials, 651 children) had significant positive gains in weight after supplementary feeding, while the group who received low nutritional adequacy (five trials, 961 children) did not. The mean difference for the moderate adequacy group was also 0.32 kg higher than that of the high-energy group. It is important to note that the high-energy intervention group for the CBAs contained only the Santos 2005 trial, which had substantial issues with unreliable delivery and leakage within the family. For example, 50% of the caregivers reported 'gaps in delivery'; 36% of caregivers reported that these gaps occurred more than twice. Furthermore, only 32.5% of the participating children received the full ration. For the remainder of the children, the ration was shared with one to three other children and one to two adults. Despite the fact that the ration should have provided a high amount of energy, the supplemented group actually took in fewer calories than the control group.

Relatedly, the realist review suggested that it is important to provide food with a high nutrient density relative to volume. This is important because young children often cannot consume high volumes of food. "A preschooler may feel satisfied even though his/her nutritional needs are not being met" (p 10, [81]).

Mode of Delivery, Supervision and Leakage

Two interrelated programmatic factors influencing child's access to the supplement are mode of delivery and supervision. These in turn, can impact on the level of leakage and substitution. Our analyses showed that when the supplement was given at home, the children took in only 36% of the energy provided by that supplement. When it was given in day-care and feeding centres, however, the children benefited from an average of 85% of this energy. It is likely that this reduction in energy benefits from the take-home supplement was at least partially due to ''leakage' within the family. This issue has been well-documented. [81] Although 'this is understandable in the context of food-insecure families' (p. 4, [119]), the result of such leakage is that the targeted child gets less food, and therefore less impact on growth and development can be expected.

There were not enough data to fully test our hypotheses about mode of delivery in the RCTs, as only one study provided feeding on the spot. Among the CBAs, there was no evidence of subgroup differences for weight. However, children who were fed in day-care or feeding centres were the only ones who gained significant amounts of weight relative to controls. For height, there was a non- significant effect for any of the subgroups, but the subgroup that was fed 'on-the spot' had a mean that was 0.93 cm higher than those who were fed at home. We believe that the lack of statistical significance may have been due to other differences in implementation. An exploratory sensitivity analysis showed that when Manjrekar [89] (whose results were markedly different from those of the other studies) was removed from the subgroup analyses for weight and height, heterogeneity was slightly lower, there was evidence of an effect for both subgroup analyses, and the effects in the day-care group were stronger. It is notable that this study had a very high dropout rate.

Our hypothesis that programmes with stricter supervision would be more effective was partially supported. There was no evidence of subgroup differences for RCTs, but this analysis only compared moderate to strict supervision. There was also no evidence of an effect in the CBAs, but we did find that children in the studies with the strictest supervision gained more weight as a result of feeding than children in the studies with moderate or little supervision (0.24 kg and 0.29 kg more respectively). The same was true for height (0.54 cm and 0.85 cm difference between high and moderate and low supervision respectively). As with the above sensitivity analysis, we redid this analysis without Manjrekar [89] and found a significant subgroup effect for weight.

These findings are consistent with findings from Beaton [26] and Rondo [118] who also found greater effectiveness for feeding programs where food was given directly to the children 'on-the spot'. Two studies compared spot feeding with home feeding and showed greater growth with the former[103] [85].

Our hypothesis that multiple interventions would be more effective for growth was unsupported. Among the RCTs, both single and multiple interventions were effective for weight gain but the effect size for multiple interventions was higher. For height, two RCTs that provided multiple interventions (495 children) did not show effects while the seven RCTs that provided single interventions (952 children) were effective for increasing height. Among the CBAs (1782 children), neither single nor multiple interventions were effective for increasing height.

For psychosocial outcomes, there was no evidence of subgroup differences, but the effect size for the supplementation + stimulation group in one study (n = 65) was twice as high as effects for feeding only. It is likely that stimulation combined with feeding is especially effective for psychosocial development.

Program Staff motivation, training and flexibility

The realist review found that program staff are integral to the success of the food supplementation. Staff must first of all ensure that the supply is delivered. Two of our studies reported breakdowns in the supply chain such that supplements only reached the families part of the time. Such failures in delivery have been reported by others who reviewed preschool feeding programs [81] and those who reviewed school feeding programs. [114]

Staff must also be highly motivated, well trained and capable of preparing and delivering the supplement safely and consistently. Finally, they need to be flexible and able to adapt the program as they learn what works and what does not.

Overall completeness and applicability of evidence

We believe that our review provides very comprehensive coverage of the literature. We screened almost 33,000 studies from a well-designed literature search; we also carefully scanned reference lists of included studies and of reviews. Our included studies covered many countries and regions, including Latin America, Africa, Asia, North America, and Australia. Studies in low-income countries predominated; this is not surprising, as 81% of the world's people who suffer from hunger live in LMIC. [120] However, it does mean that results of the review are probably not generalisable to high-income countries.

The small effect sizes for weight and height are not what we expected. However, this finding of small effects on growth is consistent with Beaton and Ghassemi.[26] In the past, failure to show consistent effect on growth has been attributed to the use of inappropriate indicators in measuring impact as well as poor targeting of the intervention. [30] However, in our review we considered several indicators of growth and assessed impact by age, interventions targeted at children under two years, a period in which linear velocity is highest. [121] Many of the newer interventions were based on the latest scientific findings about what is efficacious. But for programmes to effect changes in growth and be sustainable, there has to be a connection between science and quality of implementation. [122]

The evidence base on psychosocial effects of supplementation is rather sparse; we found that only eight of 32 studies assessed psychosocial outcomes. We found mixed, but generally positive effects of feeding on psychomotor development and cognition. Our findings on psychomotor development support Pollitt. [21] Interestingly, the effect sizes for psychosocial outcomes were somewhat larger than those found for growth. There could be several reasons for this. First, most of the studies on cognition were among those that demonstrated better implementation, including higher nutritional adequacy. Second, they were also relatively small studies and thus were able to have tighter control over the intervention. Third, there were far fewer studies on cognition; it is possible that with more studies, effects might be diluted. Fourth, it is possible that if more studies were done, effects might be diluted. Fourth the pathways between feeding and growth and between feeding and cognition are likely different.

It is possible that psychosocial outcomes are more sensitive to nutritional intervention. [34] The concept of "brain sparing" may be relevant here. Brain sparing refers to the hypothesis that, when nutritional resources are scarce early in life, they are preferentially directed to the developing brain at the expense of other parts of the body. [123] This is supported by animal studies. [124] Brain sparing has been shown during intra-uterine growth and the neonatal period resulting in slowed body growth (height and weight) with normal brain growth. Brain sparing has also been shown in the context of micronutrient deficiencies. [125] This suggests that when a child is given supplemental energy, protein and micronutrients, they may be used for brain development first and then for growth and other aspects of health.

The possible link between increased nutrition and psychomotor and mental development is complex and involves a number of possible mechanisms. Such mechanisms include increased myelination, increased alertness and curiosity [55] and increased motor activity resulting in enhanced motor development and consequent improved mental development Pollitt. [126] This latter mechanism is somewhat controversial; while support for this was found in the Tea Plantation study, [126] the Jamaican study found no increase in motor activity and no effect of motor activity on later development. [55] Meeks Gardner [55] suggested that effects of nutrition on increased motor activity might be dependent on context or age of the child, or both, and hypothesised that the quality of play and exploration might be more important for child development than the quantity of increased activity. Clearly there is a need for more carefully developed studies of the mechanisms that may link improved nutrition to psychosocial development.

Strengths and limitations of this review

The current study combined the strengths of Cochrane review methodology and quantitative process evaluation with the insights into mechanisms of effect provided by the realist methodology. Thus we were able to go beyond the “what works?” question and consider the more nuanced question of “what works for whom in what circumstances?” A particular strength of this review was that we followed the recently produced RAMESES guidance and publication standards for undertaking realist reviews. [37]

Minimizing bias. We minimized bias by having at least two independent people involved in every aspect of identifying potential studies, deciding on inclusion/exclusion, extracting data, and doing both realist and quantitative analyses and synthesis. However, a few potential sources of bias may remain.

Publication bias. We searched web sites of relevant agencies and found a number of evaluations of feeding programs, but it is possible that we have missed some. This is probably not too serious, however, as the reports found on the web sites failed to meet our inclusion criteria.

Bias in correcting for clustering. As noted above, we corrected for clustering in a number of studies. This is vital in order to ensure that confidence intervals are not artificially too narrow. However, these corrections are highly dependent on the ICCs and on the cluster size (both of which were estimated). We did carry out a sensitivity analysis with different ICCs and, reassuringly, it made little difference.

Quality of primary studies/lack of descriptive detail in primary studies

Feeding interventions for young children are complex interventions that are difficult and fairly costly to implement. Studying them therefore requires consideration of a number of factors pertaining to the context, the family, and the children.

Our judgments on the quality of the evidence ranged from very low (CBAs) to moderate (RCTs). However, it is important to note there are many old studies in the review, and that the quality of the studies, in terms of both design and implementation, has improved markedly in the last 10 to 15 years. In general, we placed more weight on the RCTs when drawing our conclusions.

One important problem was attrition rates. Among those that provided them, these rates ranged from 1% to 78%; 10 studies had attrition rates above 20%. Correspondingly, most of the analyses were conducted on completers rather than on an intention-to-treat (ITT) principle.

Another issue is that authors of several studies did not mention whether those who assessed study outcomes were blinded to the allocation status of the children. Blinding of outcome assessment is crucial in order to ensure that there is no bias because of prior knowledge. [127]

Finally, ten study authors did not adequately control for clustering in their analyses. We adjusted for clustering for eight of them, but could not do so for the other two as we did not have access to the standard deviations.

One key limitation of the realist review was the dearth of descriptive detail in many of the primary studies. In particular, very few studies gave detail on how programme staff were selected and trained, how they engaged with the programme, and how they adapted the intervention to local circumstances – or why they chose not to do this or were prevented from doing so. Such detail is essential for identifying, refining and testing programme theories. Because so few of the studies included process detail on these (and other) aspects of the programme-in-action, the findings and conclusions of this review should be seen as preliminary.

Finally, we were not able to assess whether or not the food actually reached those children who were most in need. Rondo [118] and Beaton [26] pointed out that feeding programs in developing countries often fail to reach those who need it most. Lutter [107] has called for all studies of supplemental feeding to assess reach.

Agreements and disagreements with other studies or reviews

We found one Cochrane review of RCTs of the effectiveness of supplementary feeding on growth, [128] two systematic reviews on complementary feeding, [34] [129] two earlier reviews of the effectiveness of supplementary feeding on growth[20] [26] and other outcomes [20] as well as one short review and meta-analysis of nutrition and cognition. [21]

Our review has a wider scope than the above reviews and is somewhat more recent. Nonetheless, our conclusions that feeding interventions for young children can be effective for growth are fairly consistent with those of Dewey[34] and Beaton, [26] somewhat consistent with Lassi [129] and inconsistent with Sguassero. [128] For example, like Beaton[26] and Dewey, [34] we found small effects on growth and concluded that feeding interventions are currently underperforming. Our findings that feeding interventions were generally more effective for growth in younger children concur with those by Beaton in his two review. [20] [26] However, we feel that there has not been enough research on their effectiveness in older children. We also agree with Beaton [20] that the pathways between feeding and growth and feeding and psychosocial development are quite different, and that feeding can have an important impact on psychosocial development beyond the age of two. Finally, we concur with Pollitt [21] that feeding has positive impacts on psychomotor development.

Our findings on factors that can impact on success are very similar to some of those described by Kennedy and Alderman. [81] For example, our findings concur with their paper on leakage within the family and substitution. Our results also support their findings that 'on site' feeding can markedly curtail leakages.

Authors' conclusions

Implications for practice

Our review has found that overall, supplementary feeding programmes for young children are underperforming. We have provided some evidence that feeding interventions can work, but this evidence strongly suggests that good implementation is key. Our findings lead to several suggestions for program development, implementation, and monitoring of nutritional interventions for children. However, it is important to realize that all programs need to be tailored to the context and to the needs of children and their caregivers. Furthermore, the realist review emphasized the importance of adaptability and flexibility in the program staff in response to ongoing learning about what is working and what is not.

Supplementation should begin early in the child's life. Our findings largely concur with those of other researchers [26] [20] that younger children seem to benefit more in terms of growth than older children. We suggest that supplementation should begin in infancy after a period of exclusive breastfeeding. As it may take time for supplementation to affect certain aspects of growth (Rivera, pers. comm.) and cognitive development (see, for example [51]), two authors have suggested that supplementation should continue for at least 18 months[130] or two years [131]

Target the poorest or most undernourished children or areas. Our review provides evidence that poorer and more undernourished children seem to be more responsive to supplementary feeding; this concurs with Kennedy and Alderman. [81] Thus when funding is limited it is both an ethical imperative and necessary from a cost-effectiveness point of view to target poorer areas, families and children. [81] However, careful attention needs to be paid to the other conditions in which the children are living.

Closely supervise the distribution and intake of the supplement. Our findings concur with previous work [81] as they show that children take in more total energy if feeding is delivered in a supervised feeding centre, day care, or preschool; the evidence also suggests that they may benefit more.

Build family capacity. Work is needed with parents, caregivers and the community to enhance motivation and capacity to deliver the supplement to their children. Relatedly, evidence from our review and from other studies on household food distribution suggests that the provision of education about the importance of feeding all children according to their needs may be necessary.

If possible, provide extra rations for other family members, and measure benefits to the whole family. Beaton[26] suggests that instead of viewing 'leakage' as totally undesirable, it may be seen as a benefit to the family. He noted that, at the least, feeding interventions increase family purchasing power. We concur with the view that the net benefit to the entire family should be measured. However, we believe that emphasis should still be placed on providing adequate nutrition to the children most in need within the family. One way to facilitate this may be to provide some rations for the entire family in order to reduce redistribution of the target child's supplement. Seven studies in the current review gave the family extra rations to reduce sharing of the target child's supplement. Similarly, the World Food Program's school feeding programmes are increasingly using take-home rations to ensure that children, especially girls, are able to go to school regularly.

In general, at least 30% of the dietary reference intake (DRI) for energy is desirable.

We found some suggestion that children may grow more in programmes that provide moderate (30% to 59%) or high (60% or more) percentage of the dietary reference intake (DRI) for energy. This is consistent with findings from Kennedy and Alderman. [81] According to Kennedy and Alderman, [81] it is important for programmes to account for leakage by providing more energy than needed to fill the 'existing calorie deficit' (the difference between the amount taken in and the amount needed).

Food should be palatable and culturally acceptable to children and their parents. Furthermore, foods that have a higher energy density for their volume are generally desirable.

In order to make it more likely that children will consume all of the food, we suggest that the food should be energy dense and lower in volume. Ready-to-use therapeutic food (RUTF) may be ideal for younger children or for children who are severely malnourished: it is energy-dense and requires little or no preparation on the part of the caregiver. However, for older children energy-dense local foods may be better in terms of palatability, acceptability, and sustainability. Interventions that deliver locally sourced foods can also provide stimulation to the local economy.

Monitor and evaluate on a continual basis. In addition to evaluating a range of appropriate outcomes, our review highlights the importance of evaluation that assesses all factors that can impact on the success of feeding. It is also important to monitor children's dietary intake, growth, and development on a regular basis.

Implications for research

It seems inevitable that reviewers will call for more research, and we follow this trend. However, we are NOT calling for more of the same research, but for research on relatively understudied areas. Furthermore, we believe that there should be guidelines for such research, and that process evaluation needs to be undertaken in addition to outcome evaluation. We have identified the following research needs:

More research is needed on preschool feeding and psychosocial development. Only eight out of thirty-four studies in this review assessed effectiveness for psychosocial development. Yet, we know that an individual's life chances are dependent on adequate motor, behavioural, and mental development in the first years of life. For example, early cognitive and social-emotional development are major determinants of school progress in developed and developing countries, which in turn, is related to adult employment status and income and contributions to family, community and society. [17] Findings from our review suggest that feeding interventions may have effects on psychomotor and cognitive development. As Dewey [34] noted, psychosocial outcomes may be particularly sensitive to nutrition intervention. Relatedly, we concur with Bhutta[36] that it is important to learn to what extent the cognitive deficits caused by early undernutrition are reversible. We realize that psychomotor and mental testing can be time-consuming and expensive to do on a large scale. However, more feasible, yet valid tests have been developed. [132] It is time that psychosocial development is given higher priority as an outcome of interventions.

More research is needed on the impact of feeding on older children. There is a dearth of research on feeding interventions for older children; we only found four such studies and they were all older (done before 1990), and generally not as well implemented as the newer studies. Therefore, we believe that the jury is still out on the question of effectiveness of feeding interventions for growth after the age of two and concur with Bhutta[36] that this is a major gap in our knowledge.

More research is needed on the question of the impact of feeding on gender and income equity in growth and psychological development. Our review has provided some evidence that supplementary feeding might be more effective for poorer children, and possibly for girls, but more evidence is needed. Surprisingly few studies have addressed this question. Relatedly, the question of how to reduce inequities in the distribution of household food is needed.

More high quality research on the implementation and sustainability of large scale feeding programs is needed. Most of the evidence presented here is from smaller scale studies; only four evaluations of larger scale studies met inclusion criteria (Brazil's Milk Supplement Program [43], PANN in Ecuador [107]; Progresa in Mexico[103] and Vietnam's Integrated Health and Nutrition Program [33]. While knowledge from these studies has contributed greatly to the review and to our process analyses, there is a need for more high quality RCTs of such large-scale programs.

More research is needed on interventions of high quality. Many studies in this review were of relatively low quality in terms of implementation and design. It is encouraging that the more recent studies were generally of much better quality, although there are still issues in process and implementation. As well as careful attention to outcome measurement that is guided by theory and logic, attention needs to be paid to ensuring adequate power to detect change, methods of randomization, allocation concealment, blinding of outcome assessment and to attrition. Research that examines the causes of attrition and explores how to reduce it is also needed.

Finally, given the importance of process evaluation for understanding ‘how’ and ‘why’, we recommend that all evaluations of feeding program include both process and outcome analyses.

Tables

Table 1. Characteristics of studies included in the review

Bhandari [100]	**South Delhi, India. Urban slum of Nehru place. 80% of women and 40% of men have never been to school. Most families are migrants from rural areas. Live in dwellings made of mud, concrete or a mixture.** **Age: Children were enrolled at the age of 4 months.** **Number: 87 supplemented, 97 nutritional. Counseling, 93 no intervention, 91 visitation**	**RCT**	**Supplement only. Home Delivered/Given to Mothers to prepare and to give to infants twice daily. Twice weekly delivery and morbidity assessments** **Energy 941 KJ, 7g fat, 8g protein, 30g carbohydrates, 2.5g minerals,** **Duration: 8 months**
Coyne [108]	Australia. Aboriginal children. High- ncome country. Aboriginal children in remote communities. Low SES, marginalized population Nutritional status: Initial height, weight, nutrients below 'acceptable levels" Age: Average of 4 years Number: 180 enrolled initially 116 available at follow-up. 73 experimental, 43 control	CBA	Feeding: Hot lunches in day cares. Provided 2/3 of the RDA for nutrients for the age group. Multivitamin supplements Duration: 9 months
Devadas 1971 [105]	India. Vulnerable groups in a community development block in Columbore. Age: preschool (no age mentioned) N: Experimental 25, Control 25.	CBA	Supplement + Production of protective foods and nutrition education in community Feeding: Supplement including 28.4g of skim milk given daily and one egg given three days a week. Part of ANP program. Not clear where it was given, but probably in day-care or feeding centre.

			Energy: 123 kcal and 11g of protein. Duration: 6 months
Fauveau 1992[41]	Bangladesh. 75% of slum dwellers were 'daily labourers' Income per day less than $2 USD. Among sample, only 22% of mothers employed and those had 'low wages' Age: Average of almost 8 months in both groups. Number: 127 entered. 48 experimental, 43 controls completed.	RCT	Supplement + parental education. Weekly ration of 450g of pre-mixed rice, wheat and lentil powder and 90g of cooking oil. Delivered to home. All local ingredients. Mothers were taught how to prepare the cereal. Mothers of children in both groups received health education that focused on frequency of feedings and caloric content of food. Duration: 6 months
Gershoff 1988[106]	24 villages Northern Thailand Children delayed in growth compared to middle class children. Study conducted in day-care centres where children went all day. Nutritional status: not provided. Age: Children were enrolled between the ages of 6 months to 5years. 5 groups. We compared Group 1. No intervention to Group 5. Exp. Day care centre + everything and snack. Number: 123 boys & 146 girls supplemented and full data, 144 males & 121 females day care no other intervention, full data.	CBA	Supplement + sanitation-health programme with village health worker to pick up illness. Feeding: locally baked fortified cookies given as mid-morning snack. In Day-care. Energy: 300 kcal with 40% of fat and 8% of protein. Given once per day mid morning for 5 days per week Duration: 22 months
Gopalan 1973[87]	India. Nine villages near Hyderabad. Low-income children.	CBA	Supplement only. Feeding: sweet cakes supplement

	Age: 1-5 years N: 306 Exp. (211 reported). 108 Control (83 reported)		consisted of wheat flour (23 g), sugar (35 g), and edible oil (10 g). Given in a feeding centre once daily for 6 days a week. Energy: 310KCal, 3g protein
Grantham-McGregor 1989[94]	Jamaica. Poor neighbourhoods in Kingston. Age: 19-24 months N: 129 (33 controls, 30 stimulated, 32 supplemented, 32 both).	RCT	Supplement + medical care + weekly visits + structured play sessions. Different groups. Feeding: 1 kg milk based formula per week, Supplement delivered to home. Supposed to be given once daily. Energy: 750 Kcal (3.15 MJ) per day, 20g protein per day Duration: 2 years
Heikens 1989[94]	Kingston, Jamaica. Moderately and severely malnourished children referred to hospital but treated in community. Nutritional status: Malnourished children enrolled in community rehabilitation. Less than 80% of NCHS weight for age. Age: 3 to 36 months Number: 39 supplemented, 43 unsupplemented	RCT	Supplementation. Both controls and exp. received health care. Feeding: High-energy supplement. Supplement delivered to home with instructions on how to prepare and measuring cup. Energy 526 Kcal, 13.75 g protein. Delivered once a week. Duration: 3 months of supplementation, 3 months of follow-up.
Husaini 1991 [88]	Indonesia. Children of workers on tea plantation. Low education: fathers about 5 years, mothers about 3 years. In paper, it says that child weight z-scores average -1.57 and -1.66 and height z-scores were -2.34 and -2.42	CBA	Supplement + additional support (details unclear) Feeding: Snacks including rice, rice flour, wheat flour, bread, cassava, potatoes, sweet potatoes, coconut milk, refined sugar, brown sugar, and edible oil. Given in day-care

	Age: 6-59 months (But up to 20 months are the only ones included in this paper). N = 113. 75 exp. and 38 controls.		Energy: 1660 kJ (400 kcal) and 5g protein. Duration: 6 days/week for 3 months.
Ianotti[133]	Urban slums of Haiti The average WAZ at baseline ranged from -0.70 - -0.85 6 - 11 months at start of study. Slightly more girls than boys in all groups N = 589 recruited to 3 groups (after 6 months follow-up there were: control = 144, intervention = 150, other treatment = 126)		Feeding: RUTF. LNS. Home-delivered. Duration: 6 months Energy: On average, the daily supplements provided 108 kcal and 23% of protein % DRI for energy: 15%. % DRI for protein: 23% Control: No supplement
Isanaka 2009 [86]	Nigeria (Niger). 12 villages with a 15% or higher prevalence of wasting. Low income, diet dependent on annual crop harvest. Nutritional status: height for weight 80% or more of NCHS median Age: 6-60 months. No longer fed once they reached 60 months N = 3166; 3026 after 7 months	RCT	Supplement only. Feeding: 92g packet of ready-to-use therapeutic food (RUTF). Monthly distribution of enough for one sachet daily. Energy: 500Kcal Duration: Intervention was 3 months long. Followed up for 8 months (32 weeks).
Joshi 1988 [42]	India. Four bawdies (preschools) in Pune City, India Two were in a poor living area consisting of families of low socio-economic classes, slum dwellers and illiterate parents without facilities for sanitation, sewage systems and personal hygiene. Two were in a middle socio-	CBA	Supplement only. Supplement included commonly consumed snack with which the children were familiar. Milk, biscuits, curd, and seasonal fruits etc. Each child was served the same quantity of food on a clean

	economic class area with enough space and clean surroundings. Age: 30 months -5 years. N: Exp. 50 low SES and 74 middle SES, Control 42 low SES and 81 middle SES.		plate. Given once daily in kindergarten. Energy: 167 kcal and 5.1g protein Duration: 7 months.
Kuusipalo 2006 [95]	Rural Malawi. Most children undernourished. Study was conducted during rainy season when food security is the lowest and weight and height gain of the children is poorer than the rest of the year.	RCT	Supplement only. Milk based fortified spread and soy based fortified spreads of different quantities. Supplements delivered to homes prepackaged weekly for first four weeks and bi-weekly thereafter. Duration: 3 months (12 weeks)
Leroy[43]	Mexico. Low income urban families 432 children in panel study. Ages 0 to 24 months.	Quasi-experimental. Propensity score matching	Supplement for children 6 to 23 months + cash transfers + preventative and curative health care (including nutrition counseling).
Lopez de Romaña 2000 [44]	Peru. Area with high prevalence of infant malnutrition. High prevalence of diarrhoea, inadequate infant feeding practices, low prevalence of exclusive breastfeeding and use of inadequate foods for complementary feeding Age: 6-36 months Number: Exp. 125, Control 125	RCT	Supplement + nutritional education to caregivers. Feeding: precooked food with instant preparation and high nutritional value. 100% of the iron, zinc, iodine, vitamin A and vitamin C requirements, and 60% of the other micronutrient Energy: 33% of energy requirements of 6- to 36-month-old children, 20% of animal protein.
Lutter 2008 [107]	Ecuador. Poor peri-urban and rural communities. poor urban, peri urban and rural communities,	CBA	Supplement + caregiver education + training of health workers in child nutrition and

	low and insecure income, poor housing, and a general lack of 1 or more essential services (piped water, reliable electricity supply, sewage disposal) Nutritional status: included all children in communities Age: 9-14 months at enrolment. N: Experimental, 338 for anthropometry, 170- at end. 324 for morbidity, 324 at end.		counseling + community participation Feeding: 65g dry milk-based product. Given to mothers to prepare once daily. Energy: provided 275kcal/day and 10g of protein, 6g lipids. Duration: 11 months (44 weeks)
Mangani 2014[134]	LMIC. Rural Malawi Average WAZ: -0.70 - -0.80 Age: 6 months N = 840 randomised into 4 groups. 183 - 191 finished in each of the 4 groups, 53% boys		Feeding: The Milk-LNS group received a LNS with milk. Duration: 12 month. Control: Usual diet Energy: provided 285 kcal/day for Milk-LNS % DRI for energy: 40. % DRI for protein: 94.1%
Manjrekar 1986[89]	India. Mysore City. Poor urban area. Age: 0-5 years Number: Exp. 72 Control 51	CBA	Supplement only Bread and 'Miltone', a groundnut protein based milk substitute. Children received two slices of bread and 150 ml milk, infants one slice of bread and 200ml ml. Duration: 18 months Energy: child 250 kcal and infant 200 kcal. Given 6 days a week.
McKay 1978 [104]	Cali Colombia. Low income urban community SES: LMIC: Cali Colombia. Low income urban community	RCT	Supplement + integrated health + nutritional and educational activity. Feeding: Given as part of the program in centres.

	Nutritional status: subnormal (undernourished). Except for T0, who were average. Age: ~ 3 years Number in each group: T0, 116, T1a, 56, T1b, 57, T2, 64, T3, 62, T4, 62		Duration: 3.5 years % RDA for energy: 75% of the recommended calories % DRI for protein: 75% of the recommended protein
Meller 2013[135]	Ecuador.	Quasi	Supplement + caregiver education + training of health workers in child nutrition and counseling + community participation Feeding: 65g dry milk-based product. Given to mothers to prepare once daily.
Mittal 1980 [103]	Cali Colombia. Low-income urban community. Single community block, low and insecure income, poor housing and a general lack of 1 or more essential services (piped water, reliable electricity supply, sewage disposal Age: 6 to 24 months, Number in each group. 201 Experimental, 125 Control	CBA	Supplement only Take-home feeding. 55g nutritional supplement in packets collected by mother or older sibling at a distribution point. Collected once weekly. Measuring cup provided. Energy: 100g of the supplement provided 14g of protein and 360 kcal. Given once daily. Duration: 12 months
Obatolu 2003[45]	Rural Nigeria. Low income families compared with 2 controls: unsupplemented and children of more affluent families Low-income group had low and insecure income. Most parents had no formal education or only primary education. Age: 4 months at baseline	CBA	Supplement only. Home-delivered. Seems like once a week. Pre-prepared gruel given to mothers to mix up. Instructions on how to prepare. Duration: 14 months Energy: DK

	N: Experimental, 30 in low income feeding group. 15 boys and 15 girls Control. 30 in low-income non-feeding group.		
Oelofse 2003 [91]	South Africa. Urban disadvantaged Black community. Most of the inhabitants work in industries in the city or as domestic workers in private homes Age:6 months N: 25 Experimental, 21 control started.	RCT	Supplement only. 60g dry cereal. Enough for 1 and 1/2 weeks delivered to home. Mothers instructed on how to prepare. Energy: 1304 kj, 12g protein and 6g fat Duration: 6 months (52 weeks)
Pollitt 2000[109]	Indonesia. Rural West Java. Children in government day-care. Workers on tea plantation. Children in government day-care. Workers on tea plantation Age: 2 cohorts. 12 and 18 months at enrolment. N: Experimental, 17 12months, 21 18 months, M 16 12 month	RCT	Supplement only. Snack made of rice, rice flour, bread, cassava, potatoes, sweet potatoes, coconut milk, refined sugar, brown sugar and edible oil. Given twice daily in day-care. Energy: 1171 kJ + 12 mg iron or 209 kJ + 12 mg iron or 104 kJ Duration: 12 months
Rivera 2004[103]	Mexico. Low-income households in poor rural communities in 6 central states. Age: 12 months or younger at enrolment. N: 650 Children (n= 373 Intervention group, n= 277 crossover intervention group) 3	RCT	Supplement + nutritional education + healthcare + cash Feeding:240g dry whole milk, sugar, maltodextrin, and micronutrient given in 3 flavours that required hydration before consumption. Packages were distributed at health centres. Mothers given instruction to add 4 spoons of boiled water to 1 ration.

			Energy: 5 daily rations of 44g.provided 275kcal/day and 10g of protein, 6g lipids. Duration: 24 months
Roy 2005[46]	Bangladesh (Chandpur). Low-income families. Age: 6-24 months Number in each group: 94 Supplementation + NE, 94 NE, and 94 control	RCT	Supplement + nutrition education. Feeding: food made of roasted and powdered rice and pulse, molasses and oil Energy: 300 Kcal (8-9g protein, 40g rice, 20g pulse, 10g molasses and 6g oil) Duration: 6 months (24 weeks)
Santos 2005 (Santos)	Brazil. 20 municipalities in the Stage of Alagoas Age: 6-18months. N: 191. 99 exp., 92 control	CBA	Supplement + basic health actions. Feeding: Milk powder + cooking oil to be added to prepared milk. Milk to be distributed to other children under 5 to avoid redistribution. Supplement delivered to mothers at health care centres once a week. Take home rations. Mothers had to prepare. Duration: 6 months=
Schroeder 2002[33]	Vietnam. 12 rural communes. Age: 5 to 30 months on entry. N: 238 at entry; 119 and 119. At month 6, 114 and 118 (controls).	RCT	Supplement + deworming (all groups) + facilitated group learning oriented to hands-on learning of ‘positive deviance’ Feeding: Breastfeeding in addition to positive deviant local foods. Common local sources of protein, tofu, fish oil, etc. Caregivers prepared foods at health centres. Sounds like they prepared it in rotation.

			Multi-faceted approach. Feeding, attendance at health centre where mothers taught positive deviant behaviours. Also all children in both groups de-wormed. Intensity: 12 days a month. But all day. One full meal. Duration: 12 months. Data in meta-analysis is from 6-month follow-up.
Simondon 1996[93]	Four areas in Central (peri urban) and West Africa (poor rural area), South America (peri urban), and the South Pacific (farming community) Age: 4 months Number: Congo 74 Exp. (53 completed) 74 control (67 completed), Senegal: 66 exp. (53 com), 68 control (57 com), Bolivia: 78 exp. (65 completed), 82 exp. (62 com), New Caledonia: exp.: 63 (43 completed), 53 controls (47 com).		Supplement + counseling. Feeding: Ready to used supplement (precooked wheat, maize, millet, soybean flour, milk powder, soybean oil, palm oil, and sugar and was enriched with minerals and vitamins). Supplements taken to home and feeding observed. Energy: 4-5 months 103 Kcal/meal, and at 5-7 months 205 Kcal/ meal. But twice daily. Duration: 12-13 weeks
Thakwalaka 2010[61]	Malawi. Small farming community. Age: 6-15 months N in each group: Control. 59, LNS (lipid based): 66, Corn-soy based: 67	RCT	Supplement only. Feeding: 43g lipid based nutrient supplement and a premade vitamin mix. Delivered to home. Given twice daily Energy: 921kj (10.4g protein) or 1189 kj (6.0g protein) Duration: 12 weeks
Tomedi 2011[102]	Kenya. Subsistence farmers who rely on rain-fed agriculture.	CBA.	Supplement + nutrition education. Feeding: Monthly

	Age: 6 -20 months Number: 139 in experimental, 147 in control.		rations given to family for child and the rest of family. Millet (150g), pigeon peas (25g), milk (125g), eggs (50g), vegetable oil (10g), mango (100g) and sugar (15g) Energy: 4058 kJ Duration: 7 months
Waber 1981[47]	Colombia. Barrios of Southern Bogotá. Age: 6 months to 3 years Number: 433	RCT	Supplement, or supplement + maternal education. Enriched bread, dry skim milk and cooking oil for entire family. Index child given dry skim milk, high protein vegetable mixture and ferrous sulfate. Supplements delivered in store like atmosphere once a week. Maternal education. Trained home visitors worked directly with the children and trained mothers to become more responsive.
Yueng 2000[98]	Canada. Urban communitynear-100% female literacy level. Age: 6 months Number: 49 Exp.; 52 Control	RCT	Supplement only. Feeding: pureed meat, iron fortified infant cereal and whole cow milk Duration: 6 months
Ziegler 2009 [99]	Iowa, USA. Rural, predominantly White population, middle-income community.	RCT	Supplement only

Table 2. Characteristics of papers that did not meet the criteria for inclusion in the Cochrane review

Author / date	Setting	Study design	Rejected from Cochrane sample because
Beartl, 1970 [136]	Rural Peru	Before/after survey of whole villages.	Did not follow specific children, just surveyed whole population before and after.
Das Gupta 2005 [137]	Entire country of India	Before/after survey of intervention and control areas	Did not follow individual children. Just based on survey data
Gartner 2006, 2007 [65,138]	Urban Senegal.	Before/after survey of whole village	Did not follow specific children, just did survey of whole population before and after.
Goulart, 2009 [66]	Sao Paolo, Brazil.	Before and after study without control group, using time series analysis.	No control group.
Hanafy 1967 [139]	Rural Egypt	Before and after study without control group.	No control group, included children up to age 6.
Hicks 1982 and 1985 [68,140]	Poor families in rural Louisiana, USA.	Sibling pair before and after study (one supplemented from perinatal period, one deferred).	Did not meet inclusion criteria for adequacy of control group.
Hillis, 1994 [141]	Poor families, in urban Columbia.	CBA.	No clear starting point for feeding. No description of foods given at all
Huybreghts, 2012			Children were given RUTF in addition to a general food distribution programme
Khan, 2011 [142]	Rural Bangladesh.	RCT	Supplemented mothers prenatally.
Matilsky 2009 [72]	Rural Malawi.	RCT.	Two components: supplement and increasing normal diet.
Mora 1981 [143]	Bogotá, Columbia	RCT	Some children were over 5 years with no disaggregated data presented.

Rivera 1991 [144]	Rural Guatemala. INCAP	RCT	Mothers received supplementation prior to birth of child.
Rosado [145]	Rural communities in Mexico	RCT	Control groups received more than 100 kcal
Van Hoan [146]	Vietnam	RCT	No primary or secondary outcome of interest. Focused on energy intake and effect on breast-feeding.

Table 3. Summary of Studies with Clustered Design

Study	Adjusted clustering appropriately?	Our adjustments
RCTs		
Coyne 1990	No	Cluster size: 15 Exp. and 9 controls. Used ICC of 0.025 for weight and length.
Fauveau 1992	No	Cluster size: 5. Used ICC of 0.025 for weight and length.
Husaini 1991	No	7 for intervention, 5 for control. Used ICC of 0.025 for weight and length, 0.24 for psychosocial outcomes.
Isanaka 2009	Yes	N.A.
Lopez De Romano	No	Not corrected because not in meta-analysis
McKay 1978	No	Cluster size. 16 in each. Used ICC of 0.24 for psychological outcomes.
Pollitt 2000	No	
Rivera 2004	Yes	N.A.
Roy 2005	Yes	N.A.
CBAs		
Devadas	No.	Cluster size: 25 in each. Used ICC of 0.025 for weight and length.
Gershoff 1988	No	Cluster size: 43. Used ICC of 0.025 for weight and length.
Joshi 1988	No	We didn't correct; no appropriate data.
Lutter 2008	Yes, but we used unadjusted data	Cluster size: 17 experimental, 25 control
Santos	Yes	N.A.
Schroeder 2002	No	Cluster size: 20.Used ICC of 0.025 for weight and length.
Tomedi 2011	Yes	N.A.

Table 4. Adequacy of energy content

Study	4-5mo	6-12mo	12-24mo	24-36mo	36-48mo	48-60mo
Bhandari	H (89.9)	H (94.7)				
Simondon	L (20.6)	L (28.8)				
Rivera	M (38.7)	L (27.4)				
Faveau		L (17.6)				
Oelofse		M (42)				
Grantham-McGregor		H (105.2)	H (86.3)			
Husaini		M (48.1)	M (39.5)			
Lutter		M (38.6)	M (31.6)			
Mittal 1980 (girls)		L (27.8)	L (22.8)			
Roy		M (42.1)	M (34.5)			
Thakwalakwa		M (30.9)	L (25.4)			
Kuuisipalo		L (18.3)	L (15.0)			
Lopez de Romana		M (56.1)	M (46.0)			
Santos		H (60)	H (60)			
Tomedi		H (136.2)	H (111.7)			
Pollitt			L (24.7)			
Isanaka		H (69.83)	M (57.5)	M (57.5)	M (34.7)	M (33)
Manjrekar		M (30.1)	L (28.8)	L (28.3)	L (17.4)	L 16.5)
Gershoff		M (42.1)	M (34.5)	M (34.5)	L (20.8)	L (19.8)
Gopalan			M (30.6)	M (30.6)	L (18.5)	L (17.5)
Devadas				L (14.2)		
McKay					M (53.6)	
Joshi					L (8.3)	L (7.9)
Coyne					M (47.6)	M (47.6)
% RDA for Energy: L = Low (0-29%), M = Moderate (30-60%) and H = High (60%+).						

Table 5. Summary of Findings table: Growth (RCTs)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants in meta-analyses (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	**Corresponding risk**				
	Control - growth RCT	**Lower middle-income countries: Feeding**				
Weight gain (kg) kg Follow-up: 3 - 12 months; average 6 months	Weight change of control group ranged from 0.32 to 2.42 kg.	The mean weight gain in the intervention groups was **0.12 higher** (0.06 to 0.18 higher)		1057 (9 studies)	⊕⊕⊕⊝ **moderate**[1]	
Height gain (cm) Follow-up: 3 - 12 months; average 6 months	Growth in height of control group ranged from 0.90 to 3.4 cm	The mean height gain in the intervention group was **0.27 cm higher** (0.07 to 0.48 higher)		1463 (9 studies)	⊕⊕⊕⊝ **moderate**[1]	
Weight-for-age: z-scores (WAZ) Follow-up: 3 - 24 months; average	Change in WAZ in the control group ranged from -0.30 to 0.98	The mean change in WAZ in the intervention group was **0.15 higher** (0.05 to 0.24 higher)		1565 (8 studies)	⊕⊕⊕⊝ **moderate**[1]	

6.5 months				
Height-for-age: z-scores (HAZ) Follow-up: 3 - 24 months; average 6.5 months	Change in HAZ in the control group ranged from -0.84 to 0.11	The mean change in HAZ in the intervention group was **0.15 higher** (0.06 to 0.24 higher)	4544 (9 studies)	⊕⊕⊕⊖ **moderate**[1]
Weight-for-height: z-scores (WHZ) Follow-up: 3 - 12 months; average 6.5 months	Change in WHZ in the control group ranged from -0.70 to 0.10	The mean change in WHZ in the intervention group was **0.10 higher** (0.02 lower to 0.22 higher)	4073 (7 studies)	⊕⊕⊕⊖ **moderate**[1]
***The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval**				
GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.				

Footnotes

[1]Risk of bias rated as moderate because most studies lacked blinding and most studies report a completer analysis rather than intention-to-treat.

Table 6. Summary of Findings Table. Growth Lower Middle Income Countries: CBAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Control. CBA	Lower middle-income countries: Feeding			
Weight gain (kg) Follow-up: 6 months - 1.8 years; average 1 year	Weight change of control group ranged from 0.5 to 3.93 kg	The mean weight gain (kg) in the intervention group was **0.24 higher** (0.09 to 0.39 higher)		1784 (7 studies)	⊕⊖⊖⊖ very **low**[1]
Height gain (cm) Follow-up: 6 months - 1.8 years; average 1 year	Growth in height of control group ranged from 1.88 to 20.1 cm	The mean height gain (cm) in the intervention group was **0.52 higher but non-significant** (0.07 lower to 1.10 higher)		1782 (7 studies)	⊕⊖⊖⊖ **very low**[1]
Weight-for-age: z-scores (WAZ) Follow-up: 9 - 12 months	Change in WAZ in the control group ranged from -0.42 to 0.07	The mean change in WAZ in the intervention group was **0.27 higher** (0.13 lower to 0.68 higher)		999 (4 studies)	⊕⊖⊖⊖ **very low**[1]
Height-for-age: z-scores (HAZ) Follow-up: 9 - 12 months	Change in HAZ in the control group ranged from -0.82 to 0.26	There was little mean change in HAZ in the intervention group compared to the control group **0.01 higher** (0.10 lower to 0.12 higher)		999 (4 studies)	⊕⊖⊖⊖ **very low**[1]
Weight- for-height: z-scores (WHZ)	Change in WHZ in the control group ranged	The mean change in WHZ in the intervention group was **0.29 higher**		999 (4 studies)	⊕⊖⊖⊖ **very low**[1]

Follow-up: 9 - 12 months	from -0.92 to -0.01	(0.11 lower to 0.69 higher)				

Footnotes

[1] Studies are rated as high risk of bias due to lack of randomization

Table 7. Summary of Findings Table. Lower Middle Income Countries: RCTs Psychosocial Development

Outcomes	**Illustrative comparative risks* (95% CI)**		**Relative effect (95% CI)**	**Number of participants in meta-analyses (studies)**	**Quality of the evidence (GRADE)**	**Comments**
	Assumed risk **Control - psychosocial development RCT**	**Corresponding risk** **Lower middle-income countries: Feeding**				
Mental Development Index (total) **Follow-up: 3 - 21 months**	The mean change in mental development index score for the control group was 15.8 points	The standardised mean mental development index (total) in the intervention group was 0.40 **lower** (-0.79 lower to -0.00) in one study		113 (1 study)	⊕⊕⊕⊝ **moderate**[1]	
		In another study, the standardized mean difference in change in cognitive ability was 0.58 over 21 months of supplementation (0.17 **higher** to 0.98 **higher**).		99 (1 study)		
		One study not included in the meta-analysis, intervention group was significantly **higher** ($F_{1,\ 107}$ = 4.44, P < 0.0).		107 (1 study)		
Psychomotor development **Follow-up: 3 months** **6 - 24 months for 4 other studies**	The mean change in psychomotor development index score for the control group was 2.7 points	The standardised mean psychomotor development in the intervention group was **0.41 higher** (0.10 higher to 0.72 higher)		178 (2 studies)	⊕⊕⊕⊕ **Moderate**	
		Two-year study: Mean gain in psychomotor development was 6.5 points **higher** in supplemented group and 13.4 points **higher** in the supplemented + stimulated group than controls. (Change in control compared to supplemented was -6.5 (-11.1 to -		94 (1 study)		

	1.9) points; Change in control compared to supplemented + stimulated was -13.4 (-17.9 to -8.8) points.		
	One study: No main effect but change-over-time contrasts showed that after 6 months of treatment, younger children in the experimental group showed significantly less decline on the Bayley Motor score than younger children in the placebo group ($F_{1,48} = 6.01$, $P < 0.05$). The differences in Bayley Motor Score disappeared at 12 months of intervention.	136 (1 study); 48 younger children.	
	One study. Boys who received 2½ years of supplementation beginning at 6 months had better overall scores on the Griffiths Mental Development Scales than those who had no supplementation; this was not true for girls. We could not test significance.	104 in analysis	
	One study: non significant	30 (1 study)	
Follow-up. 4 years after the end of supplementation	Supplemented and Supplemented + Stimulated performed better than controls on 14 out of 15 cognitive tests. Supplementation had a significant effect on the perceptual motor factor for children whose mothers had high baseline scores on the Peabody Picture Vocabulary Test.	122 (1 study)	⊕⊕⊕⊝ **moderate**[1]

***The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).**
CI: Confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate

Appendix 1

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Contributions of authors

Elizabeth Kristjansson - Led both the protocol and review, writing most of it. Dr. Kristjansson also screened studies, decided on inclusion/exclusion, assessed ROB, oversaw data extraction and analyses, conducting some of them, and wrote the results and the discussion.

Damian Francis - was involved in proposal development and writing the protocol. He helped to assess the nutritional composition and quality of the meals (intervention) administered to the participants, extracted data, performed much of the data analysis and helped with writing and knowledge translation.

Selma Liberato - contributed to the proposal and protocol writing. She screened studies, decided on inclusion/exclusion of retrieved studies, helped with data extraction, and writing. She led the assessment of the nutritional composition administered to the participants; she also judged the amount of supervision in each program.

Vivian Welch - Vivian contributed to the policy influence plan, proposal development and development of the search strategy. She carried out the correction for clustering and advised on all analyses. Vivian was also involved in the implementation analysis.

Trish Greenhalgh - contributed to proposal writing and led the process evaluation. She also contributed to writing and editing the final review.

Maria Benkhalti Jandu - was involved in writing the protocol as well as logic model development. She also developed the data extraction sheet performed data extraction and edited the review.

Malek Batal - was involved in the proposal and protocol writing and the drafting of the logic model. He also provided input into the assessment of nutritional quality of food/drink given and helped to edit the review.

Eamonn Noonan - assisted with development of the Policy Influence plan, wrote the plain language summary, helped with policy briefs and with knowledge translation. He also edited the review.

Laura Janzen - contributed to the proposal and protocol writing, assessed the quality of the psychological measures, and contributed to the discussion of the cognitive and behavioural results.

George A Wells - provided statistical advice on analyses.

Beverley Shea - reviewed the protocol, assessed Risk of Bias, and edited the review.

Tamara Rader developed and ran search strategies according to the Cochrane Handbook for Systematic Reviews of Interventions and in collaboration with subject experts. She also drafted the sections on searching.

Mark Petticrew - reviewed the proposal and edited the final review.

Declarations of interest

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Differences between protocol and review

Outcomes

We changed the names of some psychosocial outcomes (mental and cognitive development to mental development) and reordered them (we put psychomotor development first). We also put intelligence under cognitive development.

Searches

In some cases we amended the choice of database or replaced it with an equivalent source from the source listed in the protocol due to availability of the resource. For example, we searched Social Sciences Citation Index (SSCI) instead of Sociofile, as the coverage was comparable and it was available in our institution. Similarly, Health Management Information Consortium (HMIC) and Dissertation Abstracts International were not available but have similar coverage to OVID Medline, and Proquest Dissertations and Theses. We did not search SCOPUS as originally planned, neither did we run supplementary citation searches.

We added Clinicaltrials.gov for all years in January 2014.

We had planned to identify key researchers in the field and write to them to ask about any unpublished or forthcoming works. However, we did not carry this out. We believe that the risk of missing key studies was low because of the extensive searching in many different databases (more than 30,000 references identified).

Risk of bias

We had planned to use the EPHPP tool in addition to the Cochrane and EPOC tools to assess bias; however this proved to be too time-consuming.

There were no ITS studies, so we did not assess their risk of Bias. Our appraisal criteria for ITS studies were adapted from the 'Risk of bias' checklist developed by the EPOC Group. [39] In assessing risk of bias in the ITS designs, we would have considered protection against secular changes, predefined shape of effect, effect on data collection, knowledge of allocated interventions, incomplete outcome data, selective outcome reporting, and other biases.

Analyses

We had planned to do an intention-to-treat (ITT) analysis, but nearly all studies reported only on completers. We wrote to some authors for other information but received very few replies. Our analyses, therefore, are completion analyses.

If scales had been measured in different directions (high on some representing greater disease severity while high on others represents less severity), we would have multiplied the mean values from one set of studies by –1 to ensure that all the scales measured in the same direction.

We would have analysed categorical and continuous data separately had there been any categorical data. We would have analysed categorical data using odds ratios (ORs) and risk ratios (RRs).

We had planned to draw funnel plots to assess the presence of possible publication bias as well as the relationship between effect size and study precision. However, we did not have the recommended minimum number of studies (10) for any analysis. Furthermore, while funnel plot asymmetry may indicate publication bias, this is not inevitably the case. [147]

We had planned to do sensitivity analyses by five factors: reliable primary outcome measure/not, placebo versus no treatment control, allocation concealment, attrition (< 10% versus > 10%), and imputed correlation coefficient. However, we did not do these and only did sensitivity analyses to check whether more conservative ICCs in the clustering adjustments would make a difference.

Finally, due to the high number of potential variables and insufficient number of studies, we were unable to conduct a meta-regression as planned.

Subgroup Analyses

We added two subgroup analyses to those in the protocol: location of feeding (take-home rations versus feeding centre or day-care or preschool, or both) and level of supervision (i.e. monitoring). We added these analyses because it became evident from consultation with each other and from gaining a better understanding of the context that these were potentially important factors in success/failure.

Appendix 2: Review Methods

2.1 Inclusion Criteria

We accepted randomised controlled trials (RCTs), controlled clinical trials (CCTs), controlled before-after studies (CBAs), interrupted time series (ITS), and quasi-experimental studies with comparison groups that used statistical methods of analysis to match participants with non-participants.

Children aged three months to five years, from all countries of the world were eligible. Results were analysed separately for LMIC and higher-income countries (includes upper-middle and high-income countries). Country income was classified according to the 2011 World Bank List of Country Economies. [148]

To meet our study objectives (studying the effectiveness of giving energy to children who need it) studies included children from:

- Socio-economically disadvantaged groups; OR
- Both high and low socioeconomic groups if results are or can be stratified by some indicator of socioeconomic status (for example, high/low income, high/low education, rural/urban).

The interventions had to provide energy and macronutrients through:

- Hot or cold meals (breakfast or lunch);
- Snacks (including both food and beverages such as milk or milk substitutes);
- Meals or snacks in combination with take-home rations;
- Take-home rations.

We also included co-interventions (for example, psychological stimulation, micronutrient fortification, nutrition education). Studies had to compare children who received feeding to a no-feeding control. We accepted either no treatment controls (no feeding) or placebo controls (for example, low energy foods (less than 5% of the energy provided by the intervention) or drinks (without fortification). For example, a low energy, unfortified (e.g. 30 kcal) drink was acceptable as a control.

2.2 Outcomes

The primary outcomes included growth, psychomotor development, cognitive/mental development, attention, language and memory.

Primary adverse outcomes included substitution and leakage.

The secondary outcomes included biochemical markers of nutrition (Vitamin A, haemoglobin, hematocrit), physical activity, morbidity and mortality.

Secondary adverse outcomes included overweight/obesity, stigmatization and behavior problems.

2.3 Process/Implementation Measures

The following process elements were abstracted (list modified from Arblaster [149] and Kristjansson [111].

- Type of meal.
- Energy and protein provided, %RDA and %RDI.
- Multifaceted approaches (were other supports (nutrition education, etc.) used in addition to providing food?
- Where the food was given: preschool, daycare, feeding centre, home delivered, take-home.
- Agent administering the intervention (for example, community, government).
- Agent delivering intervention (e.g. mother, health care worker, day-care worker).
- Provision of material support (was food provided free of charge or for a reduced price according to income?).
- Supervision: Whether or not intake was monitored.
- Substitution and leakage.
- Cost and time to run programme.
- Implementation fidelity.
- We used results to guide subgroup analyses, to interpret the data and to help understand the mechanisms of action.

2.4 Searching the Literature

The search strategy was developed by Margaret Anderson (Cochrane Developmental, Psychosocial and Learning Problems Group) and Tamara Rader. The searches were run by Tamara Rader.

We ran the initial searches in July 2011; the most recent update was 28 January 2014, except where stated otherwise. We applied no date or language limits.

1. Cochrane Central Register of Controlled Studies (CENTRAL), 2014, Issue 1, part of *The Cochrane Library.*
2. Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to present.

3. Cochrane Database of Systematic Reviews (CDSR), 2014 Issue 1, part of *The Cochrane Library.*
4. Database of Abstracts of Reviews of Effects (DARE), 2014 Issue 1, part of *The Cochrane Library.*
5. Social Sciences Citation Index (SSCI) (Web of Science) 1970 to the present.
6. Conference Proceedings Citation Index-Science (CPCI-S) (Web of Science) 1990 to the present.
7. Conference Proceedings Citation Index-Social Science & Humanities (CPCI-SSH) (Web of Science) 1990 to the present.
8. ERIC – Education Resources Information Centre via Proquest, 1994 to the present.
9. Proquest Dissertations and Theses.
10. PsycINFO (Ovid) 1806 to January Week 3 2014.
11. Clinicaltrials.gov (https://clinicaltrials.gov/).

Searches last updated 3 May 2012 (Appendix 2)

1. EMBASE Classic and EMBASE (OVID) 1947 to 1 May 2012.
2. CINAHL (Ebscohost) 1981 to 3 May 2012.
3. Healthstar (OVID) 1966 to 3 May 2012.
4. LILACS Last searched 10 May 2012.

Searches last updated 5 July 2011 (Appendix 3)

1. Social Services Abstracts (CSA).

Searching other resources

We searched the following grey literature sources:

1. OpenGrey (www.opengrey.eu/). Accessed: January 2014.
2. WHOLIS (dosei.who.int/uhtbin/cgisirsi/Wed+May+21+19:32:01+MEST+2014/0/49). Accessed: January 2014.
3. WHO nutrition databases (www.who.int/nutrition/databases/en/). Accessed: January 2014.

We sought information about ongoing and unpublished trials through members of our advisory panel of experts in nutrition and child development. We also scanned the references of included articles, relevant reviews, and annotated bibliographies for eligible studies, and searched the websites of selected development agencies or research firms (IDEAS: ideas.repec.org/, IFPRI www.ifpri.org/; JOLIS/World Bank: external.worldbankimflib.org/external.htm; NBER: www.nber.org/, USAID; www.usaid.gov/) in January 2014.

2.5 Data collection and analysis

2.5.1 Selection of studies

Due to the large number of hits, half of the titles and abstracts of articles retrieved by the electronic database searches were scanned for eligibility independently by two review authors while two different review authors independently scanned the second half. Two reviewers also scanned the reference lists of all included studies and full copies of all those deemed eligible by one of the review authors were retrieved. Two reviewers reviewed the full text of all retrieved studies for inclusion/exclusion.

2.5.2 Data extraction and management

Data was extracted by four people; at least two people worked on each paper. We extracted data on study design, description of the intervention (including process), details about participants, length of intervention and follow-up, definition of disadvantage, all primary and secondary outcomes, costs and resource use, critical appraisal (see below), and statistical analysis. Where possible, effects were recorded by socioeconomic status, geographic location, gender, race/ethnicity, and age.

2.5.3 Energy Content

To help us with interpretation of results and as a measure of implementation, the energy content and percentage of daily requirements was determined by the nutritionists (DF, SL, and MB). Protein content and DRI was also assessed where possible. Appendix Two provides details on how this was calculated. To assess substitution and leakage, we reviewed analyses of total nutritional intake before and after supplementation.

2.5.4 Assessment of risk of bias in included studies

RCTs. We used the Cochrane Collaboration 'Risk of bias' tool[38] to assess risk of bias in RCTs and CCTs. Most items are scored as 'high risk', 'low risk' or 'unclear risk'. We gave component ratings, but did not give an overall rating.

Quasi-experimental studies. We used the 'Risk of bias' tool from the Cochrane Effective Practice and Organisation of Care Group [39]. In addition to the domains covered by the Cochrane Collaboration's 'Risk of bias' tool, it includes similarity of baseline outcome measurement, similarity of baseline characteristics, and protection against contamination. All judgments on Risk of Bias are summarized in Figure 5.

2.5.5 Measures of treatment effect

Statistical analysis was performed using RevMan5 [150]. Appropriate measures of treatment effect were determined in consultation with our statistician, GW, depending on the type of data collected in the included studies.

Continuous data. Continuous data were analysed from means and standard deviations wherever possible. When means and standard deviations were not reported, we used other available data (for example, confidence intervals, t values, P values) and appropriate methods described in the Cochrane Handbook for Systematic Reviews of Interventions (Section 7.7.3 [151]) to calculate the means and standard deviations, in consultation with our statistician. Where other available data were not sufficient to calculate standard deviations, we contacted the trial authors.

Change data. Change data was used in all analyses. This data was either taken directly from the papers or calculated from other information presented. When we calculated change scores, we used means and standard deviation from baseline and end of study according to the methods described in section 16.1.3.2 of the Cochrane Handbook Higgins. [151,152]We used before and after correlations of 0.9 for height, weight, HAZ, WHZ and WHZ. For mental and psychomotor development, respectively, we used correlations of 0.71 and 0.69.

In cases where data were not meta-analyzed, regression analyses, multilevel analyses, or Analyses of Variance were selected as providing the better estimate of effect, because: a) multilevel analyses accounted for clustering and b) other ANOVAs and regressions provided results for change.

2.5.6 Meta-analyses

To perform meta-analyses of continuous data, we input data on means, standard deviations, and the number of participants for each outcome in the two groups. In all instances, this represents change data. These means and standard deviations were unadjusted for confounders; however, they were re- adjusted for clustering when needed. We compared the most intensive intervention (e.g. highest energy, co-intervention) to a non-intervention control.

We constructed 'Summary of Findings' tables and rated the quality of evidence using GRADE [153] for all of the primary outcomes.

Analysis of cluster randomized trials

Studies that were allocated by village, neighbourhood, or day-care could have unit of analysis errors if they did not adjust for between-cluster correlation. Where trials used clustered allocation, we reviewed them to determine whether they appropriately controlled for clustering effects (for example, variance inflated standard errors, hierarchical linear models). If analyses were adjusted in the primary study, we used them.

Methods used to correct for design effect in clustered trials or CBAs that were not adjusted for clustering

1. When we used a standardised mean difference (SMD) as the pooled estimate (because of varying metrics), we applied the methods outlined in Section 16.3 of the *Cochrane Handbook* Higgins 2011 to inflate the standard error. First, we calculated the unadjusted SMD and 95% confidence interval. We entered the unadjusted SMD as the effect estimate in the generic inverse variance method, and then we inflated the standard error of the effect estimate by multiplying by the square root of the variance inflation factor,

calculated as: 1 + ((M - 1) multiplied by ICC), where M is the average cluster size. We calculated the standard error as the confidence interval divided by 3.92.

2. When the pooled estimate was the mean difference (MD), we used the variance inflation factor (VIF) to adjust the standard deviations in the treatment and control groups separately. We then used these standard deviations in the meta-analysis, and so incorporated them in the standard error of the mean difference and the weighting procedures. The result of this analysis is equivalent to the method outlined in the *Cochrane Handbook* when the variance inflation factors are the same in the treatment and control groups.
3. We used this approach because final cluster sizes often differed between the treatment and control groups and therefore the VIF, which depends on cluster size, would be different. As far as we know, the *Cochrane Handbook* does not provide for this eventuality.

Calculating the variance inflation factor

1. First, we calculated cluster size. When the number of participants in each analysis was provided, we divided this by the number of clusters to calculate cluster size. Otherwise, we used the number of participants provided in the methods sections of the primary studies divided by the number of clusters.
2. Next, we found appropriate intra-cluster correlation coefficients (ICCs).
    1. For growth outcomes (weight, height, WAZ, HAZ, WHZ), we used ICCs of 0.025; these were based on those published in Du's 2005 letter to the editor of the *British Journal of Nutrition* [154]. We conducted sensitivity analyses with ICCs of 0.10.
    2. For the psychosocial outcomes, we used ICCs of 0.15, with sensitivity analyses at 0.20. These were based on the Schochet report [154]. for math and reading.
3. Then, for experimental and control groups separately, we calculated the VIF as follows:

1+ ((M - 1) multiplied by ICC), where M is the average cluster size [155] . We then multiplied the original standard deviation by the square root of the VIF for experimental and control groups separately. We then entered these adjusted standard deviations into the RevMan data tables, combining them with estimates from individual level trials.

2.5.7 Dealing with missing data

Where possible (e.g. studies were done after 1995), we contacted trial authors to supply any missing or unreported data such as group means, standard deviations, details of attrition or details of interventions received by the control groups. Missing data and attrition were described for each included study in the Characteristics of Included Studies Table (Table 1).

2.5.8 Assessment of heterogeneity

We considered clinical (variation in participants, interventions, outcomes) and methodological (i.e. study design, risk of bias) heterogeneity as well as statistical heterogeneity. We assessed statistical heterogeneity using a standard Chi^2 test to assess whether observed differences in results were compatible with chance alone. We used the I^2 test to assess the impact of heterogeneity on the meta-analysis. It shows the percentage of variability in effect estimates that are due to heterogeneity rather than to chance; values over 75% indicate a high level of heterogeneity [156].

If heterogeneity existed, we examined potential sources.

We obtained an estimate of the between-studies variance component (Tau^2) through a random-effects meta-analysis.

2.5.9 Subgroup analyses

We had planned to conduct subgroup analyses across six categories (Kristjansson 2012).

1. Age: three months to two years versus greater than two years to five years.
2. Sex: male versus female.
3. Socio-economically disadvantaged: more versus less.
4. Undernourished (1 SD below mean) versus normal weight. We are using this definition as participants in the sample are limited in the range of underweight they will exhibit (none below -3). This will give us a reasonable proportion in each group.
5. Percentage of daily requirements for energy provided (less than 15%, 15% to 30%, 30% to 50%, above 50%).
6. Micronutrients added versus not added.

We hypothesised that feeding would be more effective for:

1. Younger children;
2. The most disadvantaged, poorest, lowest SES;
3. Those with the poorest nutritional status (underweight, stunted); and
4. Children who received a higher percentage of the daily energy requirements.

In the review, we conducted analyses one, two and five and combined analyses three and four as undernourishment was seen as a proxy for low income. We did not perform analysis six. Furthermore, after learning more about other potential impacts on effectiveness, we added three more subgroup analyses; location of feeding, level of supervision, and single versus multiple interventions.

We hypothesized that feeding would be more effective if:

1. It was delivered in day cares or feeding centres;
2. It was strictly supervised (i.e. well-monitored); and
3. If multiple interventions were given rather than single interventions.

In total, we performed subgroup analyses across seven categories.

1. Age: three to 12 months, one to two years, and two years and older.
2. Sex: male versus female.
3. Socio-economically disadvantaged: poor versus less poor; undernourished versus well-nourished.
4. Nutritional adequacy: percentage of daily requirements (RDI) for energy provided by the supplement (low (0% to 29%), moderate (30% to 59%), and high (60% +)).
5. Location of feeding: take-home rations versus feeding centre or day care or preschool or both.
6. Level of supervision (i.e. monitoring): low supervision versus moderate supervision versus strict supervision.
7. Single versus multiple interventions.

5.2.7 2.5.11 Sensitivity analysis

We conducted sensitivity analyses to consider the impact of:

1. ICCs of 0.10 for height, weight, WAZ, HAZ, and WHZ; and
2. ICCs of 0.20 for psychosocial outcomes.

2.6 Realist review methods

2.6.1 Included papers

In addition to the papers included in the systematic review, we were interested in papers (either empirical or theoretical) that explored the *mechanisms* by which preschool feeding programmes might work (or which proposed and tested possible explanations for why they might *not* work). To that end, we employed three main approaches. First, while undertaking the Cochrane review, we prospectively identified studies we came across (e.g. in the reference lists of papers) which offered further discussion and/or process detail about the programmes in our core dataset. We also used citation tracking (in Google Scholar) to identify additional 'sister papers' to those studies. Second, we captured papers describing supplementary feeding programmes that had been pulled for the Cochrane review but rejected either on the grounds of methodology (e.g. uncontrolled study) or because they did not meet the inclusion criteria (e.g. supplement given prenatally) but which nevertheless included sufficient process detail and/or explanatory text to inform our emerging list of candidate programme theories. Third, we captured relevant additional references in the reference lists of all included papers. As is recommended in realist review, identification of papers occurred iteratively throughout the review period, with new papers being identified, considered and included as the work of the review unfolded.

2.6.2 Selection and appraisal of documents

Each study was assessed against two criteria to gain inclusion in the realist review:

- Relevance: is this paper relevant to our research question?
- Rigour: is the study, or aspects of the study we wish to draw upon, sufficiently rigorous for us to be able to trust the findings?

It is important to emphasise that including 'rejected' studies was not because we applied a lower standard of rigour to the realist review than we did to the Cochrane review. A realist review is an interpretive process, and as recommended by the RAMESES guideline, we included studies for a number of different reasons, notably if they could help the process of theory-building [37]. Process evaluations and qualitative studies were particularly important in this regard, though such studies were out of scope for the Cochrane review.

In making our final selection of studies to include, we prioritised those that offered rich descriptions of the interventions and programmes, thereby allowing us to identify mechanisms and make informed judgments about the interaction between context, mechanism and outcome.

2.6.3 Data extraction

Following a familiarisation phase of reading and re-reading the included studies to gain familiarity, two researchers (SL and BK) prepared a spreadsheet listing the studies included in the Cochrane review and extracted descriptive data under the following headings: sample, setting, study goals, intervention, control intervention(s), funder, key process data (e.g. whether intake was observed), cost to participants, demographic variables (e.g. age range, gender mix, ethnicity, education, income), baseline nutritional status of children, withdrawals and losses to follow-up, cost and cost impact of intervention. TG then checked these data.

Further data relevant to the realist analysis were extracted independently by TG, VW and SL under the following headings: the initial theory of change proposed by the authors of the primary studies why they felt the intervention was needed and what they thought it would achieve in the target population); authors' conclusions about why the intervention had worked or why it had not worked; differences in subgroups and any explanations for these differences; additional mechanisms proposed by authors (or hypothesised by reviewer on the basis of findings presented). The spreadsheets were then compared and differences resolved by checking the original paper and by discussion where necessary.

2.6.4 Analysis and synthesis

As recommended by the RAMESES methodological standards, analysis and synthesis of findings was an interpretive process, reached through reflection and discussion and requiring repeated reading and re-reading of primary studies in the light of an emerging synthesis of the wider sample. A key aspect of rigour here was the application of judgment. Particular attention was given to identifying and exploring the mechanisms by which study participants drew upon resources available in an effort to achieve the intended outcome – in particular, the efforts made by staff on the ground to ensure that the supplement was consumed by the child. This in turn required efforts to ensure that the primary caregiver understood the purpose of the intervention and that s/he had the capabilities and resources to prepare and administer the supplement.

Appendix 3: Search strategies

3.1 Cochrane Library Search Strategy

#1 MeSH descriptor: [Dietary Supplements] exp.lode all trees

#2 Mesh descriptor: [Diet Therapy] explode all trees

#3 MeSH descriptor: [Food, Fortified] exp.lode all trees

#4 MeSH descriptor: [Functional Food] exp.lode all trees

#5 MeSH descriptor: [Nutrition Therapy] exp.lode all trees

#6 ((extra or take-home or takehome) near (food* or feed* or ration*))

#7 MeSH descriptor: [Nutrition Policy] exp.lode all trees

#8 ((feed* or food*) near program*)

#9 ((fortif* or enrich*) near (food* or diet* or spread* or flour* or cereal*))

#10 (lunch* or dinner* or break-fast* or breakfast* or break fast* or supper or snack* or meal* or milk or meat* or egg*):ti,ab

#11 (plumpy* or nutri spread*)

#12 ((supplement* or complement*) near (food* or feed* or diet* or nutrition* or nutrient* or micronutrient* or micro-nutrient*))

#13 (blended near food*)

#14 (energy near supplement*)

#15 (lipid based near supplement*)

#16 MeSH descriptor: [Milk] exp.lode all trees

#17 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16

#18 MeSH descriptor: [Schools] exp.lode all trees

#19 MeSH descriptor: [Schools, Nursery] exp.lode all trees

#20 (school* or school-based or kindergarten or preschool or daycare or day care):ti,ab

#21 #18 or #19 or #20

#22 #17 and #21

3.2 MEDLINE (Ovid) Search Strategy

1 Dietary Supplements/ (26188)

2 Diet Therapy/ (9183)

3 Food, Fortified/ (7198)

4 Functional Food/ (467)

5 Nutrition Therapy/ (756)

6 ((extra or take-home or takehome) adj3 (food$ or feed$ or ration$)).tw. (227)

7 Nutrition Policy/ (5462)

8 ((feed$ or food$) adj3 program$).tw. (3004)

9 ((fortif$ or enrich$) adj3 (food$ or diet$ or spread$ or flour$ or cereal$)).tw. (7090)

10 (lunch$ or dinner$ or break-fast$ or breakfast$ or break fast$ or supper$ or snack$ or meal$ or milk or meat or egg$).tw. (235654)

11 (plumpy$ or nutri spread$).tw. (8)

12 ((supplement$ or complement$) adj3 (food$ or feed$ or diet$ or nutrition$ or nutrient$ or micronutrient$ or micro-nutrient$)).tw. (37889)

13 (blended adj3 food$).tw. (47)

14 (energy adj3 supplement$).tw. (836)

15 (lipid based adj3 supplement$).tw. (24)

16 Milk/ (40309)

17 or/1-16 (315687)

18 schools/ or schools, nursery/ (19744)

19 school$.tw. (174758)

20 (school$ or school-based or kindergarten or preschool or preschool or daycare or day care).tw. (192684)

21 or/18-20 (196809)

22 17 and 21 (6878)

3.3 WHO Clinical Trials Registry (Web) Search Strategy

(lunch OR dinner OR breakfast OR snack OR meal OR milk OR meat OR egg OR food OR feed)

AND

(child or school or student)

3.4 ERIC – Education Resources Information Centre (ProQuest) Search Strategy

TI (lunch* OR dinner* OR breakfast* OR snack* OR meal OR milk OR meat OR egg OR food OR feed) AND TI (school* OR student*) OR AB (lunch* OR dinner* OR breakfast* OR snack* OR meal OR milk OR meat OR egg OR food OR feed) AND AB(school* OR student*)

3.5 Dissertations and Theses (ProQuest) Search Strategy

TI (lunch* OR dinner* OR breakfast* OR snack* OR meal OR milk OR meat OR egg OR food OR feed) AND TI (school* OR student*) OR AB (lunch* OR dinner* OR breakfast* OR snack* OR meal OR milk OR meat OR egg OR food OR feed) AND AB (school* OR student*)

3.6 PsycINFO (OVID) Search Strategy

1 Dietary Supplements/ (982)

2 Diets/ (8146)

3 (Diet adj3 therapy).tw. (131)

4 Food/ (8213)

5 Food Intake/ (11256)

6 Nutrition/ (6017)

7 fortifi$.tw. (339)

8 (Functional adj3 Food).tw. (91)

9 (fortified adj3 food).tw. (14)

10 (Nutrition adj3 Therapy).tw. (102)

11 ((extra or take-home or takehome) adj3 (food$ or feed$ or ration$)).tw. (107)

12 Nutrition Policy.tw. (54)

13 ((feed$ or food$) adj3 program$).tw. (1042)

14 ((fortif$ or enrich$) adj3 (food$ or diet$ or spread$ or flour$ or cereal$)).tw. (276)

15 (lunch$ or dinner$ or break-fast$ or breakfast$ or break fast$ or supper$ or snack$ or meal$).tw. (10063)

16 plumpy$.tw. (0)

17 (supplement$ adj3 (food$ or feed$ or diet$ or nutrition$ or nutrient$)).tw. (2014)

18 or/1-17 (38208)

19 Junior High School Students/ or Nursery School Students/ or Preschool Students/ or Students/ or Kindergarten Students/ or Middle School Students/ or Primary School Students/ (45855)

20 Junior High Schools/ or High Schools/ or Middle Schools/ or Nursery Schools/ or Schools/ or Elementary Schools/ (30170)

21 (school$ or school-based or kindergarten or preschool or preschool or daycare or day care).tw. (306657)

22 or/19-21 (322482)

23 18 and 22 (3522)

24 limit 23 to yr="2006 - 2013" (1944)

3.7 Web of Science (Web of Knowledge)-- Conference Proceedings Search Strategy

Title=(lunch* OR dinner* OR breakfast* OR snack* OR meal OR milk OR meat OR egg OR food OR feed) AND Title=(school* OR student*)

Timespan=2006-02-01 - 2013-02-08. Databases=SSCI, CPCI-S, CPCI-SSH.

Social Sciences Citation Index (SSCI) --1900-present

Conference Proceedings Citation Index- Science (CPCI-S) --1990-present

Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH) --1990-present

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