

Systematic review on the health outcomes associated to fortified complementary foods

– Final report (R2) –

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ABSTRACT

Background

Fortified complementary foods are centrally processed foods enriched with essential micronutrients with the aim of preventing or correcting deficiency of one or more micronutrients in the critical period of complementary feeding. They provide an alternative to home or point-of-use fortification with micronutrient powders or crushable or soluble micronutrient tablets.

Objectives

To assess the health effects and safety of fortified complementary foods on health, nutrition and developmental outcomes of apparently healthy infants and children six to 23 months of age.

This review did not assess the effects of food fortificants and supplements added to the complementary food at point-of-use, typically in the homes of children. In this review only those studies were included, where effects of the fortified complementary food were compared to those of an unfortified version of the same complementary food.

Search methods

On 9 March 2021, we searched Cochrane CENTRAL, Ovid MEDLINE, Embase, CINAHL, Global Index Medicus, Web of Science and two trials registers (ClinicalTrials.gov, WHO ICTRP) for relevant studies. We also checked the reference lists of included studies and systematic reviews.

Selection criteria

We included both randomised controlled trials (RCTs) and non-randomised studies of interventions (NRSI) with individual randomisation or cluster-randomisation. Participants were infants and young children aged 6 to 23 months at the start of intervention, with no identified specific health problems. The intervention consisted of consumption of centrally fortified food with one micronutrient or a combination of vitamins and/or minerals. As an eligible comparator studies had to contain a group, which received the same complementary food, but without micronutrient fortification.

Data collection and analysis

Two review authors independently screened studies for eligibility and, for those studies included in the review, extracted data, assessed risk of bias and rated the certainty of the evidence. We carried out statistical analysis using RevMan software. We used a random-effects meta-analysis for combining data as the interventions differed significantly. We reported dichotomous outcomes as risk ratios

(RRs), with 95% confidence intervals (CIs), and continuous outcomes as mean differences (MDs) with 95% CIs. We used the GRADE approach to assess the certainty of evidence.

Main results

This review includes 16 studies with a total of 5089 participants (range of mean baseline hemoglobin values: 91 to 133 g/L; 13 out of the 16 studies performed in malaria-endemic areas). There was only one trial with an overall low risk of bias, we judged all other trials to have unclear or high risk of bias in one or more 'Risk of bias' domains. Overall, 12 studies were included in the quantitative syntheses.

Moderate-certainty evidence show that providing fortified complementary food to children aged 6 to 23 months at the start of the intervention reduced anaemia by 43%, and those who received fortified complementary food compared to those who did not had significantly higher haemoglobin concentrations (MD 3.44 g/L, 95% CI 1.33 to 5.55; moderate certainty evidence) and significantly higher ferritin concentrations (log ferritin: MD 0.43 µg/L, 95% CI 0.14 to 0.72; low certainty evidence).

Available evidence showed no difference in weight-for-age z scores (MD -0.01, 95% CI -0.07 to 0.06; moderate-certainty evidence), weight for height/length Z-scores (MD -0.05, 95% CI -0.19 to 0.10; moderate-certainty evidence), and height/length for age Z-scores (-0.01, 95% CI -0.21 to 0.20; low-certainty evidence) between groups.

The intervention led to no effects on serum zinc (MD -0.13 g/dL, 95% CI -0.82 to 0.56; low-certainty evidence), and serum vitamin A (MD 0.03 µmol/L, 95% CI -0.02 to 0.08; moderate-certainty evidence).

Children consuming the fortified as compared to those consuming the unfortified complementary food had significantly better mental skill development scores (MD 0.80, 95% CI 0.12 to 1.48; moderate-certainty evidence), and total psychomotor development scores (MD 1.13, 95% CI 0.35 to 1.91; low-certainty evidence), but no significant differences were seen when fine and gross motor scores were assessed separately (low-certainty evidence).

Low-certainty evidence showed no difference in the acceptability of fortified as compared to unfortified complementary food products.

Author's conclusions

Centrally fortified complementary foods probably reduce anaemia in infants and young children aged 6 months to two years, in malaria-endemic regions and can probably lead to better mental and psychomotor achievement. Consumption of fortified complementary foods in this age group may improve iron status, but make little or no difference to the levels of other micronutrients, including zinc and vitamin A. Several aspects of providing fortified foods to children in the complementary

feeding period should be further investigated, including the fortification dose which can lead to adequate nutrient intakes, and potential adverse effects.

INTRODUCTION

Description of the condition

Exclusive breastfeeding is recommended for the first 6 months of age by several committees, like the World Health Organisation (WHO) (1), the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) (2) and the American Academy of Pediatrics (AAP) (3). This should be followed by appropriate complementary feeding and continued breastfeeding for 1 year or more as desired for mother and infant (2, 3) or up to 24 months of age or even longer (1). Complementary feeding is the transition from exclusive breastfeeding to family foods, typically the period from 6-23 months of age (4). In this period infants and young children need to have a great dietary diversity to ensure their nutrient needs are met (5). This is a critical period not only for physical, but also for cognitive and motor development.

Infants' diet at the age of 6 to 23 months often doesn't provide sufficient quantity of micronutrients. This may be due to a number of factors, including the low mineral content of breast milk (iron, zinc), the relatively small amount of complementary food consumed and its inadequate nutrient density as well as the relatively high requirement of these nutrients. Therefore, complementary food should have a high nutrient density and locally available foods are preferred. Plant-based complementary foods are insufficient in some micronutrients, like iron, zinc or calcium, so meat, fish and eggs should also be offered as often as possible. Besides breastfeeding calcium-rich dairy products (preferably cheese, yogurt and dried milk, mixed with other foods) should also be given(6).

Vitamin and mineral (micronutrient) deficiencies are common in low and middle-income countries affecting more than two billion people worldwide. Children living in South Asia (7) and Africa (8, 9) are in particular at risk for developing it. In the background several causes can stand, like the low dietary intake of micronutrients (8), the low nutrient density of complementary foods (10, 11) as well as low consumption of haem-iron containing meat (6, 11). The highest nutrient gaps in the complementary feeding period are for iron, vitamin A, vitamin B₁₂, zinc and calcium (7, 9).

Anaemia is still a worldwide health problem in preschool-age children affecting about 273 million children worldwide. The highest percentage of affected children can be found in Africa (62.3%), South-East-Asia (53.8%), and the Eastern Mediterranean Region (48.6%) (12). Approximately half of anaemia cases is caused by iron deficiency (ID), but other micronutrient deficiencies (folate, vitamin B₁₂, zinc), infection (malaria, HIV) and disturbed haemoglobin synthesis might also stand in the background (12).

Iron is important not only for haemoglobin synthesis, but it also plays a key role in neurodevelopment, so 6-23 months-old infants with iron deficiency are at increased risk for poorer cognitive, motor and

neurodevelopmental outcomes (13). The prevalence of iron deficiency in children under 5 years of age is higher (18% in Ethiopia – 35% in Kenya) than in the 5-19 age group (4% in Kenya – 18% in South Africa) (8). In these countries a big number of children also have inadequate intake of iron (13% - 62%) (8).

Vitamin A is required for vision, epithelial integrity and both innate and adaptive immunity (14). Vitamin A deficiency (VAD) is the main cause of preventable blindness (15), but children with VAD also have an increased risk of morbidity and mortality (16). It affects about 190 million preschool-age children worldwide, mainly in Africa and South-East Asia (2). The prevalence of VAD is also high in Africa in children <5 years ranging between 15% (in Kenya) and 35% (in South Africa) that greatly correlate with inadequate intake in this age group ranging between 1 – 100% (8).

Zinc is essential for normal physical and mental development and as part of zinc-finger proteins for both DNA and RNA synthesis as well as in several enzymatic functions (17, 18). Many children <5 years have zinc deficiency with prevalence from 35% (in Ethiopia) to 63% (in Nigeria) that correspond to the inadequate intake in 51 – 99% of these children (8). This can lead to increased risk of childhood infections and death from infectious diseases (18).

Description of the intervention

In the first two years of life the need for nutrients is high due to rapid growth that should be covered by complementary feeding providing a wide variety of foods to ensure proper nutrient content after the age of 6 months in addition to breastfeeding (6) or milk products for non-breastfed children (19). However, unfortified complementary foods as well as plant-based foods may provide insufficient amounts of some nutritionally important minerals like iron, zinc or calcium. In these populations the use of fortified complementary food or vitamin-mineral supplementation of the infant can be beneficial.

Food fortification means the addition of micronutrients to processed food with the aim to increase the intake of these micronutrients and thereby correcting or preventing deficiency. Fortification differs from supplementation, which means the provision of relatively large doses of micronutrients in the form of pills, capsules, or syrups. (20). Food fortification can mean the addition of micronutrients at the time of food production (including mass, targeted, and market-driven fortification), at point of use (home fortification), or the breeding and genetic modification of plants so as to improve their micronutrient content (biofortification).

Food fortification can improve the micronutrient status of a population quite rapidly and can be a very cost-effective intervention in public health. However, fortified food must be consumed in adequate amounts to achieve proper effect and fortificant should be well absorbed and shouldn't affect the smell and taste of enriched foods (20).

Fortification of complementary foods might be done either by the industry or at point of use. In the present systematic review, we discuss the potential health effects of adding micronutrients (minerals, vitamins) to industrially processed and widely consumed complementary food products (i.e. fortified ready-to-eat or ready-to-cook products).

The first complementary food for an infant is usually a porridge, gruel or infant cereal, so fortified cereals can be beneficial in meeting the infants' micronutrient requirements. There are several ready-to-eat porridges, grains, blended foods (e.g. corn-soy blend or wheat-soy blend) and ready-to-cook products (e.g. made from rice, wheat, corn, millet, grains, legumes, soy, peanuts, sugar and oil) and instant infant flours. In the first months of complementary feeding infants also consume fruits and vegetables in form of different purees and sauces or baby jars that also can be fortified with one or more micronutrients. When the child is old enough to consume lumpy food, different finger foods, snacks, pastas, noodles, bakery products (e.g. rusk, biscuit, cake) can be given. Besides breastmilk other drinks and beverages, like fruit juices can be offered to the infant. All of these complementary food types can be industrially fortified with one or more micronutrients.

How the intervention might work

In infants, the small amount of complementary food consumed and their increased demand due to rapid growth and development may result in micronutrient deficiencies. Most of the complementary foods are fortified with iron to meet this increased need. Studies conducted in 6-12 months old infants indicated that iron containing rice porridge (22), or with highly bioavailable iron containing maize and soy-flour based complementary food can significantly reduce the prevalence of ID (23). Cereal fortified with ferrous fumarate, ferric pyrophosphate or ferrous sulphate was described to have similar effects on maintaining haemoglobin concentrations and preventing ID in Bangladeshi children (24). In US infants, both electrolytic iron and ferrous fumarate containing cereal had the same effectiveness on iron status (25). In a malaria-endemic region iron-fortified complementary food also improved ID and iron deficiency anaemia (IDA) (26). Commercially fortified complementary food can effectively reduce the risk of ID and IDA in developing countries when its dose and chemical form is appropriate (11).

The same beneficial effects were indicated, when fortification was done with multiple micronutrients. Micronutrient fortification in form of fortified rusk was described to efficiently maintain haemoglobin concentration (27), while multi-fortified instant flour was reported to decrease the prevalence of ID, IDA and anaemia (28). Results of other studies indicated that multi-fortified rice-based infant cereal was not only an effective way to decrease the prevalence of ID and IDA in infants, but might have beneficial effects on language and mental developmental scores on Bayley-III scale (29) and motor development in infants living in poor areas (30). However, effects of micronutrient fortification on mental and motor development are conflicting (31, 32).

Some studies suggested that there might be differences based on the type of complementary food fortified: different effects in reducing anaemia were described for fortified wheat flour, (33), maize flour (34) and rice (35). Furthermore, intervention was indicated to be effective in reducing risk of anaemia to a different level in different age groups (36).

Some researchers reported that locally produced ready-to-use foods as well as fortified blended complementary foods may reduce linear growth deceleration and decrease the prevalence of stunting (37). Micronutrient-fortified complementary food might have not only short-term (during experimental period), but even longer term (6 months after the intervention) beneficial effect on length and ponderal growth (38).

In zinc-deficient areas zinc supplementation for children over 6 months of age can be beneficial in reducing the duration of diarrhoea (39) and mortality as well as morbidity due to diarrhoea (40). Adding zinc to food during infancy and early childhood can improve child growth (41), but results are conflicting (42).

In South-Africa, provitamin A-biofortified maize as well as provitamin A and iron rich orange-fleshed sweet potato is available (43), and their acceptance suggested that these biofortified foods can replace the unfortified ones in traditional dishes (44). Micronutrient fortified complementary food might prevent the decline in serum retinol concentration over a 6-month intervention period (32, 45).

Why it is important to do this review

Micronutrient deficiencies are common in low- and several middle-income countries (mainly in South-Asia and Africa), where staple foods do not provide enough nutrients to cover the daily demand. The most vulnerable groups are pregnant and lactating women and children as well. Therefore, most studies are investigating the possible positive health effects of supplementing the diet in these groups

at increased risk. Large scale food fortification for example had a positive impact on goitre, neural tube defect and anaemia and reduced both ID and VAD in children and in women of reproductive age (46).

IDA is one of the major health problems worldwide with a high prevalence in 6-24-month-old children. In several developing countries, like South-Asian and African countries complementary foods don't provide sufficient amount of iron, so iron supplementation or fortification might be beneficial in preventing IDA. Complementary food containing substantial amount of iron in form of meat or iron-fortified cereal help to prevent ID during the first year of life in infants who are at risk of insufficient iron stores (47).

Several Cochrane Reviews evaluated the possible effects of different micronutrient powder or lipid-based nutrient supplements containing vitamins or minerals in children. De-Regil et al found that point-of-use fortification of foods with iron-containing micronutrient powder (MNP) reduces anaemia and ID in both preschool- and school-age children (48). Similarly, home (point-of-use) fortification of foods with MNP (containing at least iron, zinc and vitamin A) reduced anaemia and ID in 6-23 months old infants (49). Multiple micronutrient fortification may reduce anaemia by 32%, the prevalence of IDA by 72%, ID by 56% and VAD by 58% compared to placebo (50). Lipid-based nutrient supplements with complementary feeding were also effective in improving growth in this age group in low- and middle-income countries reducing the prevalence of moderate stunting by 7% and moderate wasting by 18% (51).

Several trials exist also on the potential beneficial and harmful effects of complementary feeding with fortified foods (22-27, 31, 32, 37, 38, 45, 52, 53), although, there is currently no up-to-date systematic review summarising these results.

OBJECTIVES

To assess the effects of the consumption of fortified complementary food (excluding milk) as compared to unfortified version of the same complementary food on beneficial or harmful dietary and health outcomes in infants and young children 6-23 months of age.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) with both individual randomisation and cluster randomisation. We also included controlled clinical trials (CCTs), if concurrently controlled (i.e. with the intervention group and control group chosen from the same population and treated concurrently). Studies with external (historical) control groups, or with matched cross-sectional control groups were excluded.

Types of participants

We included infants and young children aged six to 23 months at the start of the intervention. We did not include infants under six months, as exclusive breastfeeding is the recommendation for infants from birth to six months of age. We intended to include apparently healthy children from the general population, although some may be at risk of having highly prevalent diseases (e.g. malaria, HIV, diarrhoea, undernutrition).

We included studies targeted to broader age groups and attempted to extract data for children six to 23 months from these studies, if possible.

For populations in malaria-endemic areas, we planned to report on malaria incidence and malaria severity. Because this was not reported by trial authors, we investigated, whether authors mentioned the region to be malaria endemic, whether children with malaria were included or excluded. As malaria prevalence was not reported in most of the cases, we defined an area as malaria endemic based on the WHO classification (54).

Types of interventions

Consumption of fortified complementary products (excluding milk and milk-based formula). Products might have been fortified with one micronutrient or a combination of vitamins and/or minerals.

The following fortified complementary food products were eligible to be included:

- ready-to-eat porridges
- infant cereal, grains/ ready-to-cook products (e.g. made from rice, wheat, corn, millet, grains, legumes; soy, peanuts, sugar; and oil)/ blended foods (e.g. corn-soy blend, wheat-soy blend)
- ready-to-cook/instant infant flour

- pastas, noodles
- bread and other bakery products (including rusks, biscuits, cakes)
- baby food
- purees, sauces
- finger food, snacks
- beverages (drinks, juices)

There was no restriction based on the dose of fortification, nor based on the frequency and duration of the fortified complementary food consumption. All fortification strategies were eligible, if food products were fortified processed centrally.

We excluded food supplements (e.g. lipid-based nutrient supplements) and micronutrient powders, or any other ways of home (point-of-use) fortification.

Comparator was consumption of an unfortified version of the same complementary product. Studies comparing two or more different fortified products to each other, without comparing them to an unfortified version of the same complementary food product were excluded.

Types of outcome measures

Main outcomes

- Growth, measured by the following growth indicators:
 - Weight for age Z-scores (reported continuously; WAZ)
 - Weight for height/length Z-scores (reported continuously; WHZ)
 - Height/length for age Z-scores (reported continuously; HAZ)
 - Other growth measures (e.g. head circumference or arm circumference for age; as measured by trialists)
- Stunting (reported as a categorical outcome; defined as HAZ more than 2 SDs below the reference WHO standard; [1])
- Wasting (reported as a categorical outcome; defined as WHZ more than 2 SDs below the reference WHO standard; [1])
- Nutrient adequacy (evaluated relative to estimated average requirements or adequate intakes; as defined by trialists) for iron, zinc, vitamin A, or any other micronutrient investigated by trialists

- Nutrient excess (intakes above the tolerable upper intake level (UL), as defined by trialists) for iron, zinc, vitamin A, or any other micronutrient investigated by trialists
- Anaemia (as defined by trialists)
- Haemoglobin concentration (measured as g/L)
- Iron status (as defined by trialists)
- Serum zinc concentration (g/dL)
- Serum retinol concentration ($\mu\text{mol/L}$)

Additional outcomes

- All-cause mortality
- Adverse effects (any)
- Mental and motor skill development (as defined by trialists; might include: Bayley Mental Development Index (MDI), Bayley Psychomotor Development Index (PDI), Stanford-Binet Test, DENVER II Developmental Screening Test)
- Morbidity (Including: incidence of diarrhoea, acute respiratory tract diseases, fever diseases)
- Ferritin level ($\mu\text{g/L}$)
- Serum/urine concentration of other vitamins or minerals (including vitamin D, vitamin B₁₂, folate, iodine, selenium)
- Gut microbiota composition (measured as relative abundance of specific Bacterium spp.)
- Taste preference
- Displacement of other foods

We included outcomes that are measured for as long as follow-up is carried out at any given time point.

Search methods for identification of studies

Electronic searches

We searched the following electronic databases and trial registers from the inception of each database up to March 2021, without restrictions on the language of publication:

- Ovid MEDLINE
- Cochrane Central Register of Controlled Trials (CENTRAL)

- CINAHL Cumulative Index to Nursing and Allied Health Literature
- Global Index Medicus, comprising
 - African Index Medicus (AIM)
 - Index Medicus for the Eastern Mediterranean Region (IMEMR)
 - Index Medicus for the South-East Asia Region (IMSEAR)
 - Latin America and the Caribbean Literature on Health Science (LILACS)
 - Western Pacific Region Index Medicus (WPRO)
- Embase.com
- Web of Science, comprising:
 - Science Citation Index
 - Emerging Citation Index
- Trials registers
 - ClinicalTrials.gov (clinicaltrials.gov)
 - WHO ICTRP (International Clinical Trials Registry Platform) (apps.who.int/trialsearch)

Details for all search strategies are available in **Appendix 1**.

Searching other resources

We tried to identify other potentially eligible trials or ancillary publications by searching the reference lists of included trials and related systematic reviews, meta-analyses, and health technology assessment reports.

We searched for grey literature, which we defined as searching the Global Index Medicus, as well as the trials registers.

Data collection and analysis

Selection of studies

Pairs of review authors (IC, RF, ES, SL) independently screened the abstract, title, or both, of every record retrieved by the literature searches to determine which trials should be assessed further. We performed the screening using Covidence software (55). We obtained the full texts of all potentially relevant records and screened these for eligibility. Any disagreements were resolved through consensus or by recourse to a third review author. We have presented a PRISMA flow diagram to

describe the process of trial selection (56). All articles excluded after full-text assessment and the reasons for their exclusion are described in *Characteristics of excluded studies* tables (**Appendix 5**).

Data extraction and management

From full-text publications, we extracted data on study methods, participants, intervention, control, reported outcomes, source of funding and potential conflict of interest statements from all included studies. If studies reported outcomes at multiple time points, we extracted data for each time point. Data extraction was performed by one reviewer and checked for completeness, accuracy and consistency by a second independent reviewer (IC, RF).

We attempted to extract data on food consumption for children six to 23 months from those studies targeted to broader age groups. Long-term outcomes were extracted as long as participants were followed up.

We did not use abstracts or conference proceedings for data extraction, because this information source does not fulfil the CONSORT requirements, which consist of “an evidence-based, minimum set of recommendations for reporting randomised trials) (57, 58). Key data of included abstracts are listed in **Appendix 4**.

If data from included trials were available as study results in clinical trial registries such as ClinicalTrials.gov or similar sources, we made full use of this information and extracted the data. If there was also a full publication of the trial, we collated and critically appraised all available data. If no results were available (in the registries, as publication, or both), we added this trial to the 'Characteristics of studies awaiting classification' table (**Appendix 4**).

Assessment of risk of bias in included studies

Two review authors (ES, SL) independently assessed the risk of bias of each included trial. Any disagreements were resolved by consensus. Risk of bias was evaluated with version 2 of the Cochrane risk-of-bias tool for randomised trials (RoB 2) (59). The following domains were considered: bias arising from the randomization process; bias due to deviations from intended interventions; bias due to missing outcome data; bias in measurement of the outcome; and bias in selection of the reported result. For cluster-randomised trials we additionally assessed the risk of bias arising from the timing of identification or recruitment of participants in cluster-randomised trials, and for cross-over trials bias

due to potential period and carryover effects. Overall risk of bias was defined for each trial as the least favourable assessment across the domains of bias.

Measures of treatment effect

For *dichotomous data*, we presented results as risk ratios (RRs) or odds ratios (ORs) with 95% confidence intervals (CIs). For *continuous data*, we used mean differences (MDs) with 95% CIs for studies measuring outcomes in the same way, and standardized mean differences (SMDs) with 95% CIs for studies measuring outcomes in a variety of ways.

Unit of analysis issues

We combined results from cluster-randomised and individually randomised studies. We labelled all cluster-randomised studies with '(C)'. Where trial authors had adjusted their results for the effect of clustering, we aimed to extract the cluster adjusted RR and standard error and enter the natural log of these into Review Manager (RevMan) using the generic inverse variance method as recommended by Higgins 2011 (60). Where trial authors had not adjusted their results for the effect of clustering, we extracted the simple summary data for all relevant outcomes and calculated crude RR and 95% CI using Review Manager (RevMan). We adjusted for the effects of clustering using the approximate analysis method (as described in Section 23. 1. 5 of the Cochrane Handbook). This involves inflating the standard error of the RR using an estimate of the design effect, and entering the natural logs of the adjusted RR and corresponding Standard Errors (SE) into Review Manager (RevMan) using the generic inverse variance method. Intraclass correlation coefficient (ICC) was unfortunately not reported in any of the trials, so the value of 0.03 was used as suggested by Leyrat et al (61) referring to the data collected by Campbell et al (62). Sensitivity analysis with respect to ICC was not undertaken.

We examined the potential effects of clustering using sensitivity analyses.

For outcomes with skewed data (ferritin, retinol) a part of the included studies presented their results as geometric means, or medians with interquartile ranges. In such cases we calculated log-transformed data for all studies and performed a meta-analysis on the scale of the log-transformed data.

Studies with more than two treatment groups

For studies with more than two intervention groups (multi-arm studies), we reported all arms in the Characteristics of included studies tables (**Appendix 2**) and included the directly relevant arm only, including each group in the analysis only once (63). If we came across a study that compared two possible fortified products with one unfortified comparator, we combined groups to create a single pair-wise comparison (as described in Section 6.5.2.10 of the Cochrane Handbook).

Assessment of heterogeneity

We assessed methodological heterogeneity by examining risk of bias, and clinical heterogeneity by examining similarities and differences between studies regarding types of participants, interventions, and outcomes. We considered the size and direction of effect and used a standard χ^2 test with a significance level of $\alpha = 0.1$ (64) and I^2 statistic — which quantifies inconsistency across trials — to assess the impact of heterogeneity on the meta-analysis (65, 66). We explored heterogeneity by conducting pre-specified subgroup analyses (See Section ‘Subgroup analysis and investigation of heterogeneity’ below).

Assessment of reporting biases

We used funnel plots to assess reporting bias (such as publication bias) and to investigate the relationship between effect size and standard error when 10 or more studies were included in a meta-analysis. Degree of funnel plot asymmetry was quantified using Egger’s test (67). Visualisation of risk of bias was done with Robvis Tool (<https://mcguinlu.shinyapps.io/robvis/>).

Data synthesis

We carried out statistical analysis using RevMan 5 (version 5.4.1). As we expected differences between studies in both the population and the intervention, we decided to combine the data using a random effects model, when it was clinically meaningful to do so, to provide an average treatment effect across studies. We used Mantel-Haenszel weighting for dichotomous outcomes and inverse variance for continuous outcomes. In case both individually randomised and cluster-randomised trials were included in a meta-analysis, we used the inverse variance method, as described in the “Unit of analysis issues” section.

Subgroup analysis and investigation of heterogeneity

We expected the following characteristics to introduce clinical heterogeneity, and we planned to carry out subgroup analyses for these, for all outcomes, where enough trials were available:

- Age groups (6-8 months; 9-11 months; 12-23 months)
- Different types of nutrients added through fortification
- Different types of products fortified
- By duration of intervention: less than six months versus six months or more
- The country income classification (HIC vs. LMIC)
- By anaemic status at start of intervention (anaemia defined according to trialists): anaemic, non-anaemic or unknown anaemic status
- Sponsor: industry vs. academy (investigator)

Sensitivity analysis

When possible, we conducted sensitivity analyses to examine the potential effects of clustering on the CIs of summary estimates.

Grading of recommendations assessment, development, and evaluation (certainty of the evidence)

We followed the GRADE approach to rate the certainty of evidence. Each outcome was evaluated with the following GRADE criteria: risk of bias, indirectness, inconsistency, imprecision, and dissemination bias. GRADE specifies four levels of certainty of evidence: high, moderate, low, and very low (68, 69).

RESULTS

Description of studies

Results of the search

The search was run on 09.03.2021. We retrieved 15496 unique records through database searching. After removing duplicates 8313 records were screened based on their titles and abstracts. Most of the references clearly did not meet the inclusion criteria based on title and abstract review and were excluded (**Figure 1.**). We evaluated 494 full texts or records to determine their eligibility for inclusion in the review (8 further records will be assessed after their full texts could be retrieved). 21 studies met our inclusion criteria (16 studies with full-text publications and further 5 studies where results are not yet published).

Included studies

For a detailed description of included trials, see Characteristics of included studies (**Appendix 2**).

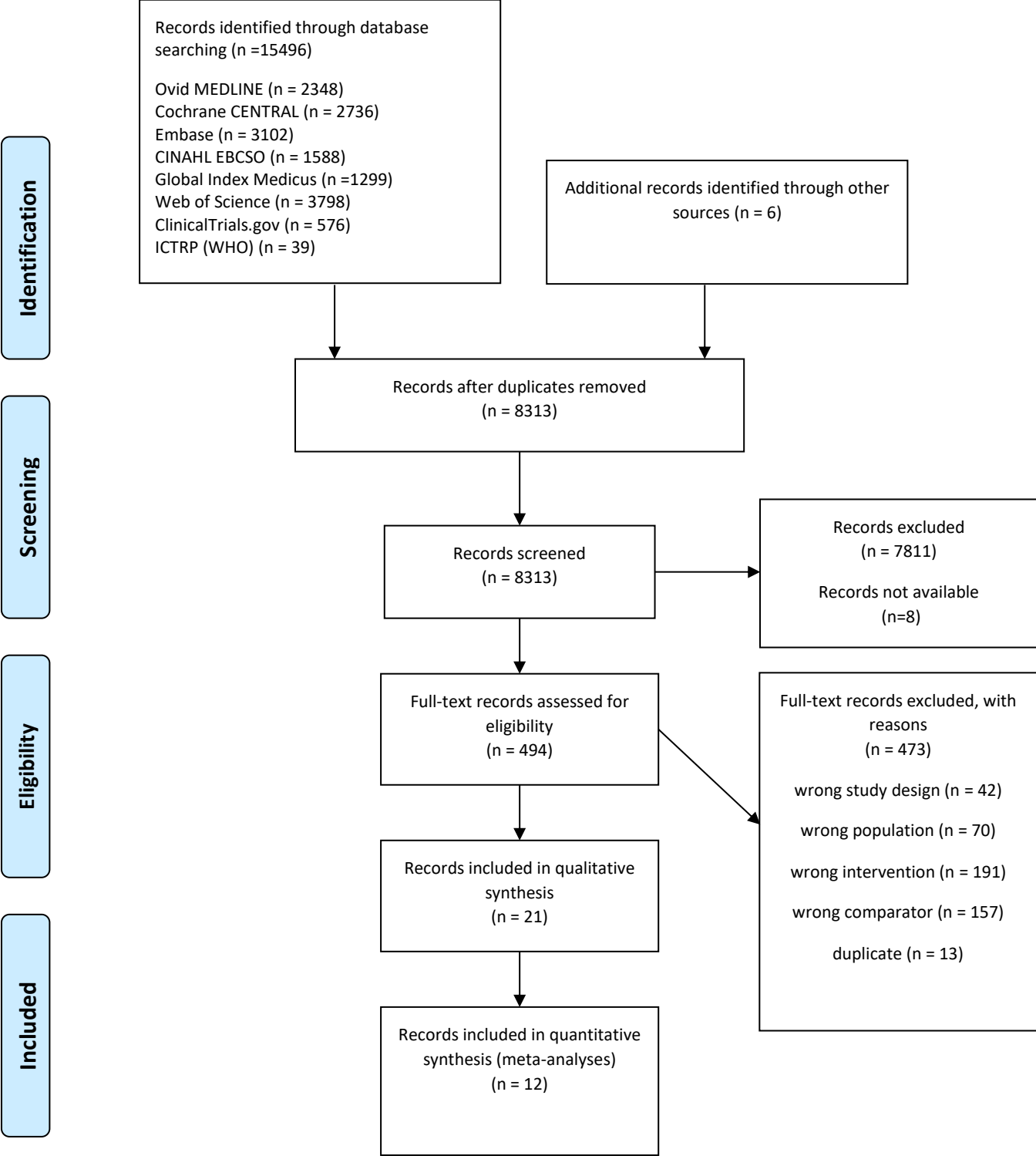
Study design

We included 16 studies with 5089 participants. Eight studies were RCTs randomised at the individual level (Bovell-Benjamin 1999; Faber 2005; Gannon 2019; Lartey 2000; Nesamvuni 2005; Palmer 2021; Quintero 2011; Schumann 2005), one was a non-randomised controlled trial (Huey 2018) and seven were cluster-RCTs (Arcanjo 2012, Arcanjo 2013, Bagni 2009, Ekoe 2020, Gershoff 1977, Liu 1993, Ma 2016,).

Setting

Only one study was conducted in a high income country (USA: Bovell-Benjamin 1999); ten studies were conducted in upper middle income countries including China (Ma 2016; Liu 1993), Brazil (Arcanjo 2012; Arcanjo 2013; Bagni, 2009), Thailand (Gershoff 1977); Mexico (Quintero 2011); South Africa (Faber 2005, Nesamvuni 2005); Guatemala (Schumann 2005); while five studies were conducted in lower middle income countries including Zambia (Palmer 2021), Cameroon (Ekoe 2020), India (Huey 2018; Gannon 2019), and Ghana (Lartey, 2000), and no study was conducted in a low income country.

Figure 1. Trial flow diagram



According to the WHO classification (54), 13 out of the 16 studies were performed in malaria-endemic areas (see **Appendix 7**). Three studies, conducted in the USA and China, were classified as non-malaria-endemic (Bovell-Benjamin 1999; Ma 2016, Liu 1993).

Participants

Participant age ranged from 6 to 60 months. All studies included children of both sexes. Sample sizes ranged from 40 in Bovell-Benjamin 1999 to 1465 in Ma 2016. However, the analyses include only participants allocated to the study arms relevant for this systematic review in case of studies with more than two arms and the estimated effective sample size calculated for cluster-randomised trials in order to adjust study data to account for the clustering effect.

Out of the 16 studies included in the systematic review nine studies reported anaemia prevalence at baseline. In two studies participants were reported to be anaemic (Eko 2020) or moderately anaemic (Schumann 2005). Seven trials included both anaemic and non-anaemic children (Palmer 2021; Ma 2016; Arcanjo 2013; Arcanjo 2012; Faber 2005; Lartey 2000; Liu 1993). In the remaining seven trials baseline anaemia status was not reported.

Interventions

There were three acute studies with an intervention duration of three subsequent feeding sessions (Bovell-Benjamin 1999) to three consecutive days (Gannon 2019, Huey 2018). Among studies investigating longer-term effect of fortified complementary food consumption, intervention duration lasted between 10 weeks (Schumann 2005) and 18 months (Arcanjo 2012, Arcanjo 2013). Study duration was variable in one study (Gershoff 1977).

Products fortified were cereals in most of the cases, including 2 studies with fortified wheat-based products (Liu 1993; Eko 2020); five with fortified maize/corn-based products (Bovell-Benjamin 1999; Quintero 2011; Faber 2005; Palmer 2021; Nesamvuni 2005); five with fortified rice or rice cereal (Ma 2016; Gershoff 1977; Bagni 2009; Arcanjo 2012; Arcanjo 2013) and one with fortified pearl millet (Huey 2018). In two studies the fortified complementary food product was a cereal-legume blend (Lartey 2000; Gannon 2019), while in one study legume (beans) were fortified (Schumann 2005).

Vitamin and mineral composition

Macro-and micronutrient composition of the fortified products and the micronutrients added to these products as fortificants are shown in **Appendix 3**. In six studies complementary food products were fortified with iron only (Ekoe 2020; Arcanjo 2012; Arcanjo 2013; Bagni 2009; Schumann 2005; Bovell-Benjamin 1999). In the remaining studies fortification was done with a combination of two or more micronutrients: iron and zinc in one study (Huey 2017); iron, zinc and vitamin B₁₂ in one study (Ma 2016); iron, vitamin A acetate and thiamine in one study (Gershoff 1977), iron, zinc, vitamin A, niacin and folic acid in one study (Quintero 2011); vitamin A palmitate (or biofortification) in one study (Palmer 2021); vitamin A, thiamine, riboflavine and pyridoxine in one study (Nesamvuni 2005). There were three studies where a combination of ten or more vitamins and minerals was used (Faber 2005, Lartey 2000; Liu 1993). Biofortification was done in two studies (Gannon 2019; Palmer 2021).

Outcomes

Out of the primary outcomes of this systematic review the following were measured in the included studies: growth measured by weight for age Z-scores (WAZ) in 5 studies, by weight for height/length Z-scores (WHZ) in 4 studies, by height/length for age Z-scores (HAZ) in 4 studies; nutrient adequacy for zinc and vitamin A in one study; anaemia in 6 studies; haemoglobin concentrations in 13 studies (but results reported only in 11 studies); iron status measured by ferritin concentrations in 6 studies, by body iron in one study and by free erythrocyte porphyrin in one study; serum retinol concentrations in 5 studies; serum zinc concentration in 2 studies. Stunting, wasting, and nutrient excess (intakes above the tolerable upper intake level) were reported in none of the included studies.

Out of the secondary outcomes of this systematic review the following were measured: mental skill development in 2 studies, motor skill development in 3 studies; morbidity (including diarrhoea, acute respiratory tract diseases, fever diseases) in two studies (but appropriately reported only in one study); plasma vitamin E concentration in one study; acceptability of fortified as compared to non-fortified complementary food products in 3 studies. Adverse effects were mentioned in one study. All-cause mortality, gut microbiota composition and displacement of other foods were reported in none of the included studies.

Funding sources

Funding sources of included studies are described in the “Publication details” of each Characteristics of included studies table (see **Appendix 2**). A total of 8 studies were funded by government programmes or by other non-commercial organisations (Gannon 2019; Huey 2017; Ma 2016; Arcanjo

2012; Arcanjo 2013; Bagni 2009; Liu 1993; Gershoff 1977), while there were 6 partly or fully commercially funded studies (Palmer 2021; Ekoe 2020; Quintero 2011; Nesamvuni 2005; Lartey 2000; Faber 2005). Two studies did not report any funding source (Schümann 2005; Benjamin-Bovell 1999).

Ongoing studies

We identified a total of 5 trials, potentially eligible to be included in the systematic review, but not yet published as a full-text publication. For further details of these trials, see **Appendix 4**.

Excluded studies

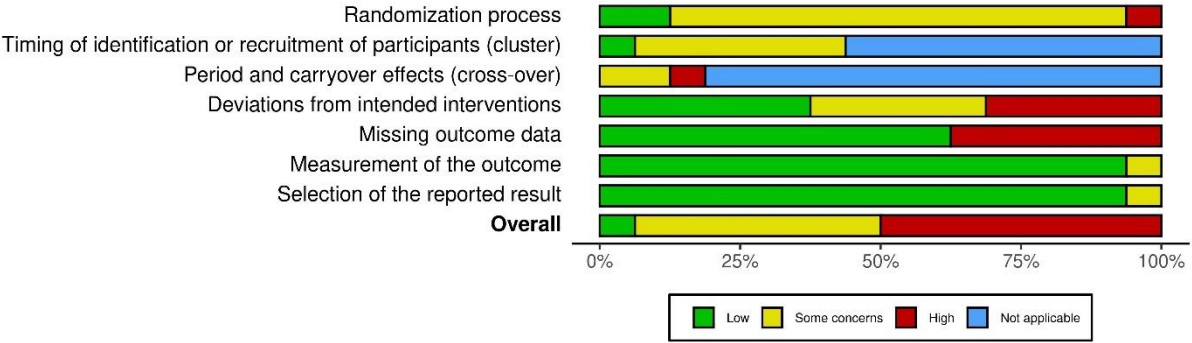
For a detailed description studies excluded in the full text screening phase, see **Appendix 5. Characteristics of excluded studies**. A total of 42 studies were excluded, because they were not primary studies with participants allocated to two or more intervention groups. In 70 studies participants were not children aged 6-23 months: in 9 studies children were younger at the start of the intervention, while 61 studies included older children or women. We excluded 191 studies because the intervention was not a complementary food fortified with vitamins and/or minerals. In 157 studies there was no eligible comparator (i.e. none of the participants received the same complementary food as in the intervention group, just without fortification); at this stage also studies comparing two different dosages of fortification were excluded. Further 13 studies were identified as duplicates of already included/excluded studies and were excluded as duplicates.

Risk of bias in included studies

For an overview of review authors' judgements about each 'Risk of bias' item for individual trials and across all trials, see **Figure 2** and **Figure 3**.

The randomisation process was appropriately described in only two studies (Palmer 2021; Gannon 2019), while in 13 studies there were some concerns due to lack of information about the randomisation process (Ma 2016; Quintero 2011; Nesamvuni 2005; Schümann 2005; Benjamin-Bovell 1999; Gershoff 1977) or the allocation sequence concealment (Ekoe 2020; Ma 2016; Arcanjo 2012; Arcanjo 2013; Quintero 2011; Bagni 2009; Nesamvuni 2005; Faber 2005; Schümann 2005; Lartey 2000; Benjamin-Bovell 1999; Liu 1993; Gershoff 1977). In one study the allocation sequence was clearly non-random, as all the participants received the non-fortified products first (Huey 2017).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included trials.



Deviations from intended intervention were rated with high risk of bias in five cases (Bagni 2009; Nesamvuni 2005; Faber 2005; Schümann 2005; Gershoff 1977); because there was a potential for a substantial impact on the result of the failure to analyse participants in the group to which they were randomised. In five cases there were some concerns about potential deviations from the interventions (Ekoe 2020; Ma 2016; Quintero 2011; Lartey 2000; Liu 1993), while in the remaining six cases this risk of bias domain was evaluated with low risk of bias.

Missing outcome data lead to high risk of bias in six studies (Nesamvuni 2005; Faber 2005; Schümann 2005; Benjamin-Bovell 1999; Liu 1993; Gershoff 1977), while in the remaining ten studies this domain was evaluated to be of low risk of bias.

Measurement of the outcome and selection of the reported results raised concerns in only one case each (Ma 2016 and Gershoff 1977, respectively).

There were seven cluster-randomised trials, where we additionally assessed the timing of identification or recruitment of participants; in one case this domain was judged to be of low risk of bias (Ekoe 2020) and in four cases we had some concerns (Ma 2016; Arcanjo 2012; Arcanjo 2013; Bagni 2009; Liu 1993; Gershoff 1977).

There were three cross-over trials, where we additionally assessed the presence or absence of period and carryover effects. In one case this domain was judged to be of high risk of bias, because the number of participants allocated to each of the two sequences was clearly not equal (Huey 2017), while in two

cases we had some concerns due to lack of information about allocation to sequences and whether period effects were accounted for in the analysis (Gannon 2019; Benjamin-Bovell 1999).

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included trial

		Risk of bias							
		D1	D2	D3	D4	D5	D6	D7	Overall
Study	Palmer 2021	+	○	○	+	+	+	+	+
	Ekoekoe 2020	-	+	○	-	+	+	+	-
	Gannon 2019	+	○	-	+	+	+	+	-
	Huey 2017	✗	○	✗	+	+	+	+	✗
	Ma 2016	-	-	○	-	+	-	+	-
	Arcanjo 2012	-	-	○	+	+	+	+	-
	Arcanjo 2013	-	-	○	+	+	+	+	-
	Quintero 2011	-	○	○	-	+	+	+	-
	Bagni 2009	-	-	○	✗	+	+	+	✗
	Nesamvuni 2005	-	○	○	✗	✗	+	+	✗
	Faber 2005	-	○	○	✗	✗	+	+	✗
	Schumann 2005	-	○	○	✗	✗	+	+	✗
	Lartey 2000	-	○	○	-	+	+	+	-
	Benjamin-Bovell 1999	-	○	-	+	✗	+	+	✗
	Liu 1993	-	-	○	-	✗	+	+	✗
Gershoff 1977	-	-	○	✗	✗	+	-	✗	

D1: Randomization process
 D2: Timing of identification or recruitment of participants (cluster)
 D3: Period and carryover effects (cross-over)
 D4: Deviations from intended interventions
 D5: Missing outcome data
 D6: Measurement of the outcome
 D7: Selection of the reported result

Judgement

- ✗ High
- Some concerns
- + Low
- Not applicable

Overall, 8 studies (50%) were rated with high risk of bias, due to the randomization process and carryover-effects (Huey 2017), deviations from the intended interventions (Bagni 2009; Nesamvuni

2005; Faber 2005; Schümann 2005; Gershoff 1977) or missing outcome data (Nesamvuni 2005; Faber 2005; Schümann 2005; Benjamin-Bovell 1999; Liu 1993; Gershoff 1977).

Effects of intervention

This review includes 16 studies with 5089 children. In trials with more than two treatment arms some of the children were allocated to interventions, which were not relevant to our systematic review and therefore not included in our analyses. Most of the included studies focused on anaemia and haematological indices; few reported on growth measures and developmental outcomes. There were three acute studies measuring acceptability of the products; their results were summarised narratively. There was one further trial (Gershoff 1997) not providing any quantitative data separately for the intervention groups. A total of 12 studies provided data for the quantitative analyses.

For detailed results on primary and secondary outcomes see the **Main outcomes** section below, and **Data and analyses** in **Appendix 6**.

Main outcomes

Growth

Growth was measured by weight for age Z-scores (WAZ) in five studies (Eko 2020; Faber 2005; Lartey 2000; Ma 2016; Quintero 2011), by weight for height/length Z-scores (WHZ) in four studies (Eko 2020; Faber 2005; Ma 2016; Quintero 2011), by height/length for age Z-scores (HAZ) in four studies (Eko 2020; Faber 2005; Lartey 2000; Ma 2016). All these studies had an intervention duration longer than 6 months (**Analysis 1.21; Analysis 1.29; Analysis 1.37**).

Available evidence showed no difference in weight-for-age z scores (MD -0.01, 95% CI -0.07 to 0.06; P = 0.88; 5 trials; 1206 participants; moderate-certainty evidence; **Analysis 1.17**), weight for height/length Z-scores (-0.05, 95% CI -0.19 to 0.10; P = 0.54; 4 trials; 1109 participants; moderate-certainty evidence; **Analysis 1.25**), and height/length for age Z-scores (-0.01, 95% CI -0.21 to 0.20; P = 0.93; 4 trials; 811 participants; low-certainty evidence; **Analysis 1.33**) between groups.

Subgroup analyses for weight-for-age z scores are shown in **Analyses 1.18 – 1.26**; those for weight for height/length Z-scores in **Analyses 1.26 – 1.31** and for height/length for age Z-scores in **Analyses 1.34 – 1.40**; in none of the subgroups a significant difference between children consuming fortified as compared to unfortified complementary food was detected.

We investigated the effect of clustering by removing cluster-randomised trials from the meta-analyses as part of sensitivity analyses and saw no changes in the direction of the pooled estimate either for weight-for-age Z-scores (MD -0.02, 95% CI -0.07 to 0.03; P = 0.57; 3 trials; 658 participants), for weight for height/length Z-scores (-0.01, 95% CI -0.28 to 0.26; P = 0.94; 2 trials; 683 participants), or for height/length for age Z-scores (-0.03, 95% CI -0.24 to 0.18; P = 0.93; 2 trials; 385 participants).

Stunting and wasting

No studies reported data on stunting and wasting.

Nutrient adequacy

We intended to evaluate nutrient adequacy relative to estimated average requirements or adequate intakes; as defined by trialists for iron, zinc, vitamin A, or any other micronutrient investigated by trialists. Only one study reported on nutrient adequacy (Lartey 1999), although for the three non-fortified groups of this study (cereal legume blend, cereal legume blend plus fish powder, fermented maize dough plus fish powder) only summary results were reported for the entire study population: the total zinc intake from all complementary foods in this three groups combined was 81% of the recommended amount (2.8 mg/d; reference: (70)), whereas the fortified cereal-legume blend group consumed an average of 281% of the recommended intake. In the same study total vitamin A intake (from breast milk and other foods) between 6 and 10 mo of age by infants in the three non-fortified groups combined was 50–70% of the recommended 350 mg/d (reference: (71)). By contrast, children in the fortified cereal-legume blend group consumed 2–3 times the recommended intake as a result of fortification.

Nutrient excess

Nutrient intakes above the tolerable upper intake level (UL), as defined by trialists were described in none of the included studies.

Anaemia (as defined by trialists)

Six studies (1205 children) evaluated this outcome (Arcanjo 2012; Arcanjo 2013; Bagni 2009; Ekoe 2020; Lartey 2000; Ma 2016). Children receiving fortified complementary food products were significantly less likely to have anaemia at follow-up than children receiving a non-fortified version of the same complementary food product (risk ratio (RR) 0.57, 95% confidence interval (CI) 0.39 to 0.82; P = 0.003; 6 trials; 1209 participants; moderate-certainty evidence; **Analysis 1.1**).

This favourable effect on anaemia prevalence was seen in the subgroup of children aged 12 to 23 months (risk ratio (RR) 0.43, 95% confidence interval (CI) 0.19 to 0.99; P = 0.05; 2 trials; 330 participants

Analysis 1.2), but no statistically significant difference was present between groups in children aged 6 to 11 months (RR 0.65, 95% CI 0.32 to 1.35; P = 0.11; 2 trials; 368 participants) and in the group of children with mean age >23 months (RR 0.48, 95% CI 0.19 to 1.18; P = 0.13; 2 trials; 507 participants). Children receiving wheat and rice-based complementary food products fortified with iron or a combination of iron, zinc and vitamin B₁₂ were less likely to have anaemia, while this favourable effect on anaemia prevalence was not seen in one small study (with 95 participants) where cereal-legume blend was fortified with multivitamins and minerals (**Analysis 1.3-1.4**).

The favourable effects on post-intervention anaemia prevalence did not vary among subgroups by duration of the intervention (**Analysis 1.5**), and were seen independently from anaemia status at the start of the intervention (**Analysis 1.6**) and from the income classification of the country where the study was performed (**Analysis 1.7**). The effect was seen in the noncommercially, but not in the commercially funded studies (**Analysis 1.8**).

Iron deficiency (as defined by trialsists, not prespecified outcome)

Three studies with 571 participating children assessed iron deficiency at follow-up after an intervention with iron-containing fortified food (Eko 2020; Lartey 2000; Ma 2016). All of these studies defined iron deficiency as ferritin concentrations less than 12 ug/L. These studies found that children consuming iron-fortified complementary food were significantly less likely to have iron deficiency at follow-up than children consuming an unfortified version of the same complementary food (RR 0.39, 95% CI 0.21 to 0.75; P = 0.004; moderate-certainty evidence; **Analysis 1.56**).

Haemoglobin concentration (measured as g/L)

Eleven studies evaluated this outcome (Arcanjo 2012; Arcanjo 2013; Bagni 2009; Eko 2020; Faber 2005; Lartey 2000; Liu 1993; Ma 2016; Nesamvuni 2005; Quintero 2011; Schumann 2005). Compared to children receiving a non-fortified complementary food product, children consuming fortified complementary food had higher haemoglobin concentration at follow-up (MD 3.44 g/L, 95% CI 1.33 to 5.55; P = 0.001; 11 trials; 2175 participants; moderate-certainty evidence; Analysis 1.9).

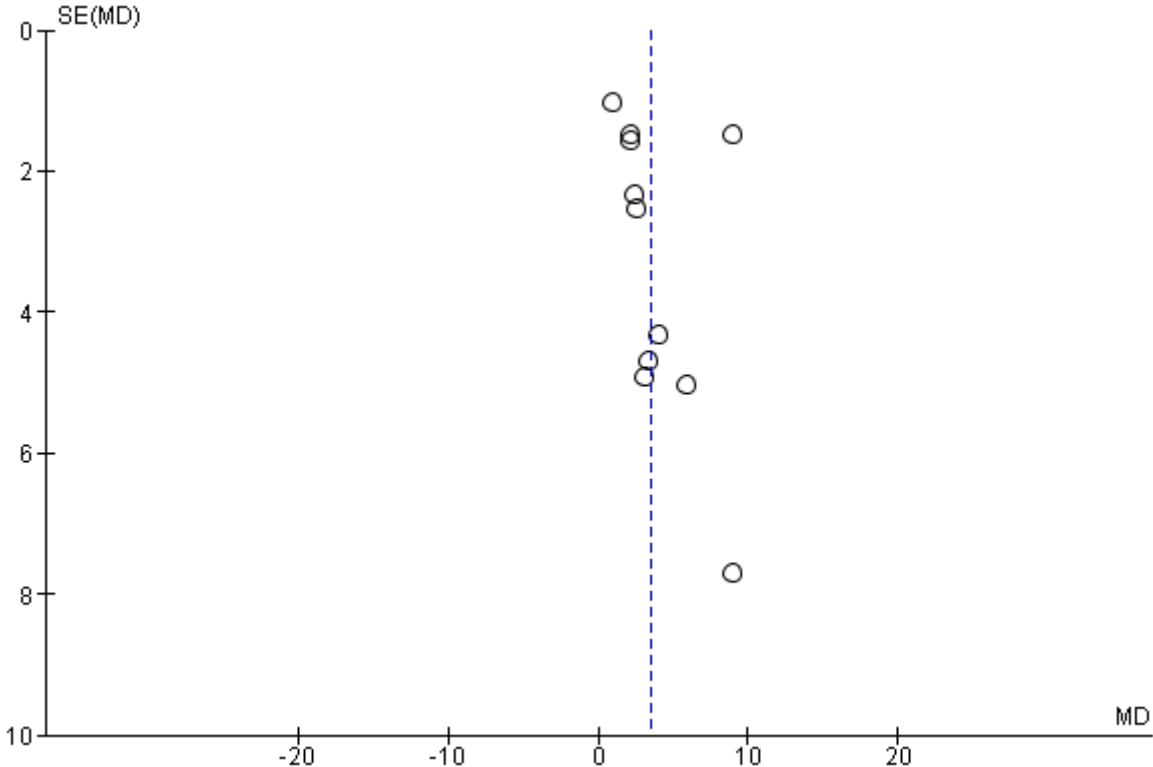
The intervention was effective in children aged 6 to 11 months (MD 4.37 g/L, 95% CI 0.39 to 8.35; P = 0.03; 4 trials; 816 participants; **Analysis 1.10**), but no significant difference in haemoglobin concentrations were seen at follow-up in the age group of 12 to 23 months' children (MD 1.48 g/L, 95% CI -0.34 to 3.29; P = 0.11; 5 trials; 852 participants), neither in studies including children both younger and older than two years of age (MD 2.60 g/L, 95% CI -1.51 to 6.71; P = 0.22; 2 trials; 307 participants). We saw significant improvement in haemoglobin concentration when complementary foods were fortified with iron only (MD 2.89 g/L, 95% CI 0.01 to 5.77; P = 0.05; 5 trials; 928 participants). There was no significant variation in the mean effects when studies with different types of products

fortified (Analysis 1.12) were compared. Effect on haemoglobin concentration was independent from intervention duration (Analysis 1.13). In two studies including slightly anaemic children no effect on haemoglobin concentrations was seen (MD 2.69 g/L, 95% CI -1.69 to 7.07; P = 0.23; 2 trials; 244 participants; Analysis 1.14). The intervention was shown to be effective in studies conducted in upper middle-income countries, while in lower middle-income countries haemoglobin concentrations tended to be higher, without a statistically significant difference between groups (**Analysis 1.15**). The intervention was shown to be effective in studies funded by a noncommercial organisation, and tended to be effective in studies funded by the industry (**Analysis 1.16**).

The beneficial effect of fortified complementary food on haemoglobin concentration was not significant any more, when removing all the cluster-randomised trials from the meta-analysis as part of a sensitivity analysis (MD 4.48 g/L, 95% CI -0.10 to 9.05; P = 0.06; 5 trials; 903 participants)

As 11 trials were included in the meta-analysis, we investigated the relationship between effect size and standard error by drawing a funnel plot (Figure 4), and we found no evidence of reporting bias (Egger’s test p = 0.3663).

Figure 4. **Funnel plot of comparison: Fortified versus non fortified complementary food; outcome: Haemoglobin (g/L)**



Iron status (as defined by trialists)

Seven studies (1047 children) provided information on ferritin concentration (Ekoe 2000; Faber 2005; Lartey 2000; Liu 1993; Ma 2016; Palmer 2021; Schumann 2005). In six of these studies the fortified product contained iron; these studies were included in the meta-analyses on ferritin. Daily dose of iron added to the complementary food products via fortification varied among studies, with a daily amount of 0.36 mg (Ma 2016), 2.5 mg (Ekoe 2020), 3.66 mg (Faber 2005), 4.6 mg (Schumann 2005) 4.93 mg (Liu 1993) of elemental iron consumed, or with >10.9 mg/day or <21.9 mg/day (Lartey 2000).

Children receiving fortified complementary foods had on average higher ferritin concentrations at follow-up than children consuming non-fortified complementary food (MD 0.43 µg/L on log scale, 95% CI 0.14 to 0.72; P = 0.003; 6 trials; 903 participants; low-certainty evidence; **Analysis 1.42**).

Subgroup analyses indicated that the intervention appeared to be effective in children aged 6 to 11 months, while there was only one study conducted in children aged 12 to 23 months, with a total number of 153 participants, which showed no significant difference between groups (**Analysis 1.42**).

Intervention was shown to be effective, when fortification was done with iron alone (**Analysis 1.43**).

Subgroup analysis based on types of products fortified indicated effects for maize/corn-based complementary food products, but not for wheat-, or rice-based food products, for fortified cereal-legume blends or fortified legumes (**Analysis 1.44**). Consumption of fortified complementary food appeared to be effective in increasing ferritin concentrations in populations with different anaemia status at baseline (**Analysis 1.46**), independently from the duration of the intervention being more or less than 6 months (**Analysis 1.45**), in both upper and lower middle-income countries (**Analysis 1.47**), and independently from the fact whether the study was commercially or noncommercially funded (**Analysis 1.48**).

The significant beneficial effects were still seen, when removing the three cluster-randomised trials from the meta-analysis as part of a sensitivity analysis (MD 0.64 µg/L on log scale, 95% CI 0.23 to 1.05; P = 0.002; 3 trials; 423 participants).

There was one study where complementary food was supplemented with retinyl palmitate (Palmer 2021); this intervention did not increase ferritin levels (MD -0.13 µg/L on log scale, 95% CI -0.45 to 0.15; 1 trial; 144 participants).

One study investigated body iron (Ma 2016) and described iron, zinc and vitamin B₁₂-fortified rice cereal to be effective in increasing body iron in 6-month-old children (MD 1.47 µg/L on log scale, 95% CI 0.63 to 2.31; 1 trial; 201 participants; low-certainty evidence; **Analysis 1.49**).

One further study investigated iron status as free erythrocyte porphyrin (Liu 1993) and found no effects of an iron, zinc, and calcium-containing rusk on free erythrocyte porphyrin levels (MD 30.0 µg/L, 95% CI -26.06 to 86.06; 1 trial; 147 participants; very-low-certainty evidence; **Analysis 1.50**).

Serum zinc concentration (g/dL)

Two studies with a total of 333 children reported on serum zinc concentration after consuming a complementary food fortified with zinc and other micronutrients (Lartey 2000; Faber 2005). Studies provided <10.26 mg/day and 6 mg/day daily doses of zinc, respectively. The percent of children with low serum zinc values (cut-off values defined as serum zinc <10.7 µmol/L in Lartey 2000 and <9.9 µmol/L in Faber 2005) at baseline was 3.6% and 43-48%, respectively. These studies found no effect of the provision of a zinc-fortified complementary food on children's serum zinc concentrations (MD - 0.13 g/dL, 95% CI -0.82 to 0.56; 2 trials; 333 participants; low-certainty evidence; **Analysis 1.52**).

Zinc deficiency (as dichotomous outcome, not prespecified)

One study investigated the number of children with values of serum zinc below a given cutoff at follow-up, in 61 children (Lartey 2000). In this study, zinc values <10.7 µmol/L were defined as low. Prevalence of children with low zinc values decreased from 6.5 to 3.2% in the unfortified, and increased from 3.3 to 10.0% in the fortified groups (**Analysis 1.58**).

Serum retinol concentration (µmol/L)

Five trials with 475 children reported on serum retinol concentrations (Faber 2005; Lartey 2000; Liu 1993; Nesamvuni 2005; Palmer 2021). The percentage of children with serum retinol concentrations less than 0.7 µmol/L at baseline were 17-19% (Faber 2005), 21.6-34.5% (Lartey 2000), 0-7% (Nesamvuni 2005), 19.6-34.5% (Palmer 2021), and not reported for one study (Liu 1993). Overall, the provision of fortified complementary food as compared to non-fortified complementary food products had no effects on serum retinol concentrations (MD 0.03 µmol/L, 95% CI -0.02 to 0.08; 5 trials; 475 participants; moderate-certainty evidence; **Analysis 1.51**).

Vitamin A deficiency (as dichotomous outcome, not prespecified)

Three trials reported on vitamin A deficiency at follow-up. All these trials defined vitamin A deficiency as serum retinol concentrations less than 0.70 µmol/L. The percentage of children with marginal vitamin A deficiency (defined as serum retinol 0.35 – 0.7 µmol/L by trialists) remained unchanged in both groups in one study providing vitamin A fortified maize meal to children for 12 months (Nesamvuni 2005). In another study providing daily >560 RE or <1100 RE vitamin A for 6 months to children, the prevalence of low plasma retinol concentrations decreased from 34.5 to 10.4% in the fortified group, but increased from 21.6 to 27.0% in the unfortified group (Lartey 1999). The third study compared fortification with retinyl palmitate, biofortification and unfortified maize; the prevalence of

children with low plasma retinol increased in all three groups (from 21.2 to 26.9% in the retinyl palmitate-fortified, from 19.6 to 29.4% in the biofortified, and from 31.0 to 34.5% in the unfortified maize group) (Palmer 2021). Overall, these studies found no differences in the likelihood of children consuming iron-fortified complementary as compared to those consuming an unfortified version of the same complementary food to have vitamin A deficiency at follow-up (RR 0.97, 95% CI 0.24 to 3.90; P = 0.97; very low certainty evidence; **Analysis 1.57**).

Additional Outcomes

All-cause mortality

No studies reported data on all-cause mortality.

Adverse effects (any)

In one study authors reported, that fortified complementary foods “were well tolerated and no side effects were reported in either group” (Ekoe 2020).

Mental and motor skill development

Mental skill development was assessed in two studies, the one measuring it on the first version (Quintero 2011), the other on the third version (Ma 2016) of the Bayley child development scale (BSID). Overall, children consuming fortified complementary food had higher scores than children consuming the unfortified version of the same complementary food (MD 0.80, 95% CI 0.12 to 1.48; 2 trials; 308 participants; moderate-certainty evidence; **Analysis 1.54**).

Motor skill development was reported as fine motor and gross motor score (measured on BSID III) in one study (Ma 2016), as psychomotor score (measure on BSID I) in one study (Quintero 2011) and 25-item motor development score (Bayley II) in one study (Faber 2005). Psychomotor development was improved in children consuming fortified complementary food (MD 1.13, 95% CI 0.35 to 1.91; 2 trials; 661 participants; low-certainty evidence; **Analysis 1.55**). This effect was not seen in the one study investigating fine and gross motor scales separately (**Analysis 1.55**).

Morbidity

One trial with 97 children reported on morbidity (Lartey 2000), as number of new episodes/ 100 days at risk. Number of diarrhoeas, acute respiratory tract disease, and fever disease episodes did not differ

between children consuming fortified and unfortified complementary food (very-low-certainty evidence; **Analysis 1.53**).

Gut microbiota composition

No studies reported data on gut microbiota composition.

Taste preference

Acceptability of fortified as compared to unfortified complementary food was measured in three acute studies (Bovell-Benjamin 1999; Gannon 2019; Huey 2018) with a total of 215 children. All studies evaluated acceptance on a 9-point hedonic scale (answers of toddler interpreted by mothers), a higher score representing better acceptance. Degree of liking did not differ significantly in any of these studies between fortified and unfortified groups.

Displacement of other foods

No studies reported data on this outcome.

DISCUSSION

Summary of main results

This review includes 16 studies with a total of 5089 participants, comparing the consumption of fortified complementary food with the consumption of an unfortified version of the same complementary product. There was only one trial with an overall low risk of bias, we judged all other trials to have unclear or high risk of bias in one or more 'Risk of bias' domains. Overall, 12 studies contribute data to the quantitative syntheses.

Results show that providing fortified complementary food to children aged 6 to 23 months at the start of the intervention reduced anaemia by 43%, and those who received fortified complementary food compared to those who did not had significantly higher haemoglobin concentrations and significantly higher ferritin concentrations. The intervention led to no effects on zinc status, and vitamin A status. Children consuming the fortified as compared to those consuming the unfortified complementary food had significantly better mental skill development scores, and total psychomotor development scores, but no significant differences were seen when fine and gross motor scores were assessed separately.

Overall completeness and applicability of evidence

This review summarises findings from 16 studies. The studies were published between the years 1977 and 2020. Most of the studies were conducted in upper- or lower middle-income countries, and in malaria-endemic regions. Both the foods fortified and the micronutrients used for fortification were diverse; most of the studies providing iron either alone or in combination with other micronutrients. Most studies used low-dose iron for fortification, though, a low number of studies used high-dose (>12.5 mg). Foods fortified included mainly cereals (wheat-, maize/corn-, rice, and millet-based complementary food products), there were only two studies with cereal-legume blends and one study with fortified legumes.

There were five studies where fortification was done in 6 to 11-month-old children. Further seven studies included children aged 12-23 months and one in 6 to 23-month-old children. In three studies the age range was broader and children aged 6 to 60 months were included.

The findings of this review are generalisable to apparently healthy and non-hospitalised children in LMIC settings in Asia and Africa, although some children may be at risk of having highly prevalent diseases such as malaria, diarrhoea or even malnutrition. Although complementary food fortification might have implications also for children in developed countries, studies investigating the effects of

this intervention in high-income countries are lacking. Use of fortified complementary food in the studies included in this review is limited for preventive purposes, and hence this review does not evaluate their effectiveness in treating any form of malnutrition.

Certainty of the evidence

After evaluating available evidence using GRADE, we judged the evidence to be of moderate-certainty for the outcomes anaemia, haemoglobin concentration, weight-for-age (z scores), weight-for-length (z scores), serum retinol, mental skill development, and motor skill development measured on Baley scale. We judged the outcomes length-for-age (z scores), ferritin concentrations, body iron, serum zinc, fine motor scores and gross motor scores to be of low certainty, and the outcomes free erythrocyte porphyrin, diarrhoea, acute respiratory tract diseases, and fever diseases of very low certainty.

The evidence was downgraded due to design limitations (risk of bias) with at least one level in case of all outcomes, for inconsistency in case of the outcomes length-for-age (z scores) and ferritin levels, for imprecision with at least one level in case of the outcomes body iron, free erythrocyte porphyrin, serum zinc, morbidity, fine motor score and gross motor score.

Potential biases in the review process

The search for trials in this area was performed using a broad search strategy, by searching in both electronic databases and trials registries, without applying restrictions, such as based on language. It is unlikely that trials that have been conducted and published have been missed; however, unpublished trials, or ongoing trials not registered in clinical trials registries could be missing.

We aimed to reduce bias wherever possible by having at least two review authors work independently on trial selection, data extraction, and 'Risk of bias' and GRADE assessments.

We were able to explore the potential for publication bias using funnel plots only for the outcome haemoglobin concentration, as other outcomes were investigated in less than 10 trials.

Agreement and disagreements with other studies or reviews

To our knowledge this is the first systematic review summarising evidence on the consumption of fortified complementary food as compared to the unfortified version of the same complementary food in 6 to 23-months-old children.

Health effect of centrally-processed micronutrient-fortified food products were already assessed in children aged 6 month to 5 years (72) and in 5 to 15 years (73) by Eichler et al; these systematic reviews included both fortified dairy products and fortified cereals. In our systematic review milk, formula, and fortified milk-based products were excluded.

A broadly focused systematic review assessed the effects of all types of interventions, which might have an effect on the development of children aged 6 months to 2 years, including also micronutrient-fortified complementary foods (both central and home fortification was eligible to be included) (21). Health effects of fortification of foods with multiple micronutrient powders at home (at point-of-use) was assessed in a recent systematic review, where, similar to our review, the authors included children aged 6 to 23 (49).

The above-mentioned systematic reviews all concluded, that fortification of food products with micronutrients is an effective tool to reduce anaemia in children in the complementary feeding period in developing countries. However, the literature is sparse to draw firm conclusions for functional health outcomes. These conclusions are in line with our findings.

CONCLUSIONS

Implications for practice

Use of centrally fortified complementary foods is probably an effective intervention to reduce anaemia in infants and young children aged 6 months to two years in malaria-endemic regions, therefore this intervention can be integrated into strategies to prevent anaemia in this age group. The currently available evidence showed, based on results from two studies, that consumption of fortified complementary foods likely results in a slight increase of mental and motor scores. Most of the available studies contained a daily dose of iron less than 12.5 mg. Effects of food fortification on nutrition adequacy or nutrition excess for iron was assessed in none of the studies.

Fortification with the applied micronutrient composition and doses probably makes little or no difference to growth outcomes. There seems to be no significant difference in the acceptability of fortified and unfortified food products among children aged 6 to 23 months.

Currently available evidence does not show the intervention to be effective in improving zinc and vitamin A status; while there is no available evidence on further vitamins and minerals.

Implications for research

It has to be further explored, whether consumption of fortified complementary foods

1. has an effect on all-cause mortality
2. has any adverse effects
3. can lead to adequate or excess nutrient intakes (and at what level of fortification)
4. have an effect on stunting or wasting
5. can influence vitamin and mineral status (other than iron)
6. and under what circumstances can influence mental and motor skill development
7. can influence microbiota composition
8. has an effect on taste preference
9. can lead to displacement of other foods.

Studies with both higher and lower nutrient content has to be conducted, so that dose-response effects can be determined. Effects of complementary food fortification should be further investigated in developing countries, but should be also assessed in high-income countries, and in regions where malaria is not endemic. Planned randomised controlled trials should be conducted with rigorous methodology and with large sample sizes.

APPENDICES

Appendix 1. Search strategies

Medline (Ovid)

1. Food, Fortified/
2. ((complement* or supplement* or fortif* or enrich*) adj3 (food* or feed* or nutri*)).tw.
3. ((fortif* or enrich*) adj3 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*)).tw.
4. ((fortif* or enrich*) adj3 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*)).tw.
5. or/1-4
6. exp Infant/
7. (baby or babies or infant* or toddler* or child or children* or kid or kids).tw.
8. or/6-7
9. 5 and 8
10. randomized controlled trial.pt.
11. controlled clinical trial.pt.
12. randomized.ab.
13. placebo.ab.
14. clinical trials as topic.sh.
15. randomly.ab.
16. trial.ti.
17. or/10-16
18. exp animals/ not humans.sh.
19. 17 not 18
20. 9 and 19
21. remove dupliates from 20

Cochrane Central Register of Controlled Trials (Cochrane Register of Studies Online)

1. MESH DESCRIPTOR Food, Fortified
2. ((complement* or supplement* or fortif* or enrich*) ADJ4 (food* or feed* or nutri*)):TI,AB,KY

3. ((fortif* or enrich*) ADJ4 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*)):TI,AB,KY
4. ((fortif* or enrich*) ADJ4 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*)):TI,AB,KY
5. #1 OR #2 OR #3 OR #4
6. MESH DESCRIPTOR Infant EXPLODE ALL TREES
7. (baby or babies or infant* or toddler* or child or children* or kid or kids):TI,AB,KY
8. #6 OR #7
9. #5 AND #8

CINAHL (EbscoHost)

1. MH "Food, Fortified"
2. TI ((complement* or supplement* or fortif* or enrich*) N3 (food* or feed* or nutri*)) OR AB ((complement* or supplement* or fortif* or enrich*) N3 (food* or feed* or nutri*))
3. TI ((fortif* or enrich*) N4 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*)) OR AB ((fortif* or enrich*) N4 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*))
4. TI ((fortif* or enrich*) N4 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*)) OR AB ((fortif* or enrich*) N4 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*))
5. S1 OR S2 OR S3 OR S4
6. MH "Infant+"
7. TI (baby or babies or infant* or toddler* or child or children* or kid or kids) OR AB (baby or babies or infant* or toddler* or child or children* or kid or kids)
8. S6 OR S7
9. S5 AND S8
10. MH "treatment outcomes+" OR MH "experimental studies+" or random*
11. S9 AND S10

Web of Science (Science Citation Index Expanded and Emerging Sources Citation Index)

1. TI=((complement* or supplement* or fortif* or enrich*) NEAR/3 (food* or feed* or nutri*)) OR AB=((complement* or supplement* or fortif* or enrich*) NEAR/3 (food* or feed* or nutri*))

2. TI=((fortif* or enrich*) NEAR/4 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*)) OR AB=((fortif* or enrich*) NEAR/4 (cereal* or porridg* or maize or grain* or rice or wheat or corn or millet or cowpea* or soy or peanut* or pasta* or noodle* or bread* or bakery or rusk* or biscuit* or cake* or puree* or sauce* or snack* or drink* or juice*))
3. TI=((fortif* or enrich*) NEAR/3 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*)) OR AB=((fortif* or enrich*) NEAR/3 (vitamin* or multivitamin* or mineral* or micronutrient* or multimicronutrient* or nutri*))
4. #1 OR #2 OR #3
5. TI=(baby or babies or infant* or toddler* or child or children* or kid or kids) OR AB=(baby or babies or infant* or toddler* or child or children* or kid or kids)
6. #4 AND #5
7. TI=(random* OR placebo OR trial OR groups) OR AB=(random* OR placebo OR trial OR groups)
8. #6 AND #7, Indexes=SCI-EXPANDED, ESCI Timespan=All years

Embase

- #1. 'fortified food'/exp
- #2. ((complement* OR supplement* OR fortif* OR enrich*) NEAR/3 (food* OR feed* OR nutri*)):ti,ab
- #3. ((fortif* OR enrich*) NEAR/3 (cereal* OR porridg* OR maize OR grain* OR rice OR wheat OR corn OR millet OR cowpea* OR soy OR peanut* OR pasta* OR noodle* OR bread* OR bakery OR rusk* OR biscuit* OR cake* OR puree* OR sauce* OR snack* OR drink* OR juice*)):ti,ab
- #4. ((fortif* OR enrich*) NEAR/3 (vitamin* OR multivitamin* OR mineral* OR micronutrient* OR multimicronutrient* OR nutri*)):ti,ab
- #5. #1 OR #2 OR #3 OR #4
- #6. 'infant'/exp
- #7. baby:ti,ab OR babies:ti,ab OR infant*:ti,ab OR toddler*:ti,ab OR child:ti,ab OR children*:ti,ab OR kid:ti,ab OR kids:ti,ab
- #8. #6 OR #7
- #9. #5 AND #8
- #10. 'randomized controlled trial'/exp
- #11. 'double blind procedure'/exp
- #12. 'crossover procedure'/exp
- #13. 'parallel design'/exp
- #14. 'single blind procedure'/exp
- #15. random*:ti,ab
- #16. doubl* NEAR/1 blind*
- #17. singl* NEAR/1 blind*

#18. assign*:ti,ab

#19. allocat*:ti,ab

#20. volunteer*:ti,ab

#21. placebo*:ti,ab

#22. factorial*:ti,ab

#23. crossover*:ti,ab

#24. 'cross over':ti,ab

#25. #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23
OR #24

#26. #9 AND #25

Global Index Medicus (WHO)

((complement* OR supplement* OR fortif* OR enrich*) AND (food* OR feed* OR nutri*)) OR ((fortif* or
enrich*) AND (cereal* OR porridg* OR maize OR grain* OR rice OR wheat OR corn OR millet OR cowpea* OR
soy OR peanut* OR pasta* OR noodle* OR bread* OR bakery OR rusk* OR biscuit* OR cake* OR puree* OR
sauce* OR snack* OR drink* OR juice*)) OR ((fortif* or enrich*) AND (vitamin* OR multivitamin* OR mineral*
OR micronutrient* OR multimicronutrient* OR nutri*)) AND (baby OR babies OR infant* OR toddler* OR child
OR children* OR kid OR kids) AND (random* OR placebo OR trial OR groups)

ICTRP (Standard search)

fortif* AND infant* OR

fortif* AND child* OR

fortif* AND bab* OR

food* AND complement* AND infant* OR

food* AND complement* AND child* OR

food* AND complement* AND bab* OR

food* AND enrich* AND infant* OR

food* AND enrich* AND child* OR

food* AND enrich* AND bab* OR

feed* AND complement* AND infant* OR

feed* AND complement* AND child* OR

feed* AND complement* AND bab* OR

feed* AND enrich* AND infant* OR

feed* AND enrich* AND child* OR

feed* AND enrich* AND bab*

ClinicalTrials.gov (Expert search)

((fortified OR fortification OR fortificant OR enriched) AND (food OR foods OR feeding OR cereal OR cereals OR porridge OR porridges OR maize OR corn OR wheat OR rusk OR drink OR vitamin OR vitamins OR multivitamin OR multivitamins OR mineral OR micronutrient OR micronutrients OR nutrient OR nutrients OR nutrition)) OR "complementary food" OR "complementary foods" OR "food complement" OR "complementary feeding" OR "micronutrient fortified" OR "vitamin fortified" OR "supplemented food" OR "supplemented foods") AND (baby OR babies OR infant OR infants OR toddler OR toddlers OR child OR children OR kid OR kids)

Appendix 2. Characteristics of included studies

Study (Covidence identifier)	Palmer 2021 (#4720) (74, 75)
Methods	Study design: parallel randomized control trial Unit of randomisation: individual Blinding: blinding (colour-coded containers) not mentioned single-blind or double blind Number of study arms: 3 arms
Participants	Location/Setting: Mkushi District in the Central Province of Zambia Country where trial was performed: Zambia Sample size: 255 Dropouts/withdrawals: Lost to follow up: 18 (refused), 7 (moved), and incomplete biospecimen: 69 infants Sex: both male and female Inclusion criteria: Infants: <ul style="list-style-type: none"> • healthy • singleton infants • hemoglobin concentration ≥ 7.0 g/dL • received a vitamin A capsule (105 μmol) at 6mo of age Mothers: <ul style="list-style-type: none"> • age 18-45 years • Hemoglobin concentration ≥ 8.0 g/dL • free from chronic health conditions (i.e., any issue requiring regular medical visits) • breastfeeding and planning to continue through ≥ 12 mo postpartum • not currently pregnant • not planning to relocate Exclusion criteria: Infant(s): <ul style="list-style-type: none"> • not receiving the 105 μmol dose of vitamin A at ~ 6 months • or intent to move from the study area Mother(s): <ul style="list-style-type: none"> • pregnancy • not currently breastfeeding or planning to cease breastfeeding prior to the infant's first birthday Both (Mother/infants pairs): <ul style="list-style-type: none"> • chronic health condition in the mother or infant • severe anemia in the mother (Hb < 8.0 g/dL) or infant (Hb < 7.0 g/dL) Health status: healthy infants Ongoing treatment: no treatment Anaemic status: mixed (Defined as hemoglobin < 12 g/dL for women and < 10 g/dL for infants) Age range at start of intervention: 9-12 months

	Mean age: no data
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> retinyl palmitate–fortified white maize (FM) (n=85); serving size (287 g dry weight/d for women; 50 g dry weight for infants; 2 meals/day, for 6d/wk for 90 d biofortified orange maize (BM) (n=85); serving size (287 g dry weight/d for women; 50 g dry weight for infants; 2 meals/day, for 6d/wk for 90 d) <p>Comparator(s):</p> <ul style="list-style-type: none"> conventional low-carotenoid white maize (CM) (n=85); serving size (287 g dry weight/d for women; 50 g dry weight for infants; 2 meals/day, for 6d/wk for 90 d) white maizes (for the WM and FM) purchased from the same harvest season <p>Duration of intervention: 90-d Duration of follow-up: 90 days Run-in period: – Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: plasma retinol, total body stores (TBS), liver retinol concentration, weight for age Z-scores (WAZ), Height/length for age Z-scores (HAZ), Stunting, Anaemia, Haemoglobin concentration</p> <p>Primary outcomes: Total body vitamin A stores of infants measured by retinol isotope dilution</p> <p>Secondary outcomes: Breast milk retinol concentrations of women measured by high performance liquid chromatography Plasma retinol concentrations of women measured by high performance liquid chromatography Pupillary responsiveness of women measured by portable field dark adaptometer</p> <p>Timing of outcome assessment: baseline and endline</p>
Identification	<p>Trial identifier: NCT02804490 Trial terminated early: no</p>
Publication details	<p>Language of publication: English Funding: HarvestPlus (www.HarvestPlus.org). In-kind support was provided by DSM Nutritional Products, Inc. (fortificant) and Bioanalyt GmbH (iCheck Fluoro and consumables). Additional funding was provided by the Sight and Life Global Nutrition Research Institute at Johns Hopkins University, with support from the Christian Blind Mission. Conflict of interest: „The authors report no conflicts of interest” Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “To determine whether biofortified or industrially fortified maize consumption by Zambian women and their breastfeeding infants could improve milk retinol concentration and infant TBS.”</p>
Note	<p>Study start date: March 2016 Study end date: June, 2017</p>

Study (Covidence identifier)	Ekoe 2020 (76, 77) (# 5741)
Methods	Study design: cluster randomised trial Unit of randomisation: cluster (30 villages) Blinding: double-blind Number of study arms: 2 arms
Participants	Location/Setting: Salapoumbé Country where trial was performed: (East) Cameroon Sample size: 205 Dropouts/withdrawals: 52 (14 moved away, 13 absent, 25 refused blood collection) Sex: both male and female children included Inclusion criteria: <ul style="list-style-type: none"> • Apparent good health • 18 to 59 months • Haemoglobin rate ranging 7 to 11 g/dl Exclusion criteria: <ul style="list-style-type: none"> • iron supplementation in progress • Clinical presentation of severe malnutrition (e.g., bilateral pitting oedema) • Diagnosis of any chronic infection (tuberculosis, HIV); • Severe acute infection (e.g., severe malaria, pneumonia, meningitis); • Blood transfusion < 3 months prior to enrollment; • Allergy/intolerance to the cow's milk and/or to the gluten Health status: „apparent good health” Ongoing treatment: no data Anaemic status: anaemic („anemic (hemoglobin 7–11 g/dl) but otherwise healthy children”) Age range at start of intervention: 18 to 59 months Mean age: Age (months) Iron-fortified IC group (N = 106): 32.1 ± 10.9; Age (months) Control IC group (N = 99): 36.1 ± 10.8
Interventions	Intervention(s): <ul style="list-style-type: none"> • Iron fortified infant cereal (IC): two 50 g servings/day IC with 7.5 mg of ferrous fumarate providing 3.75 mg iron/serving; (n = 106) Comparator(s): <ul style="list-style-type: none"> • Control IC: infant cereal two 50 g servings/day IC Control IC group (N = 99) Duration of intervention: 6 months Duration of follow-up: 6 months Run-in period: no Number of study centres: 1
Outcomes	Reported outcomes in full text of publication:

	<p>Haemoglobin rate/level, Se ferritin, Se iron, CRP, transferrin, frequencies of anaemia, nutrition status, iron deficiency, iron deficiency anaemia, weight, height, weight-for-age z-scores, height-for-age, weight-for-height z-score</p> <p>Primary outcomes: seven parameters: hemoglobin, serum ferritin adjusted to CRP, serum iron, transferrin saturation, prevalence of anemia, iron deficiency, iron deficiency anemia.</p> <p>Secondary outcomes: changes in weight, height, and other anthropometric z-scores</p> <p>Timing of outcome assessment: baseline, 3 months, 6 months</p>
Identification	<p>Trial identifier: PACTR201802003069111</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: Nestlé Nutrition Institute of Africa; Helen Keller Foundation for Research and Education; Cameroon Ministry of Public Health; UNICEF; National Statistics Institute</p> <p>Conflict of interest: „NPH is employed by Société des Produits Nestlé SA. No other author has any conflict of interest to report”</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “To evaluate the efficacy of iron fortified wheat flour for the correction and the prevention of iron deficiency anaemia among 18-59 months old children in Salapoumbé in Cameroon.”</p>
Note	<p>Study start date: February 2017</p> <p>Study end date: August 2017</p>

Study (Covidence identifier)	<p>Gannon 2019 (78) (#6180)</p>
Methods	<p>Study design: cross-over randomised controlled trial</p> <p>Unit of randomisation: individual (mother infant pairs)</p> <p>Blinding: no data</p> <p>Number of study arms: 2 arms</p>
Participants	<p>Location/Setting: „near Madanapalle, Andhra Pradesh”</p> <p>Country where trial was performed: India</p> <p>Sample size: 52 children-mother pairs</p> <p>Dropouts/withdrawals: „Twelve participant pairs attended for less than 6 days. Of the remaining, median (Q1, Q3) daily attendance compliance was 62.8% (44.1%, 83.5%).”</p> <p>Sex: both male and female children included</p> <p>Inclusion criteria: age: 6- to 24-months old</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • dietary allergies • currently diagnosed with malaria or dengue • ever diagnosed with HIV or tuberculosis, or severe malnutrition (ie, weight-for-length Z-score [WLZ] < 3) determined using World Health Organization (WHO) field tables <p>Health status: no data</p>

	<p>Ongoing treatment: no data</p> <p>Anaemic status: no data</p> <p>Age range at start of intervention: 6-24 months</p> <p>Mean age: 14.3 (5.6) months</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> Multiple biofortified food crops, three times per day, six days per week, median daily intake was 75 g, (n = 52) <p>Comparator(s):</p> <ul style="list-style-type: none"> Commercially available non-fortified food crops, three times per day, six days per week, median daily intake was 75 g, (n = 52) <p>Duration of intervention: 3 days</p> <p>Duration of follow-up: 3 days</p> <p>Run-in period: –</p> <p>Number of study centres: 2 feeding centers</p>
Outcomes	<p>Reported outcomes in full text of publication: weight, stunting, wasting, acceptability</p> <p>Primary outcomes: not defined</p> <p>Secondary outcomes: –</p> <p>Timing of outcome assessment: after each feeding</p>
Identification	<p>Trial identifier: NCT02648893; IRB #: 1508005782</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: non-commercial (HarvestPlus, grant number #2015H8336 awarded to Cornell University)</p> <p>Conflict of interest: „The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/ or publication of this article: S.M. is an unpaid board member for a diagnostic startup focused on developing point-of-care assays for nutritional status informed by his research as a faculty member at Cornell University.”</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “To determine whether biofortified or industrially fortified maize consumption by Zambian women and their breastfeeding infants could improve milk retinol concentration and infant TBS.”</p>
Note	<p>this paper reports short-term results of a longer, ongoing study</p> <p>Study start date: December 2017</p> <p>Study end date: April 2018</p>

Study (Covidence identifier)	Huey 2018 (79) (#3636/1)
Methods	<p>Study design: cross-over, controlled clinical trial</p> <p>Unit of allocation: individual</p> <p>Blinding: no data</p> <p>Number of study arms: 2 arms</p>
Participants	<p>Location/Setting: a feeding center within a large slum known locally as Nehru Nagar, in Vile Parle, a suburb in Mumbai</p>

	<p>Country where trial was performed: India Sample size: 125 Dropouts/withdrawals: no information Sex: both male and female children included Inclusion criteria: – Exclusion criteria: – Age at the start of the intervention: 12-24 month Country where trial was performed: India</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> • FeZnPM (iron- and zinc-biofortified pearl millet); 18 types of different recipes (n = 125) <p>Comparator(s):</p> <ul style="list-style-type: none"> • CtrlPM (conventional pearl millet) (n = 125) <p>Duration of intervention: 3 days Duration of follow-up: 3 days Run-in period: yes, 3 days Number of study centres: 1 feeding center</p>
Outcomes	Reported outcomes in full text of publication: acceptability
Identification	Trial identifier: – Trial terminated early: no
Publication details	<p>Language of publication: English Funding: non-commercial (HarvestPlus; 2014H8302) Conflict of interest: „SM is an unpaid board member for a diagnostic start up focused on developing point-of-care assays for nutritional status informed by his research as a faculty member at Cornell University. All other authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest Publication status: full article in peer-reviewed journal</p>
Stated aim for study	Quote: “The main objective of this study was to formulate and test the acceptability (in terms of volume consumed and sensory characteristics) of new pearl millet-based palatable complementary food products for weaning infants. The food products with highest acceptability would be ideal candidates for a randomized controlled trial testing the efficacy of biofortified pearl millet for improving iron status in infants and young children”
Note	<p>This is an acute study. Based on the results a longer-term study is planned (Mehta 2017) Study start date: January 2015 Study end date: December 2015</p>

Study (Covidence identifier)	Ma 2016 (Sheng 2019; Krebs 2013) (80-83) (#3906)
Methods	Study design: cluster randomized, non-masked, controlled efficacy intervention trial (“this study was a cross-sectional sub-sample nested within a larger intervention”)

	<p>Unit of randomisation: cluster (60 villages clustered, 9 districts in Xichou County)</p> <p>Blinding: nonmasked</p> <p>Number of study arms: 3 arms</p>
Participants	<p>Location/Setting: Xichou county in Yunnan province</p> <p>Country where trial was performed: China</p> <p>Sample size: 1465 (954 allocated to the arms relevant to this systematic review)</p> <p>Dropouts/withdrawals:149 (123 moved away, 22 refused to participate, 2 died, 2 were visited out of the range of the scheduled age)</p> <p>Sex: both male and female children included</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • healthy singleton infants between 3–5 months of age • born between 37 to 42 weeks gestational age • born with birth weight >2 000 g • with no metabolic or physical problems • lack of acute or chronic illness • being exclusively breastfed <p>Exclusion criteria: –</p> <p>Health status: healthy infants</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: mixed</p> <p>Age range at start of intervention: 6 months</p> <p>Mean age: –</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> • fortified infant rice cereal (commercial infant rice cereals (Nestle), fortified with iron, zinc and vitamin B12); 20g/day (n=419) • red meat (50g/day) (n=461) <p>Comparator(s):</p> <ul style="list-style-type: none"> • local (83) infant rice cereal (from a mixture of glutinous rice flour, white granulated sugar and honey), 20g/day (n= 436) <p>Duration of intervention: 12 months</p> <p>Duration of follow-up: 12 months</p> <p>Run-in period: 1-3 months after enrolment (no intervention)</p> <p>Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: WAZ, LAZ, WLZ, serum B12, Hb, iron status, ferritin, B12 concentration, MCV, MCH, MCHC, cognitive score, fine motor score, gross motor score</p> <p>Primary outcomes: based on clinicaltrial.com: Linear Growth [Time Frame: 6-18 mos of age]</p> <p>Secondary outcomes: based on clinicaltrial.com: Morbidity [Time Frame: 6-18 mos of age] Cognitive development [Time Frame: 0-18 mo of age] Zn absorption [Time Frame: 9 and 18 mos of age]</p> <p>Timing of outcome assessment: 6, 12 and 18 months were measured antropometric data, venous blood samples and cognitive scale and the fine motor and gross motor substests were collected at the end of intervention.</p>
Identification	<p>Trial identifier: NCT0072610</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: non-commercial (National Natural Science Foundation of China and Thrasher Foundation)</p>

	<p>Conflict of interest: “The authors declare that they have no conflicts of interest”</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “Our objective was to compare iron status at 18 months and growth from 6 to 18 months in rural poor toddlers fed 3 different complementary foods.”</p>
Note	<p>Study start date: March 2009</p> <p>Study end date: December 2011</p>

Study (Covidence identifier)	Arcanjo, 2012 (84) (#2936)
Methods	<p>Study design: cluster-randomised trial</p> <p>Unit of randomisation: cluster (2 day-care centers)</p> <p>Blinding: double-blind, placebo-controlled</p> <p>Number of study arms: 2 arms</p>
Participants	<p>Location/Setting: City of Morrinhos—Ceara</p> <p>Country where trial was performed: Brazil</p> <p>Sample size: 216</p> <p>Dropouts/withdrawals: 10 (3 left center, 5 absentee, 2 non-compliant)</p> <p>Sex: both male and female children included</p> <ul style="list-style-type: none"> Center A: 60:40 (male:female) Center B: 54:44 (male:female) <p>Inclusion criteria:</p> <ul style="list-style-type: none"> age: 10-23 months <p>Exclusion criteria:</p> <ul style="list-style-type: none"> infants already taking iron supplements <p>Health status: no data</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: mixed (Anemia prevalence in the study population was estimated at 40%)</p> <p>Age range at start of intervention: 10-23 months</p> <p>Mean age:</p> <ul style="list-style-type: none"> Center A: 16.4 (4.77) Center B: 15.8 (4.27)
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> fortified rice (Ultrarice), containing 56.4 mg elemental iron (micronized ferric pyrophosphate/ 50 g portion (n=100)) <p>Comparator(s):</p> <ul style="list-style-type: none"> standard rice (n=98) <p>Duration of intervention: 18 weeks</p> <p>Duration of follow-up: 18 weeks</p> <p>Run-in period: no</p> <p>Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: Hb concentration, anaemia prevalence</p> <p>Primary outcomes: hemoglobin values (before and after intervention), anemia (Hb < 110 g/L)</p> <p>Secondary outcomes: –</p> <p>Timing of outcome assessment: before and after trail</p>

Identification	Trial identifier: – Trial terminated early: no
Publication details	Language of publication: English Funding: non-commercial (Santa Casa de Misericórdia de Sobral Hospital-Research Initiative Grant) Conflict of interest: no data Publication status: full article in peer-reviewed journal
Stated aim for study	Quote: “„to evaluate the impact of iron-fortified rice (Ultrarice) weekly on hemoglobin and anemia levels compared with standard rice (control)”
Note	Study start date: August 2010 Study end date: December 2010

Study (Covidence identifier)	Arcanjo 2013 (85) (#2937)
Methods	Study design: cluster-randomised, controlled trial Unit of randomisation: cluster (two day-care center) Blinding: no data Number of study arms: 2 arms
Participants	Location/Setting: City of Sobral Country where trial was performed: Brazil Sample size: 171 Dropouts/withdrawals: 7 (1 left center, 5 absentee, 1 non-compliant) Sex: both male and female children included <ul style="list-style-type: none"> Center A: 39:35 (male:female) Center B: 34:41 (male:female) Inclusion criteria: <ul style="list-style-type: none"> 10 to 23 months written parental consent Exclusion criteria: <ul style="list-style-type: none"> Infants' parents who refused to participate infants already using iron supplementation Health status: no data Ongoing treatment: no data Anaemic status: mixed Age range at start of intervention: 10-23 months Mean age: <ul style="list-style-type: none"> Center A: 17.8 (2.85) Center B (18.0 (2.97)
Interventions	Intervention(s): Center A: fortified rice (Ultrarice), containing 56.4 mg elemental iron (micronized ferric pyrophosphate/ 50 g portion (n =74 at baseline) once weekly Comparator(s): <ul style="list-style-type: none"> Center B: standard (household) rice (n =75 at baseline) Duration of intervention: 18 weeks Duration of follow-up: 18 weeks Run-in period: no Number of study centres: 1

Outcomes	Reported outcomes in full text of publication: hemoglobin values, anaemia prevalence (Hb < 110 g/L) Primary outcomes: hemoglobin values, anaemia prevalence (Hb < 110 g/L) Secondary outcomes: – Timing of outcome assessment: baseline and endpoint
Identification	Trial identifier: – Trial terminated early: no
Publication details	Language of publication: English Funding: non-commercial (Federal University of Ceara - Research Initiative Grant) Conflict of interest: no data Publication status: full article in peer-reviewed journal
Stated aim for study	Quote: „to evaluate the impact of iron-fortified rice (Ultrarice) weekly on hemoglobin and anemia levels compared with standard rice (control)”
Note	Study start date: August 2010 Study end date: December 2010

Study (Covidence identifier)	Quintero 2011 (86) (# 2309)
Methods	Study design: parallel, randomised controlled trial Unit of randomisation: individual Blinding: double-blind Number of study arms: 2
Participants	Location/Setting: the State of Mexico Country where trial was performed: Mexico Sample size: 395 infants and pre-schoolers Dropouts/withdrawals: 5 cases at the end of the study Sex: both male and female children included Inclusion criteria: <ul style="list-style-type: none"> • 7 to 24 months • no neurological diseases • written informed consent • municipality of residence • condition of indigenismo Exclusion criteria: – Health status: „it was necessary that families resided in municipalities before mentioned, who did not have neurological diseases” Ongoing treatment: no data Anaemic status: no data Age range at start of intervention: 7-24 months Mean age: 16 months
Interventions	Intervention(s): <ul style="list-style-type: none"> • enriched maize flour: (100 grams: 1.5 g of soybean meal (3%), 42.4 mg of iron, 33.3 mg of zinc, 120 mcg of vitamin A, 6,5 mg of niacin, 548 mcg of folic acid (n = 195) Comparator(s): <ul style="list-style-type: none"> • Control group: corn flour without fortification (n =200) Duration of intervention: 10 months

	Duration of follow-up: 10 months Run-in period: no Number of study centres: 14
Outcomes	Reported outcomes in full text of publication: weight, height, nutritional status, weight for age z-score, weight for height z-score, mental and psychomotor development, blood haemoglobin levels Primary outcomes: not defined Secondary outcomes: not defined Timing of outcome assessment: before and after trial
Identification	Trial identifier: – Trial terminated early: no
Publication details	Language of publication: Spanish Funding: commercial (DICONSA; “formerly CONASUPO, which is a majority state-owned company belonging to the Secretariat of Social Development of Mexico”) Conflict of interest: no data Publication status: full article in peer-reviewed journal
Stated aim for study	Quote: “To evaluate the effect of the consumption of a corn flour enriched with 3% soy, vitamins and minerals, on the growth and development of infants and preschool children.”
Note	Study start date: no data Study end date: no data

Study (Covidence identifier)	Bagni, 2009 (87, 88) (#5201)
Methods	Study design: cluster-randomised trial Unit of randomisation: cluster (daycare centres) Blinding: double-blind Number of study arms: 2
Participants	Location/Setting: Rio de Janeiro Country where trial was performed: Brazil Sample size: 354 Dropouts/withdrawals: intervention group: loss of 57 children (22.4%), loss of 8.6%, control group: loss of 65 children (25.5%), loss of 8.4%, Sex: both male and female children included Inclusion criteria: <ul style="list-style-type: none"> all preschoolers in the established age group attending day care centres at baseline had written consent from those responsible Exclusion criteria: sickle cell anaemia, purpura Health status: no data Ongoing treatment: no data Anaemic status: mixed (“Anemia was defined as hemoglobin <11.0g / dL”; “In the IG, the frequency of anemia was 39.1%, and in the CG, it was 44.7%”) Age range at start of intervention: 12-60 months Mean age: no data

Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> white rice fortified with Iron Bisglycine Chelate, rice was held once a week at lunchtime (90g) (n= 180) <p>Comparator(s):</p> <ul style="list-style-type: none"> rice with placebo once a week (n = 174) <p>Duration of intervention: 16 weeks Duration of follow-up: 16 weeks Run-in period: no Number of study centres: –</p>
Outcomes	<p>Reported outcomes in full text of publication: frequency of anaemia, haemoglobin Primary outcomes: frequency of anaemia, haemoglobin Secondary outcomes: – Timing of outcome assessment: before and after trial</p>
Identification	<p>Trial identifier: NCT00727545 Trial terminated early: no</p>
Publication details	<p>Language of publication: Portuguese Funding: non-commercial (Universidade Federal do Rio de Janeiro) Conflict of interest: no data Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “to evaluate the effect of weekly rice fortification with iron on the frequency of anaemia and haemoglobin concentration in children from public daycare centres in the city of Rio de Janeiro”</p>
Note	<p>Study start date: March 2006 Study end date: December 2006</p>

Study (Covidence identifier)	Nesamvuni 2005 (89) (#3052)
Methods	<p>Study design: randomised, parallel, intervention trial Unit of randomisation: children and their household or families Blinding: single-blind Number of study arms: 2</p>
Participants	<p>Location/Setting: Oukasie, Brits, in the North West Province Country where trial was performed: South Africa Sample size: 44 of children randomly assigned Dropouts/withdrawals: 8 lost to follow-up Sex: both male and female children included Inclusion criteria:</p> <ul style="list-style-type: none"> 1–3-year-old children at the crèches and the well-baby clinic who had weight-for-age or height-for-age below the 5th percentile of the National Centre for Health Statistics (NCHS) reference (undernourished) <p>Exclusion criteria:</p> <ul style="list-style-type: none"> any physical or mental disability (not on disability grant), severe forms of undernutrition (marasmus and kwashiorkor),

	<ul style="list-style-type: none"> children of mothers who recently relocated to the area <p>Health status: undernourished (had weight-for-age or height-for-age below the 5th percentile)</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: no data</p> <p>Age range at start of intervention: 1-3 years old</p> <p>Mean age: no data</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> to 150 g of raw maize meal, 1700 IU vitamin A, 0.61 mg thiamine, 0.62 mg riboflavin and 0.56 mg pyridoxine were added (25 and 50 kg (depending on usual monthly consumption) of maize meal flour was provided to the families per month to replace all maize meal consumed by these households) (n =16) <p>Comparator(s):</p> <ul style="list-style-type: none"> unfortified maize (n =20) <p>Duration of intervention: 12 months</p> <p>Duration of follow-up: 12 months</p> <p>Run-in period: no</p> <p>Number of study centres: -</p>
Outcomes	<p>Reported outcomes in full text of publication: weight, height, haemoglobin, haematocrit, serum retinol and serum retinol-binding protein</p> <p>Primary outcomes: haemoglobin, haematocrit, serum retinal and serum retinol-binding protein</p> <p>Secondary outcomes: weight, height</p> <p>Timing of outcome assessment: before and after trial</p>
Identification	<p>Trial identifier: –</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: non-commercial (grants from the National Research Foundation, Potchefstroom University for Christian Higher Education) and commercial (Hoffman La Roche (Switzerland), Roche Vitamin and Fine Chemicals and a gift of maize from Maizecor)</p> <p>Conflict of interest: no data</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “To evaluate the effectiveness of a vitamin-fortified maize meal to improve the nutritional status of 1–3-year-old malnourished African children”</p>
Note	<p>Study start date: no data</p> <p>Study end date: no data</p>

Study (Covidence identifier)	Faber 2005 (30) (#6626)
Methods	<p>Study design: parallel randomized controlled trial</p> <p>Unit of randomisation: individual</p> <p>Blinding: double-blind</p> <p>Number of study arms: 2</p>

Participants	<p>Location/Setting: The Valley of a Thousand Hills in KwaZulu-Natal province Country where trial was performed: South Africa Sample size: 361 infants Dropouts/withdrawals: 72 lost to follow-up Sex: both male and female children included Inclusion criteria:</p> <ul style="list-style-type: none"> aged 6–12 mo <p>Exclusion criteria:</p> <ul style="list-style-type: none"> their parent or legal guardian did not sign the consent form, birth weight <2500 g a baseline blood sample was not obtained, haemoglobin concentration <80 g/L <p>Health status: not defined Ongoing treatment: no data Anaemic status: mixed Age range at start of intervention: 6-12 months Mean age: 8.9 months</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> milled maize meal was fortified to supply 3 mg β-carotene, 11 mg iron (ferrous fumarate), and 3 mg zinc (zinc sulfate) per 40 g dry product; ascorbic acid (sodium ascorbate) was added (56mg/40 g dry product); 110 μg copper, 10 μg selenium, 0.4 mg riboflavin, 0.15 mg vitamin B-6, 0.25 μg vitamin B-12, and 2.5 mg vitamin E per 40 g dry product; 2 sachets/d was recommended, consumed as either 1 or 2 meals (n=144) <p>Comparator(s):</p> <ul style="list-style-type: none"> same porridge, but without the added micronutrients; 2 sachets/d was recommended, consumed as either 1 or 2 meals (n = 145) <p>Duration of intervention: 6 months Duration of follow-up: 6 months Run-in period: no Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: motor development, weight, length, length-for-age, weight-for-age, and weight-for length—which were expressed as z scores, Hb concentration, serum ferritin, serum retinol, serum zinc, CRP, stunting</p> <p>Primary outcomes: Hemoglobin concentration, serum ferritin concentration, serum retinol concentration, serum zinc concentration, motor development</p> <p>Secondary outcomes: weight, length, length-for-age, weight-for-age, and weight-for length—which were expressed as z scores, stunting</p> <p>Timing of outcome assessment: before and after trial</p>
Identification	<p>Trial identifier: – Trial terminated early: no</p>
Publication details	<p>Language of publication: English Funding: non-commercial (Thrasher Research Fund and the Community-based Health Programme of The Valley Trust and commercial (Tiger Food Brands Limited donated the fortified-porridge product) Conflict of interest: None of the authors had any personal or financial conflict of interest. Publication status: full article in peer-reviewed journal</p>

Stated aim for study	Quote: „We assessed whether the fortified porridge could reduce anaemia and improve the micronutrient status and motor development of infants.”
Note	Study start date: February 2002 Study end date: March 2003

Study (Covidence identifier)	Schumann 2005 (90) (#1790)
Methods	Study design: parallel, randomised, controlled trial Unit of randomisation: individual Blinding: double-masked Number of study arms: 3
Participants	Location/Setting: Ciudad Peronia Country where trial was performed: Guatemala Sample size: 110 number of children randomly assigned Dropouts/withdrawals: 13 lost to follow-up Sex: both male and female children included Inclusion criteria: <ul style="list-style-type: none"> • 12 to 36 months age • a high susceptibility to anaemia (Hb value was in the range of 100 to 115 g l⁻¹) • give informed consent • abide by the dietary instructions involved in the 5-day-per-week bean administration Exclusion criteria: <ul style="list-style-type: none"> • recent use of vitamin or mineral preparations containing iron • recent surgery • diagnosed chronic gastric or intestinal diseases, or chronic infections • used supplements during the intervention • at any point the parents made the decision to withdraw them from the study • moved from the house of residence and re-localisation was not possible • child with Hb concentration of <115 g/l Health status: an age group with high susceptibility to anaemia) Ongoing treatment: no data Anaemic status: anaemic (“moderately anaemic”; “high susceptibility to anaemia”; [Hb value was in the range of 100 to 115 g/l]) Age range at start of intervention: 12 to 36 months age Mean age: 20,9 months
Interventions	Intervention(s): <ul style="list-style-type: none"> • FeSO₄ (inorganic salt) fortified black bean paste; 156-g cans for 5 days of a week with 31.2 mg of fortification iron (n=37) • Haem-fortified (from bovine blood) black bean paste; 35.0 mg Fe/can for 5 days of a week (n=36) Comparator(s): <ul style="list-style-type: none"> • basic black bean paste for 5 days of a week (n =37)

	Duration of intervention: 10 weeks Duration of follow-up: 10 weeks Run-in period: no Number of study centres: 1
Outcomes	Reported outcomes in full text of publication: Hb concentration, Ferritin concentration Primary outcomes: Hb, Ferritin Secondary outcomes: – Timing of outcome assessment: baseline, 5 and 10 weeks
Identification	Trial identifier: – Trial terminated early: no
Publication details	Language of publication: English Funding: no data Conflict of interest: no data Publication status: full article in peer-reviewed journal
Stated aim for study	Quote: „Haem iron as a fortificant was compared with FeSO4 and a placebo treatment for the restoration of Hb and the incrementing of circulating ferritin as an index of iron stores” „The goal was to produce the same iron fortification that, with the intrinsic iron content, would total approximately 35.0 mg Fe per can in haem iron-fortified as well as in inorganic iron-fortified beans.”
Note	Study start date: no data Study end date: no data

Study (Covidence identifier)	Lartey, 2000 (91, 92) (#4145)
Methods	Study design: randomized, controlled trial Unit of randomisation: individual Blinding: no data Number of study arms: 4
Participants	Location/Setting: Techiman (district capital is located about 400 km north of Accra) Country where trial was performed: Ghana Sample size: 216 infants Dropouts/withdrawals: 18 during the intervention (7 because child’s mother left the area, 1 because the father refused participation, 4 because the infant rejected the project food (2 for WM, 1 for WF, and 1 for KF), 4 because the mother did not feed the project food (2 for WF and 2 for KF), and the death of infant (n = 1). Sex: both male and female children included Inclusion criteria: <ul style="list-style-type: none"> • breast-fed • no health complication • birth weight ≥ 2.5 kg • no congenital abnormalities • assigned a Maternal and Child Health card

	<ul style="list-style-type: none"> the child's mother was not planning to travel or move out of study area during the study period <p>Exclusion criteria: –</p> <p>Health status: healthy</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: mixed</p> <p>Age range at start of intervention: 6 months</p> <p>Mean age: 6 months</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> Weanimix plus vitamins and minerals (Iron, zinc, calcium, vitamin A, riboflavin) (WM), (High and low refer to 2 formulations of Weanimix with vitamins and minerals added: “high” for infants consuming ≤60 g/d and “low” for infants consuming > 60 g/d of the food.) (n=47) Weanimix plus fish (smoked anchovy) powder (WF), (n=48) koko (fermented maize dough) plus fish powder (KF) (n= 45) <p>Comparator(s):</p> <ul style="list-style-type: none"> Weanimix (75% maize (corn), 15% soybeans, and 10% groundnuts (peanuts) (n = 50) <p>Duration of intervention: 6 months</p> <p>Duration of follow-up: 6 months</p> <p>Run-in period: no</p> <p>Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: plasma zinc, plasma retinol, erythrocyte riboflavin, haemoglobin, haematocrit, plasma ferritin saturation, plasma ferritin, plasma transferrin saturation, plasma transferrin, breastfeeding, iron intake, zinc intake, Vitamin A intake, riboflavin intake, weight-for-age z-score, length-for-age z score, weight gain, length gain, midupper arm circumference, head circumference, triceps skinfold thickness, subscapular skinfold thickness, midupper arm fat area, midupper arm muscle area, haemoglobin, haematocrit, plasma ferritin saturation, plasma ferritin, diarrhea, fever, respiratory illness, C-reactive protein , dietary intake (weighed food and beverages, energy intake, nutrient intake)</p> <p>Primary outcomes: not defined</p> <p>Secondary outcomes: not defined</p> <p>Timing of outcome assessment: monthly anthropometric and morbidity data; baseline and after treatment blood draw</p>
Identification	<p>Trial identifier: –</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: commercial (Roche Vitamins and Fine Chemicals) and non-commercial (Nestlé Foundation, a Rockefeller Foundation African Dissertation Internship Award, a Fulbright Scholarship)</p> <p>Conflicts of interest: no data</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “to compare the growth and micronutrient (iron, zinc, riboflavin, and vitamin A) status of Ghanaian infants 6–12 mo of age fed Weanimix (W) or 1 of 3 other improved complementary foods”; “This study describes the factors associated with hemoglobin and plasma ferritin, zinc and retinol concentrations and erythrocyte riboflavin status among 208 Ghanaian infants who participated in a complementary feeding intervention trial from 6 to 12 mo of age.”</p>
Note	<p>Study start date: November 1994</p>

	Study end date: April 1995
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Study (Covidence identifier)	Bovell-Benjamin 1999 (93) (#7084)
Methods	<p>Study design: cross-over randomized controlled trial</p> <p>Unit of randomisation: individual (mother-toddler pairs)</p> <p>Blinding: double-blind</p> <p>Number of study arms: 3</p>
Participants	<p>Location/Setting: -</p> <p>Country where trial was performed: USA</p> <p>Sample size: 40 mothers-toddlers pairs</p> <p>Dropouts/withdrawals: 2 mothers-toddlers pairs (because they did not test all three porridges at one of the three test sessions)</p> <p>Sex: both male and female toddlers included with their mothers</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • eating infant cereals • able to eat from a spoon • not allergic to milk or maize <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • not sample the porridge <p>Health status: no data</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: no data</p> <p>Age range at start of intervention: 6-24 months</p> <p>Mean age: 13,5 ± 4,8 months</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> • whole maize fortified with ferrous bisglycinate (30 mg iron/kg) in their home, at the toddlers' regular mealtime and largest meal of the day. They received in 65 ml cup, but mothers were free to feed toddlers additional porridge (n = 38) • maize fortified with ferrous bisglycinate and containing the antioxidant butylated hydroxyanisole (50 ppm) in their home, at the toddlers' regular mealtime and largest meal of the day. They received in 65 ml cup, but mothers were free to feed toddlers additional porridge. (n= 38) <p>Comparator(s):</p> <ul style="list-style-type: none"> • unfortified whole maize in their home, at the toddlers' regular mealtime and largest meal of the day. They received in 65 ml cup, but mothers were free to feed toddlers additional porridge (n = 38) <p>Duration of intervention: 3 subsequent sessions</p> <p>Duration of follow-up: 3 subsequent sessions</p> <p>Run-in period: no</p> <p>Number of study centres: 1</p>

Outcomes	<p>Reported outcomes in full text of publication: DOL (degree of liking) among porridges</p> <p>Primary outcomes: not defined</p> <p>Secondary outcomes: –</p> <p>Timing of outcome assessment: After each sample was tested, mothers indicated the toddlers' degree of liking of the sample</p>
Identification	<p>Trial identifier: –</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: Albion Laboratories, Clearfield, CT</p> <p>Conflict of interest: no data</p> <p>Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “Our ultimate goal is to use BIS as an iron fortificant in infants’ and children’s cereals in developing countries to reduce the high prevalence of ID and IDA.”</p>
Note	<p>Study start date: no data</p> <p>Study end date: no data</p>

Study (Covidence identifier)	Liu 1993 (27) (#4438)
Methods	<p>Study design: cluster randomized trial</p> <p>Unit of randomisation: cluster</p> <p>Blinding: N/A</p> <p>Number of study arms: 2</p>
Participants	<p>Location/Setting: Mi-yun rural area near Beijing</p> <p>Country where trial was performed: China</p> <p>Sample size: 164</p> <p>Dropouts/withdrawals: N/A no data</p> <p>Sex: both male and female children included</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • healthy full-term infants. • born without complication • born with birth weights > 2.5 kg. • aged 6-13 mo • enrolled from 33 villages of the Mi-yun rural area near Beijing <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • not consumed all the rusks • hemoglobin concentrations <100 g/L <p>Health status: No clinical deficiency signs attributable to micronutrient deficiencies were observed in any of the children.</p> <p>Ongoing treatment: no data</p> <p>Anaemic status: mixed (“Of the children in the present study, only 15% were anemic at the outset (hemoglobin < 110 g/L)”)</p> <p>Age range at start of intervention: 6-13 mo</p> <p>Mean age: T: 9,63 mo; C: 9,86 mo</p>

Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> Calcium (300 mg/day), ferric ammonium citrate (5 mg/day), zinc (3 mg/day), vitamin A (224ug/day), cholecalciferol (4 ug/day), thiamine (0.15 ug/day), riboflavin (0.2 mg/day), niacin (2.5 mg/day), cyanocobalamin (0.3 ug/day), folic acid (25 ug/day) fortified rusk (17 g) daily supply (n =77) <p>Comparator(s):</p> <ul style="list-style-type: none"> unfortified rusks daily supply (n =87) <p>Duration of intervention: 3 months Duration of follow-up: 3 months Run-in period: no Number of study centres: 1</p>
Outcomes	<p>Reported outcomes in full text of publication: Weight, length, free erythrocyte porphyrin in red cells, plasma ferritin, erythrocyte glutathione reductase activation coefficient, plasma vitamin E and plasma retinol, hemoglobin concentration</p> <p>Primary outcomes: not defined Secondary outcomes: not defined Timing of outcome assessment: before trail, after trail</p>
Identification	<p>Trial identifier: - Trial terminated early: no</p>
Publication details	<p>Language of publication: English Funding: Supported in part by a grant from the United Kingdom Department of Trade and Industry. Conflict of interest: no data Publication status: full article in peer-reviewed journal</p>
Stated aim for study	<p>Quote: “A micronutrient-fortified rusk for weanling children was tested in a rural area near Beijing.” “The purpose of the study was to investigate the efficacy of the micronutrients addition not of the rusk per se.”</p>
Note	<p>Study start date: February 1990 Study end date: June 1990</p>

Study (Covidence identifier)	Gershoff 1977 (Gershoff 1975) (94, 95) (#6115)
Methods	<p>Study design: parallel cluster randomized trial Unit of randomisation: cluster Blinding: no data Number of study arms: 5</p>
Participants	<p>Location/Setting: province of Chiang Mai Country where trial was performed: Thailand Sample size: 1265 children at the start; 2250 at the end (<2 years: 357) Dropouts/withdrawals: no data Sex: both male and female children included Inclusion criteria: - Exclusion criteria: “villages not selected where there is iodine deficiency area” Health status: no data Ongoing treatment: no data</p>

	<p>Anaemic status: no data</p> <p>Age range at the start of intervention: 6 months to 5 years</p> <p>Mean age: no data</p>
Interventions	<p>Intervention(s): daily received</p> <ul style="list-style-type: none"> • RFG1: rice fortification grain 1 contains 0.0873% thiamine naphthalene disulfonate (equivalent to 0.05% thiamine nitrate), 0.0.4% retinol (added starting in August of 1972), 0.0815% of retinol acetate, and 0.8% FePO₄ 4H₂O (0.2% iron), lysine HCl and 10% L-threonine. (n= no data) • RFG2: rice fortification grain 1 contains 0.0873% thiamine naphthalene disulfonate (equivalent to 0.05% thiamine nitrate), 0.0.4% retinol (added starting in August of 1972), 0.0815% of retinol acetate, and 0.8% FePO₄ 4H₂O (0.2% iron), no amino acids (n= no data) <p>Comparator(s):</p> <ul style="list-style-type: none"> • RFG3: Rice fortification grains (daily received) (n= no data) <p>Duration of intervention: 4 years</p> <p>Duration of follow-up: 4 years</p> <p>Run-in period: no</p> <p>Number of study centres: 29</p>
Outcomes	<p>Reported outcomes in full text of publication:</p> <ul style="list-style-type: none"> • data from anthropometric measurements (length, weight, bone age, head circumference, chest circumference, arm circumference, triceps skinfold, subscapular skinfold) • haemoglobin, haematocrit • morbidity data • handwrist x-ray <p>Primary outcomes: not defined</p> <p>Secondary outcomes: not defined</p> <ul style="list-style-type: none"> • Timing of outcome assessment: Two physical examinations and haemoglobin and haematocrit values were conducted every year. Morbidity data were collected on each child every 15 days for up to 3 years.
Identification	<p>Trial identifier: –</p> <p>Trial terminated early: no</p>
Publication details	<p>Language of publication: English</p> <p>Funding: Supported in part by Contract AID/CSD-3291 from the United States Agency for International Development and the Fund for Research and Teaching, Department of Nutrition, Harvard School of Public Health.</p> <p>Publication status: full article in peer-reviewed journal</p> <p>Conflict of interest: no data</p>
Stated aim for study	<p>Quote: “a large-scale field study in villages of northern Thailand designed to measure the health benefits to be derived from the fortification of rice with lysine, threonine, thiamine, riboflavin, vitamin A and iron”</p>
Note	<p>Study start date: January 1971</p> <p>Study end date: July 1975</p>

Appendix 3. Composition of fortified complementary foods

Study number #	Type of complementary food	Composition of the non-fortified complementary food			Micronutrient(s) added to the fortified products
		Total Energy	Macronutrients (Protein, Fat Carbohydrate)	Micronutrients	
Palmer 2021 (74, 75)	Maize meal	Not specified	Not specified	Not specified	Retinyl palmitate ~55 µg RE/d OR provitamin A carotenoid-biofortified
Gannon 2019 (78)	Crops	Not specified	Not specified	Not specified	Biofortified crops (not further specified)
Ma 2016 (Sheng 2019; Krebs 2013) (80-83)	Rice cereal	80 kcal/day (20 g/ day)	Not specified	Iron (0.04 mg/20g)	Iron (ferrous fumarate; 1.10 mg/20 g); zinc (zinc sulfate; amount not specified); vitamin B12 (amount not specified)
Ekoe 2020 (76, 77)	Cereal	420 kcal/100g of cereal/day	Protein 14.5g; Fat 10 g; Carbo-hydrate 68 g/ 100g	Sodium 135 mg, Calcium 450 mg, Zinc 5 mg, Vitamin A 1,300 IU, Vitamin D 180 IU, Vitamin C 50 mg, Vitamin B ₁ (thiamin) 0.6 mg /100g	Iron (ferrus fumarate; 7.5 mg/100g)
Arcanjo 2013	Rice	Not specified (~50g/day)	Not specified	Not specified	56.4 mg ferric pyrophosphate/ 50 g portion

(14)					
Arcanjo 2012 (13)	Rice	Not specified	Not specified	Not specified	56.4 mg ferric pyrophosphate/ 50 g portion
Huey 2018 (79, 96)	Pearl millet	Not specified	Not specified	Iron (21.24 ppm); zinc (19.34 ppm)	Iron (additional 61.5 ppm); Zinc (additional 14.83 ppm)
Quintero 2011 (15) (# 2309)	Corn flour	Not specified (20 kg flour/family/month)	Not specified	Iron 3.90 mg; zinc 2.00 mg; retinol 0.50 mcg; niacin 1.30mg/100 g flour	1.5 g of soybean meal, iron 42.4mg, zinc 33.3 mg, retinol 120 mcg, niacin 6.5 mg, 548mcg folic acid/ 100 g flour
Bagni, 2009 (17, 18) (#5201)	Rice	Not specified (80 g rice /once a week)	Not specified	Not specified	Iron (3.78 mg/once a week)
Nesamvuni 2005 (19) (#3052)	Maize meal	Not specified	Not specified	Not specified	1700 IU vitamin A, 0.61 mg thiamine, 0.62 mg riboflavin, 0.56 mg pyridoxine/150g raw maize meal
Faber 2005 (20) (#6626)	Porridge	Dry product: 617 KJ/ day (40 g /day)	Not specified	Not specified	3mg β -carotene; 11 mg iron (ferrous fumarate); 3 mg zinc (zinc sulfate); 56 mg ascorbic acid (sodium ascorbate); 110 μ g copper; 10 μ g selenium; 0.4 mg riboflavin; 0.15 mg vitamin B6; 0.25 μ g vitamin B12; 2.5 mg vitaminE /40 g dry product
Schüman n 2005 (21) (#1790)	Beans	Not specified (5 cans/week)	Not specified	Iron (3.1 mg/can)	Iron (FeSO ₄) 32.5 mg/can (20 mg/ 100 g beans) OR haem iron (from bovin blood) 34.0 mg/can (1.33 g haem powder/ 100 g beans)

Lartey, 2000 (22, 23)	Cereal-legume blend	4350 kcal/ 1000 g dry weight	Protein 150 g (14E%); Fat 114 g (24E%)/1000 g	Calcium 530 mg, Iron 56 mg, Zinc mg 28, Copper 4 mg, Magnesium 1400 mg, Potassium 5660 mg, Sodium 30 mg, Phosphorus 2920 mg, Ascorbic acid 1 mg, Niacin 39 mg, Pyridoxine 3.5 mg, Riboflavin 0.4 mg, Thiamine 4.8 mg, Vitamin B12 0 µg, Folic acid 670 µg, Vitamin A 360 RE	<u>for infants consuming ≤60 g/d (content/1000 g dry weight):</u> Calcium 17360 mg, Iron 366 mg, Zinc mg 171, Copper 25 mg, Magnesium 1400 mg, Potassium 18960 mg, Sodium 30 mg, Phosphorus 17900 mg, Ascorbic acid 781 mg, Niacin 259 mg, Pyridoxine 31.3 mg, Riboflavin 19.5 mg, Thiamine 22.1 mg, Vitamin B12 70 µg Folic acid 5470 µg, Vitamin A 18360 RE <u>for infants consuming >60 g/d of the food (content/1000 g dry weight):</u> Calcium 8950 mg, Iron 183 mg, Zinc mg 86, Copper 13 mg, Magnesium 1400 mg, Potassium 12310 mg, Sodium 30 mg, Phosphorus 9400 mg, Ascorbic acid 391 mg, Niacin 149 mg, Pyridoxine 17.4 mg, Riboflavin 9.8 mg, Thiamine 13.5 mg, Vitamin B12 35 µg, Folic acid 3070 µg, Vitamin A 9360 RE
Bovell-Benjamin 1999 (24)	whole maize meal	Not specified	Not specified	Not specified	Ferrous bisglycinate 30 mg/kg maize meal
Liu 1993 (26)	Rusk	9.20 KJ/g rusk 155 KJ/17 g (1 portion rusk)	Protein: 0.06 g, Fat: 0.08 g, Carbohydrate (sugar): 0.31 g/1 g Protein 1.0 g, Fat 1.4 g, Carbohydrate (sugar) 5.2 g/ portion (17 g)	Not specified	<u>Per gram:</u> Calcium 17.60 mg, Iron 0.29 mg, zinc 0.18 mg, vitamin A 13.20 µg (RE (provided as retinyl acetate)), cholecalciferol 0.22 µg, thiamin 0.009 µg, riboflavin 0.012 mg, niacin 0.147 mg, cyanocobalamin 0.018 µg, folic acid 1.47 µg <u>Per rusk:</u> Calcium 300 mg, Iron 5.0 mg, zinc 3 mg, vitamin A 224 µg (RE (provided as retinyl acetate)), cholecalciferol 4 µg, thiamin 0.15 µg, riboflavin 0.2 mg, niacin 2.5 mg, cyanocobalamin 0.3 µg, folic acid 25.0 µg
Gershoff 1977	Rice	Not specified	Not specified	Not specified	Artificial rice grain contained 0.0873% thiamin naphthalene disulfonate (equivalent to 0.05%

(Gershoff 1975) (27, 28)					thiamin nitrate), 0.04% riboflavin, 0.0815% retinol acetate, 0.8% FePO ₄ *4H ₂ O (0.2% iron), no amino acid (RFG2)
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Appendix 4. Characteristics of studies awaiting classification

a) registered trials without publication

Study identifier	NCT03573570 (97)
(Covidence ID)	(#1741)
Study title:	Reducing anaemia through food fortification at scale Acronym: –
Official title:	Reducing Anemia Through Food Fortification at Scale
Methods:	Type of trial: interventional Allocation: randomised Intervention model: parallel assignment Masking: none Primary purpose: treatment
Participants:	Age: 6 months to 5 years Enrollment: 0 Inclusion criteria: 6 months to 5 years Exclusion criteria: none
Interventions	Intervention(s): Rice will be fortified using Fortified Rice Kernels (FRKs) containing iron, zinc, vitamin A and vitamins B1, B3, B6, B9 and B12 Comparator(s): regular rice
Starting date	Trial start date: – Trial completion date: – Status: Withdrawn (The Government of Tamil Nadu decided not to proceed with implementation of fortified rice through the Public Distribution (per the original study protocol))
Contact information	Responsible party/principal investigator: Norman G Miller, Stanford University
Stated purpose of study	Quote: "This trial proposes to address anemia and other micronutrient deficiencies by providing micronutrient fortified rice through the Public Distribution System (PDS) of Tamil Nadu in a manner that requires no change in behaviour by end-user households and that can feasibly be conducted on a large scale "
Note	Recruitment Status: Withdrawn (The Government of Tamil Nadu decided not to proceed with implementation of fortified rice through the Public Distribution (per the original study protocol)) First Posted: June 29, 2018 Last Update Posted: March 18, 2021

Study identifier	NCT02532816 (98)
(Covidence ID)	(#5389)
Study title:	Nutrient-dense complementary foods on catch-up growth and nutritional status of stunting children Acronym: –
Official title:	The Effect of Higher Nutrient-Dense Complementary Foods on Catch-up Growth and Nutritional Status of Stunting Children in Dompu District, Indonesia
Methods:	Type of trial: interventional Allocation: randomised Intervention model: not clear Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Primary purpose: treatment
Participants:	Age: 12-23 months Enrollment: actual 217 Inclusion criteria: <ul style="list-style-type: none"> • identified as stunting (having HAZ \leq -2SD of the WHO Growth Standard 2006) • no clinical evidence of any acute infectious disease or other diseases or morbidity condition that could interfere with the intake of study diets • parents and children residence in the study area. • parental consent obtained Exclusion criteria: <ul style="list-style-type: none"> • presence of oedema, severe illness warranting hospitalization on the enrolment day such as persistent diarrhea and other disease which may influence feeding practices and nutrient absorption • concurrent participation in another clinical trial • severe anemia with hemoglobine concentration $<$ 7.0 g/dL
Interventions	Intervention(s): <ul style="list-style-type: none"> • Optimized Complementary Feeding Recommendation (CFR) + fortified biscuit I (ferrous fumarate 83.5 mg, zinc oxide 50.95 mg, Calcium carbonate 3104.05 mg, Thiamine Mononitrate 1.85 mg, Nicotinic Acid 30.45 mg, Pyridoxine Hydrochloride 2.90 mg, Pteroyl monoglutamic acid 764.90 mcg, Cyanocobalamin 0.95 mcg, Retinol Palmitate (dry) 742.50 mcgRE) • CFR + fortified biscuit II (ferrous fumarate 32.6 mg, zinc oxide 3.78 mg, Calcium carbonate 874.12 mg, Thiamine Mononitrate 1.25 mg, Nicotinic Acid 17.95 mg, Pyridoxine Hydrochloride 1.10 mg, Pteroyl monoglutamic acid 329.90 mcg, Cyanocobalamin 0.55 mcg) Comparator(s): <ul style="list-style-type: none"> • CFR + non-fortified biscuit
Starting date	Trial start date: April 2016 Trial completion date: July 2016

Contact information	Responsible party/principal investigator: Duma O Fransisca and Umi Fahmida, SEAMEO Regional Centre for Food and Nutrition
Stated purpose of study	Quote: "to determine and compare the effect of higher nutrient-dense complementary foods and standard nutrient dense complementary foods on the catch-up growth and nutritional status of stunting children aged 12-23 months old in Indonesia"
Note	Recruitment Status: Unknown Verified August 2015 by Duma Octavia Fransisca, MSc, SEAMEO Regional Centre for Food and Nutrition. Recruitment status was: Active, not recruiting First Posted: August 26, 2015 Last Update Posted: August 26, 2015

b) Published protocols

Study (Covidence identifier)	Mehta 2017 (96) (#3636/2)
Methods	Study design: randomised controlled trial
Participants	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • 12–18 months old • Hemoglobin ≥ 9 g/dL • living in urban slums of Mumbai <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Age <12 months, 0 days or >18 months • Hemoglobin < 9 g/dL and/or hemoglobinopathy • severe malnutrition (marasmus, marasmic kwashiorkor, kwashiorkor, weight-for-height z-score < -3) • Diagnosis: Prior: HIV/AIDS or Tuberculosis, or Current: HIV/AIDS, malaria, Dengue fever, Tuberculosis >1-day hospitalization • Children without caretaker • no migrating from the slum for 4 weeks • Prior/current consumption: iron/zinc supplements in the past 1 year • no dietary allergies <p>Age at the start of the intervention: 12-18 month Country where trial was performed: India</p>
Interventions	<p>Intervention(s):</p> <ul style="list-style-type: none"> • FeZnPM (iron- and zinc-biofortified pearl millet) <p>Comparator(s):</p> <ul style="list-style-type: none"> • CtrlPM (conventional pearl millet) <p>Duration of intervention: 9 months Duration of follow-up: 9 months Run-in period: – Number of study centres: -</p>
Outcomes	Outcomes listed in the protocol:

	Hb, serum ferritin, serum transferrin receptor and plasma zinc, growth, immune function, cognitive function
Identification	Trial identifier: NCT02233764, REF/2014/10/007731, CTRI/2015/11/006376 Trial terminated early: no
Publication details	Language of publication: English Funding: HarvestPlus (2014H8302) Publication status: published protocol in peer-reviewed journal
Stated aim for study	Quote: “This study aims to investigate the effect of the consumption of foods prepared with iron- and zinc-biofortified pearl millet (FeZn-PM) by children on biomarkers of iron and zinc status, growth, and immune function”
Note	

c) Conference abstracts

Study (Covidence identifier)	Hays 2019 (99, 100)
Methods	Study design: cluster-randomized, double-blind, controlled study
Participants	Inclusion criteria: aged 6-18 months Exclusion criteria: – Setting: La Nkwantanang Municipality of the Greater Accra Region, Ghana Age at the start of the intervention (age subgroups): 6-18 months Country where trial was performed: Ghana
Interventions	Intervention(s): micronutrient-fortified infant cereal with iron (3.75 mg iron as ferrous fumarate / 50 g cereal Comparator(s): the same cereal without iron Duration of intervention: 6 months Duration of follow-up: 8 months
Outcomes	Reported outcomes in the abstract: Hb, weight, height, mid-upper arm circumference, usual dietary intake
Identification	Trial identifier: PACTR201906885776793 Trial terminated early: no
Publication details	Language of publication: English Funding: Nestlé Company Limited (Ghana) in collaboration with the University of Ghana School of Biological Sciences Publication status: conference abstract
Stated aim for study	Quote: “to assess the effect of a micronutrient-fortified complementary food on hemoglobin, anemia prevalence, and growth of infants in the La Nkwantanang Municipality of the Greater Accra Region, Ghana.”
Note	

Study (Covidence identifier)	Krebs 2011 (101) (#4299)
Methods	Study design: randomized study

Participants	Inclusion criteria: ~ 6 mo of ag Exclusion criteria: – Setting: – Age at the start of the intervention (age subgroups): ~ 6 months Country where trial was performed: –
Interventions	Intervention(s): infant cereal with Zn fortification Comparator(s): infant cereal without Zn fortification Duration of intervention: – Duration of follow-up: 3-4 months
Outcomes	Reported outcomes in the abstract: Exchangeable zinc (Zn) pool (EzP) size, Diet Zn, daily absorbed Zn, and plasma Zn
Identification	Trial identifier: – Trial terminated early: –
Publication details	Language of publication: English Funding: – Publication status: conference abstract
Stated aim for study	Quote: “Using stable isotope methods, we measured EzP size at 9-10 mo of age in healthy breastfed infants (n=37) who had a wide range of habitual dietary Zn resulting from random assignment at ~ 6 mo of age to 1 of 3 complementary feeding groups: infant cereal, with and without Zn fortification, or meats.”
Note	

i. Full text not yet available (procurement in progress)

- Araya 1994 (102)
- Arya 2000 (103)
- Cros 1966 (104)
- OrganizaciónPanamericanadelaSalud 1989 (105)
- Viseshakul 1979 (106)
- Viteri 1981 (107)
- Zhao 2004 (108)
- Zlotkin 2000 (109)

Appendix 5. Characteristics of excluded studies

Study	Reason for exclusion
Dewey 1998 (110)	Wrong comparator
Aakko 2017 (111)	Wrong comparator
Aaron 2011 (112)	Wrong comparator
Aboud 2011 (113)	Wrong intervention (responsive stimulation)
Ackatia-Armah 2012 (114)	Duplicate
Ackatia-Armah 2013 (115)	Wrong comparator
Ackatia-Armah 2015 (116)	Wrong comparator
ACTRN12609000061235 (117)	Wrong comparator
ACTRN12620000026921 (118)	Wrong intervention (prebiotic food)
Agapova 2018 (119)	Wrong intervention (non-fortified food)
Ahmad 2019 (120)	Wrong comparator
Ahmad 2020 (121)	Wrong comparator
Ahmed 2014 (122)	Wrong intervention (non-fortified food)
Ahmed 2017 (123)	Wrong comparator
Akalu 2010 (124)	Wrong intervention (non-fortified food)
Alemán 2008 (125)	Wrong intervention (snack prepared with quality protein maize)
Amthor 2009 (126)	Wrong study design
Anorve-Valdez 2018 (127)	Wrong intervention (MNP)
Arcanjo 2019 (128)	Wrong intervention (MNP)
Argaw 2018 (129)	Wrong intervention (n-3 LCPUFA)
Ariff 2013 (130)	Wrong intervention (MNP)
Arsenault 2007 (131)	Wrong intervention (fortified porridge combined with liquid multivitamin supplement)
Arsenault 2008 (132)	Wrong intervention (fortified porridge combined with liquid multivitamin supplement)

Arsenault 2016 (133)	Wrong intervention (fortified porridge combined with liquid multivitamin supplement)
Arya 2014 (134)	Wrong intervention (Shashtikashalyadi Churna)
Asâ€™ad 2003 (135)	Wrong intervention (zinc as supplement)
Asibey-Berko 2007 (136)	Wrong population (aged > 23 months)
Associationforthe 2013 (137)	Wrong comparator
Awasthi 2020 (138)	Wrong comparator
Badau 2016 (139)	Wrong study design
Bagni 2009 (140)	Duplicate
Bajaj 2005 (141)	Wrong intervention (low energy density diet)
Baskaran 1999 (142)	Wrong study design
Bauserman 2015 (143)	Wrong intervention (caterpillar cereal)
Becroft 1965 (144)	Wrong intervention (non-fortified food)
Beinner 2010 (145)	Wrong comparator
Bergmann 1989 (146)	Wrong comparator
Bernal 2013 (147)	Wrong intervention (cereals with different carbohydrate profiles)
Bhandari 2016 (148)	Wrong intervention (non-fortified product)
Bhargava 2013 (149)	Wrong study design
Bishop 1996 (150)	Wrong population
Bisimwa 2012 (151)	Wrong comparator
Boateng 2017 (152)	Wrong comparator
Boateng 2018 (153)	Wrong intervention (flour with added moringa leaf powder)
Boateng 2019 (154)	Wrong intervention (fortified with moringa leaf powder)
Bodwell 1987 (155)	Wrong population
Borg 2017 (156)	Wrong comparator
Borg 2018 (157)	Wrong comparator
Borg 2019 (158)	Wrong comparator
Boston 2008 (159)	Wrong population (aged > 23 months)
Bouhouch 2015 (160)	Wrong population (aged > 23 months)

Brett 2018 (161)	Wrong population (aged > 23 months)
Brnic 2017 (162)	Wrong intervention (cereal porridge with phytase)
Brown 2007 (163)	Wrong intervention (fortified porridge combined with liquid multivitamin supplement)
Campbell 2015 (164)	Wrong comparator
Campbell 2016 (165)	Wrong comparator
Campbell 2016 (166)	Wrong comparator
Campbell 2017 (167)	Wrong study design
Campbell 2018 (168)	Wrong comparator
Campbell 2020 (169)	Wrong comparator
Capozzi 2011 (170)	Wrong intervention (iron fortified formula)
Carol 2019 (171)	Wrong population (children aged > 23 months)
Cercamondi 2013 (172)	Wrong comparator
Chauhan 2019 (173)	Wrong intervention (non-fortified food)
Chavasit 2015 (174)	Wrong comparator
Chilenje Infant Growth 2010 (175)	Wrong comparator
Chisenga 2011 (176)	Wrong study design
Chomba 2015 (177)	Wrong population (aged > 23 months)
Choudhury 2016 (178)	Wrong intervention (MNP)
Christian 2015 (179)	Wrong comparator
Christian 2015 (37)	Wrong comparator
Cliffer 2017 (180)	Wrong comparator
Cliffer 2020 (181)	Wrong comparator
Cook 1997 (182)	Wrong population
Cornell 2010 (183)	Wrong study design
Cornell 2012 (184)	Wrong population (aged > 23 months)
CTRI/2011/12/002259 (185)	Wrong intervention (non-fortified food)
CTRI/2017/08/009260 (186)	Wrong comparator
CTRI/2017/02/007767 2017 (187)	Wrong study design
Cubero 2009 (188)	Wrong intervention (cereal enriched with tryptophan)
Cuj 2016 (189)	Wrong study design

Dahl 2019 (190)	Wrong intervention (non-fortified porridge)
Daniels 2016 (191)	Wrong intervention (baby-led approach)
Daniels 2017 (192)	Wrong population (women)
Davidsson 2000 (193)	Wrong comparator
Davidsson 2003 (194)	Wrong population
Davidsson 2009 (24)	Wrong comparator
de Almeida 2003 (195)	Wrong study design
de Almeida 2005 (196)	
de Almeida 2014 (197)	Wrong intervention (fortified water)
Delimont 2017 (198)	Wrong comparator
Delimont 2017 (199)	Wrong comparator
Delimont 2019 (200)	Wrong comparator
DeOliveira 2006 (201)	Wrong intervention (diet with a bran-based cereal mixture)
DeOliviera 1996 (202)	Wrong intervention (fortified water)
dePaula 2001 (203)	Wrong comparator
Dewan 2009 (204)	Wrong intervention (leaf protein concentrate)
Dewan 2009 (205)	Wrong intervention (leaf protein concentrate)
Dewey 1998 (206)	Wrong comparator
Dewey 2004 (207)	Wrong intervention (iron supplementation)
Dhingra 2012 (208)	Wrong comparator
Dong 2013 (209)	Wrong intervention (vitamin and mineral supplements)
Drks 2014 (210)	Wrong comparator
Dube 2010 (211)	Wrong intervention (low or high meat content)
Duggan 2003 (212)	Wrong comparator
Duizer 2017 (213)	Wrong intervention (home fortifiers)
Dutradeoliveira 1994 (214)	Wrong population (children aged > 23 months)
Ekbote 2011 (215)	Wrong population
Emel 2006 (216)	Wrong study design
Ernst 2013 (217)	Wrong intervention (beef biscuits)
Ernst 2014 (218)	Wrong intervention (non-fortified biscuits)
Faber 2005 (219)	Wrong study design

Fatmah 2018 (220)	Wrong population (aged > 23 months)
Ferreira 2008 (221)	Wrong intervention (bran-based cereal mixture as supplement)
Fhi 2018 (222)	Wrong population (aged > 23 months)
Filteau 2011 (223)	Duplicate
Filteau 2011 (224)	Wrong comparator
Fink 2017 (225)	Wrong intervention (growth monitoring)
Finn 2017 (226)	Wrong study design
Fleige 2010 (227)	Wrong study design
Food 2018 (228)	Wrong study design
Friel 2013 (229)	Wrong comparator
Friel 2014 (230)	Wrong comparator
Friel 2015 (231)	Wrong comparator
Friel 2016 (232)	Wrong comparator
Fuchs 1991 (233)	Wrong intervention (milk + fortified cereal or formula)
Fuchs 1991 (234)	Wrong intervention (milk + fortified cereal or formula)
Fuchs 1993 (235)	Wrong intervention (milk + fortified cereal or formula)
Galpin 2007 (236)	Wrong comparator
Gannon 2014 (237)	Wrong population (aged > 23 months)
Gannon 2014 (238)	Wrong population (aged > 23 months)
Garc�a-Guerra 2009 (239)	Wrong comparator
Gartner 2006 (240)	Wrong study design
Geltman 2009 (241)	Wrong intervention (MNP)
Gershoff 1977 (242)	Wrong study design
Ghosh 2017 (243)	Wrong intervention (MNP)
Ghosh 2019 (244)	Wrong comparator
Gibson 2011 (245)	Wrong comparator (basal fortified vs. richly fortified porridge)
Glinz 2015 (23)	Wrong comparator
Glinz 2017 (246)	Wrong comparator

Glinz 2017 (247)	Duplicate
GodomarGalindo 1989 (248)	Wrong study design
Gough 2020 (249)	Wrong intervention (improved water, sanitation, and hygiene)
Grantham-McGregor 1989 (250)	Wrong intervention (full-cream powdered milk)
Granthammcgregor 1993 (251)	Wrong intervention (nutritional supplementation)
Gunaratna 2016 (252)	Wrong study design
Gutierrez 1998 (253)	Wrong intervention (received coupons)
Hambidge 1979 (254)	Wrong population (aged > 23 months)
Hambidge 2013 (255)	Wrong comparator
Harrington 2011 (256)	Wrong comparator
Haschke 1988 (257)	Wrong intervention (formula)
HaydomLutheran 2020 (258)	Wrong population (aged > 23 months)
HelenKeller 2011 (259)	Wrong comparator
HeroinstituteforInfant 2017 (260)	Wrong intervention (infant cereal with whole grain flour)
Herter-Aeberli 2017 (261)	Wrong population (aged > 23 months)
Herter-Aeberli 2017 (262)	Duplicate
Hertrampf 1990 (263)	Duplicate
Hertrampf 1990 (264)	Wrong intervention (Haemoglobin fortified cereal)
Hess 2017 (265)	Wrong intervention (zinc supplementation)
Hi 2020 (266)	Wrong population (aged <6 months)
Hilmers 2002 (267)	Wrong population (aged > 23 months)
Hlaing 2015 (268)	Wrong comparator
Hoffman 2004 (269)	Wrong intervention (fortified with DHA-enriched egg yolks)
Hoffman 2014 (270)	Wrong intervention (fortified with DHA-enriched egg yolks)
HospitalClinicoUniversitariode 2017 (271)	Wrong intervention (dairy product with prebiotic)
Hossain 2005 (272)	Wrong intervention (amylase-rich flour)

Huey 2017 (273)	Duplicate
Huo 2013 (274)	Wrong study design
Hussain 2004 (275)	Wrong intervention (lysine)
Huybregts 2012 (276)	Wrong intervention (non-fortified food)
Isanaka 2008 (277)	Wrong comparator
Isanaka 2019 (278)	Wrong comparator
ISRCTN47598408 (279)	Wrong comparator
ISRCTN30012997 (280)	Wrong comparator
ISRCTN10309022 (281)	Wrong intervention (lactose-free, chickpea flour)
Iuel-Brockdorf 2015 (282)	Wrong intervention (lipid-based nutrient supplements, non-fortified corn-soy blended flours)
Iuel-Brockdorf 2016 (283)	Wrong intervention (lipid-based nutrient supplements, non-fortified corn-soy blended flours)
Jaeggi 2015 (284)	Wrong intervention (home-fortified maize porridge)
Jahari 2000 (285)	Wrong intervention (milk plus micronutrients)
Jalla 2002 (286)	Wrong comparator
Javan 2017 (287)	Wrong intervention (multivitamin / mineral supplement)
Javaid 1991 (288)	Wrong population (aged <6 months)
Javaid 1991 (289)	Duplicate
Jilcott 2010 (290)	Wrong study design
John 1993 (291)	Wrong intervention (gruels, without micronutrient fortification)
Jong-Mee 2005 (292)	Wrong intervention (fortified chewiness)
Kaimila 2019 (293)	Wrong intervention (supplemental legumes)
Kajjura 2019 (294)	Wrong comparator
Kajjura 2020 (295)	Wrong comparator
Kalavi 1996 (296)	Wrong intervention
Kalhoff 2020 (297)	Wrong intervention
Kampstra 2018 (298)	Wrong comparator

Karakochuk 2012 (299)	Wrong comparator
Kekalih 2019 (300)	Wrong comparator
King 2007 (301)	Wrong intervention (highdiastase malted barley)
Kodkany 2013 (302)	Wrong population (aged > 23 months)
Konyole 2013 (303)	Wrong intervention ("Winfood Classic" vs. "Winfood Lite" vs. Corn Soy Blend Plus)
Konyole 2017 (304)	Wrong comparator
Konyole 2019 (305)	Wrong comparator
Krebs 2006 (306)	Wrong comparator
Krebs 2012 (307)	Wrong comparator
Krebs 2012 (308)	Wrong comparator
Krebs 2013 (309)	Wrong comparator
Krebs 2013 (310)	Wrong intervention (MNP)
Kuusipalo 2006 (311)	Wrong comparator
Laboratorios 2021 (312)	Wrong intervention (probiotics)
Lachat 2006 (313)	Wrong intervention (processing to improve protein digestibility)
LaGrone 2012 (314)	Wrong comparator
Lakkam 2014 (315)	Wrong study design
Langendorf 2014 (316)	Wrong comparator
Langlois 2020 (317)	Wrong comparator
Laylo-NavarroCelestinaRaquel 2011 (318)	Wrong intervention (non-fortified food)
Leroy 2020 (319)	Wrong intervention (micronutrient supplements)
Leroy 2021 (320)	Wrong intervention (different timing and duration of feeding)
Libuda 2016 (321)	Wrong intervention (food with rapeseed oil or oily fish)
Li 2015 (322)	Wrong population (aged > 23 months)
Lin 2008 (323)	Wrong comparator
Lind 2003 (324)	Wrong intervention (phytate-reduced products)

Lind 2004 (325)	Wrong intervention (phytate-reduced products)
Lind 2019 (326)	Wrong intervention (protein-reduced food)
LitkowskiPe 2016 (327)	Wrong intervention (non-fortified product)
Lo 2011 (328)	Wrong intervention (iron-fortified porridge combined with a liquid multivitamin supplement)
Long 2012 (329)	Wrong study design
LopezdeRomana 2005 (330)	Wrong population (aged > 23 months)
Ly 2006 (331)	Wrong comparator
Macharia-Mutie 2012 (332)	Wrong intervention (porridge with amaranth or MNP)
Macharia-Mutie 2013 (333)	Wrong intervention (porridge with amaranth or MNP)
Macharia-Mutie 2015 (334)	Wrong intervention (porridge with amaranth or MNP)
Manno 2011 (335)	Wrong comparator
Mahalanabis 1993 (336)	Wrong intervention
Mallard 2014 (337)	Wrong study design
Mamiro 2004 (338)	Wrong intervention (processed complementary food)
Manary 2004 (339)	Wrong comparator
Mank 2011 (340)	Wrong intervention (zinc supplement)
Manno 2012 (31)	Wrong comparator (richly fortified vs. basal fortified porridge)
Marron 2015 (341)	Wrong comparator
MartinezMartinez 2009 (342)	Wrong study design
Martorell 2020 (343)	Wrong study design
Masuda 2019 (344)	Wrong intervention (spirulina powder)
Masuda 2019 (345)	Wrong intervention (spirulina powder)
Matilsky 2009 (346)	Wrong comparator
Maust 2015 (347)	Wrong intervention (integrated management of malnutrition)
McDonald 2019 (348)	Wrong comparator

McGill 2014 (349)	Wrong comparator
McGill 2015 (350)	Wrong population (aged > 23 months)
MedecinsSansFrontieres 2012 (351)	Wrong intervention (MNP)
MeeksGardner 1995 (352)	Wrong intervention (milk-based supplement)
Menon 2007 (353)	Wrong intervention (MNP)
Miles 1987 (354)	Wrong population
Mize 1995 (355)	Wrong intervention (formula)
Moore 2003 (356)	Wrong intervention (fructo-oligosaccharide-supplemented infant cereal)
Morales 2008 (357)	Wrong comparator
Moursi 2003 (358)	Wrong intervention (amylase)
Nane 2019 (359)	Wrong comparator
NCT01224535 (360)	Wrong intervention (porridge enriched with amaranth)
NCT02162238 (361)	Wrong population (aged > 23 months)
NCT01790048 (362)	Wrong intervention (non-fortified food)
NCT04334538 (363)	Wrong comparator
NCT00998517 (364)	Wrong comparator
NCT01552512 (365)	Wrong intervention (Nutributter)
NCT01785680 (366)	Wrong intervention (integrated protocol)
NCT02053857 (367)	Wrong comparator
NCT02375503 (368)	Wrong population (aged > 23 months)
NCT00822380 (369)	Wrong comparator
NCT01817634 (370)	Wrong intervention (fish oil capsule)
NCT00890695 (371)	Wrong comparator
NCT00631046 (372)	Wrong intervention (fish oil)
NCT01593969 (373)	Wrong intervention (n-3 PUFA enriched food)
NCT01790542 (374)	Wrong population (aged <6 months)
NCT03355222 (375)	Wrong intervention (non-fortified food)
NCT03385590 (376)	Wrong intervention (non-fortified food)
NCT03597061 (377)	Wrong intervention (behavioral)
NCT02221063 (378)	Wrong population (aged > 23 months)

NCT03041103 (379)	Wrong study design
NCT03175003 (380)	Wrong population (aged > 23 months)
NCT02208609 (381)	Wrong intervention (maize tortillas with Amaranth)
NCT02142647 (382)	Wrong intervention (non-fortified food)
NCT04137445 (383)	Wrong intervention (non-fortified food)
NCT00653705 (384)	Wrong intervention (probiotic bacteria BB12)
NCT01282788 (385)	Wrong comparator
NCT03355287 (386)	Wrong intervention (iron drops)
NCT01184716 (387)	Wrong population (aged > 23 months)
NCT01097889 (388)	Wrong comparator
NCT01001871 (389)	Wrong intervention (MNP)
NCT01455636 (390)	Wrong intervention (MNP)
NCT02192892 (391)	Wrong comparator
NCT01061307 (392)	Wrong population (aged > 23 months)
NCT01573013 (393)	Wrong population (aged > 23 months)
NCT01321099 (394)	Wrong comparator
NCT01111864 (395)	Wrong intervention (iron and micronutrient supplement)
NCT01634945 (396)	Wrong comparator
NCT02176759 (397)	Wrong population (aged > 23 months)
NCT02437955 (398)	Wrong population (aged > 23 months)
NCT02118402 (399)	Wrong intervention (MNP)
NCT03894358 (400)	Wrong intervention (prebiotic mixture)
NCT01423162 (401)	Wrong population (aged > 23 months)
NCT01418898 (402)	Wrong population (aged > 23 months)
NCT00571948 (403)	Wrong population (aged <6 months)
NCT04174846 (404)	Wrong intervention (non-fortified food)
NCT02079961 (405)	Wrong population (aged > 23 months)
NCT04564222 (406)	Wrong population (aged > 23 months)

NCT02847962 (407)	Wrong comparator
NCT01724073 (408)	Wrong comparator
NCT02165956 (409)	Wrong intervention (cereal with prebiotics, probiotics, vegetable proteins)
NCT03617575 (410)	Wrong intervention (iron supplement)
NCT02257437 (411)	Wrong comparator
NCT02257762 (412)	Wrong comparator
NCT02078271 (413)	Wrong intervention (food-based dietary guidelines)
NCT03474276 (414)	Wrong comparator
NCT01115647 (415)	Wrong comparator
NCT03752762 (416)	Wrong population (aged <6 months)
NCT03399617 (417)	Wrong population (aged <6 months)
NCT00867867 (418)	Wrong intervention (iron supplementation)
NCT04099849 (419)	Wrong population (aged > 23 months)
NCT01553877 (420)	Wrong intervention (non-fortified product)
NCT01634009 (421)	Wrong intervention (non-fortified product)
NCT02185196 (422)	Wrong intervention (vitamin D supplementation)
NCT04099849 (423)	Wrong population (aged > 23 months)
NCT03258385 (424)	Wrong population (aged > 23 months)
NCT04015999 (425)	Wrong intervention (non-fortified food)
NCT03084731 (426)	Wrong intervention (non-fortified food)
NCT01562379 (427)	Wrong comparator
NCT01751009 (428)	Wrong intervention (vitamin A supplement)
NCT02073149 (429)	Wrong intervention (point-of-care fortification)
NCT02435524 (430)	Wrong population (aged > 23 months)
NCT03038633 (431)	Wrong population (aged > 23 months)
NCT00131222 (432)	Wrong comparator
NCT04250896 (433)	Wrong intervention (behavioral)

NCT00944398 (434)	Wrong intervention (iron-fortified porridge combined with a liquid multivitamin supplement)
NCT01783067 (435)	Wrong population (aged > 23 months)
NCT00760890 (436)	Wrong comparator
NCT00841061 (437)	Wrong comparator
NCT00098202 (438)	Wrong population (aged > 23 months)
NCT01898871 (439)	Wrong comparator
NCT03549156 (440)	Wrong comparator
Nestel 2004 (441)	Wrong population (aged > 23 months)
NCT03754543 (442)	Wrong comparator
NCT04483453 (443)	Wrong intervention (different feeding regimens)
NCT04766346 (444)	Wrong study design
NCT03111927 (445)	Wrong population (aged <6 months)
Neufeld 2019 (446)	Wrong comparator
NCT03181178 (447)	Wrong intervention (MNP)
Nicklas 2020 (448)	Wrong study design
Nikiema 2014 (449)	Wrong comparator
Nikiema 2021 (450)	Wrong intervention (non-fortified food)
North-WestUniversity 2016 (451)	Wrong comparator
Nozari 2015 (452)	Wrong population (aged > 23 months)
Nurhasan 2018 (453)	Wrong comparator
Obatolu 2003 (454)	Wrong population (aged > 23 months)
Oelofse 2003 (455)	Wrong comparator
Ordiz 2020 (456)	Wrong intervention (legume supplementation)
Orsango 2019 (457)	Wrong population (aged > 23 months)
Osendarp 2002 (458)	Wrong population
Ouedraogo 2010 (459)	Wrong intervention (micronutrient supplement)
Owino 2007 (460)	Wrong intervention (alpha-amylase)
Owino 2011 (461)	Wrong comparator
Owino 2013 (462)	Wrong comparator

Owino 2015 (463)	Wrong comparator
PACTR201604001584278 (464)	Wrong intervention (precooked maize-sorghum flour)
PACTR201809662822990 (465)	Wrong comparator
Pactr 2019 (466)	Wrong comparator
Palmer 2018 (467)	Wrong population (aged > 23 months)
Patel 2005 (468)	Wrong comparator
Paul 2007 (469)	Wrong intervention (non-fortified food)
Phu 2010 (28)	Wrong population (aged <6 months)
Phu 2012 (470)	Wrong population (aged <6 months)
Phuka 2008 (471)	Wrong comparator
Phuka 2009 (472)	Wrong intervention (LNS)
Phuka 2009 (473)	Wrong comparator
Picciano 1980 (474)	Wrong intervention (formula)
Pollitt 2002 (475)	Wrong intervention (micronutrient supplement)
Purwestri 2012 (476)	Wrong intervention (RUF-Nias biscuits)
Pynaert 2006 (477)	Wrong study design
Qasem 2017 (478)	Wrong comparator
Rahman 1994 (479)	Wrong intervention (amylase)
Rahman 1997 (480)	Wrong intervention (amylase)
Rahman 1997 (481)	Wrong intervention (amylase)
Ramirez 2013 (482)	Wrong study design
Ramirez-Luzuriaga 2016 (483)	Wrong intervention (Powdered fortified milk)
Rao 1992 (484)	Wrong intervention (sweet ready mix with amylase)
Rim 2008 (22)	Wrong intervention (point-of-use fortification)
Rivera 1991 (485)	Wrong intervention (Atole, Fresco)
Rivera 2002 (486)	Wrong intervention (Atole, Fresco)
Roberts 2017 (487)	Wrong comparator
Roberts 2020 (488)	Wrong comparator
Roediger 2020 (489)	Wrong intervention (protein quality optimized RUSF)

Rosado 2010 (490)	Wrong comparator
Ruel 1997 (491)	Wrong intervention (liquid preparation zinc)
Safaa 2003 (492)	Wrong study design
Sako 2018 (493)	Wrong study design
Salinas-Pielago 1998 (494)	Wrong population (aged > 23 months)
Samadpour 2009 (495)	Wrong intervention (MNP)
Sandjaja 2015 (496)	Wrong study design
Sarojini 1999 (497)	Wrong study design
Sato 2017 (498)	Wrong intervention (MNP)
Sayyad-Neerkorn 2015 (499)	Wrong comparator
Sazawal 2014 (500)	Wrong comparator
Scherbaum 2015 (501)	Wrong comparator
Schlossman 2015 (502)	Wrong intervention (non-fortified food)
Schlossman 2017 (503)	Wrong study design
Schlossman 2018 (504)	Wrong intervention (non-fortified food)
Schroeder 1995 (505)	Wrong intervention (highenergy, high-protein beverage)
Schumann 2009 (506)	Wrong intervention (foodLET: chewable, flavored multiple-micronutrient vehicle that was a hybrid of a food and a tablet)
Schwartz 2009 (507)	Wrong intervention (n-6 linoleic acid)
Seal 2008 (508)	Wrong study design
Shaikh 2020 (509)	Wrong comparator
Shamah-Levy 2008 (510)	Wrong comparator
Shamim 2015 (511)	Wrong comparator
Shen 2017 (512)	Wrong comparator
Shen 2017 (513)	Wrong comparator
Sheng 2019 (514)	Duplicate
Shewade 2013 (515)	Wrong intervention (non-fortified food)
Sigh 2018 (516)	Wrong intervention (non-fortified food)
Simondon 1996 (517)	Wrong population (aged > 23 months)
Simpore 2006 (518)	Wrong intervention (Spirulina, Misola)

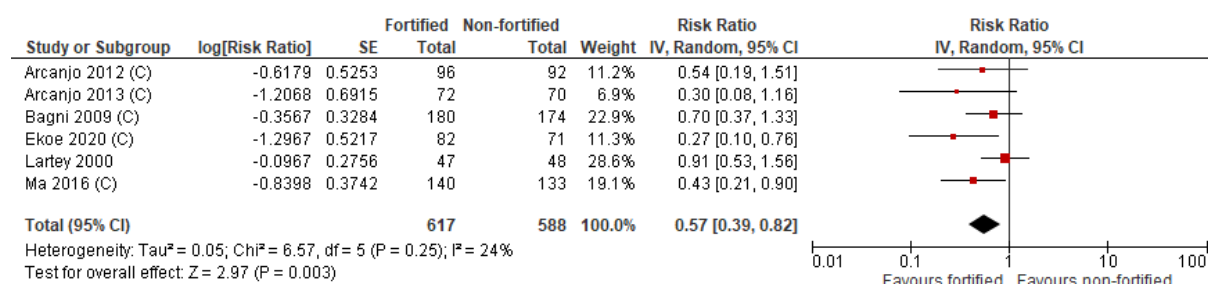
Singh 2010 (519)	Wrong intervention (fortified cereal-milk supplement)
Skau 2013 (520)	Wrong comparator
Skau 2013 (521)	Wrong comparator
Skau 2015 (522)	Wrong comparator
Stephenson 2017 (523)	Wrong intervention (cowpea or common bean flour)
Stobaugh 2016 (524)	Wrong intervention (soy vs. waxy)
Stobaugh 2017 (525)	Wrong intervention (package of interventions)
Stookey 1967 (526)	Wrong population
Tampere 2006 (527)	Wrong comparator
Tampere 2008 (528)	Wrong comparator
Tano-Debrah 2019 (529)	Wrong study design
Tekale 2015 (530)	Wrong population (aged > 23 months)
Thakur 2016 (531)	Wrong intervention (foods with different composition)
Thakwalakwa 2010 (532)	Wrong intervention (corn-soy blend, Lipid-based nutrient supplements)
Thakwalakwa 2014 (533)	Wrong comparator
Tharrey 2017 (534)	Wrong intervention (behavioural)
TheMathileInstituteFortheAdvancementofHuman 2020 (535)	Wrong comparator
Tondeur 2004 (536)	Wrong intervention (lipid-based nutrient supplement, MNP)
Traore 2005 (537)	Wrong intervention (non-fortified food)
Traore 2013 (538)	Wrong intervention (processed fortified flours with dried milk and without milk, Misola)
Trehan 2015 (539)	Wrong comparator
Tufts 2014 (540)	Wrong comparator
Tufts 2017 (541)	Wrong comparator
Tufts 2017 (542)	Wrong comparator
Tufts 2018 (543)	Wrong comparator
vanderKam 2012 (544)	Wrong comparator

VanderWal 2018 (545)	Wrong intervention (aloe-enriched, whey protein drink)
VanHoan 2009 (546)	Wrong intervention (Favina and Favilase gruels)
Varea 2011 (547)	Wrong study design
Vega 2016 (548)	Wrong intervention (food supplements: Nutrisano, Vitanino)
Verkaik-Kloosterman 2017 (549)	Wrong study design
Verna (550)	Wrong comparator
Villanueva 2016 (551)	Wrong study design
Viseshakul 1979 (552)	Duplicate
Vray 2018 (553)	Wrong intervention (flour with prebiotic)
Vuongle 2002 (554)	Wrong population (aged > 23 months)
Walker 1996 (555)	Wrong intervention (home-fortification)
Wang 2013 (556)	Wrong comparator
Walter 1993 (557)	Wrong population (aged <6 months)
Whitfield 2016 (558)	Wrong population (aged > 23 months)
Whitfield 2017 (559)	Wrong population (aged > 23 months)
Whitfield 2016 (558)	Wrong population (aged > 23 months)
Westcott 2011 (560)	Wrong comparator
Women's 2010 (561)	Wrong comparator
Yeung 2000 (562)	Wrong comparator
Ying 1956 (563)	Wrong population (aged > 23 months)
Yu 2013 (564)	Wrong intervention (education and supplementation)
Yuliarti 2017 (565)	Wrong comparator
Zakaria 2019 (566)	Wrong intervention (formulas and Moringa Oleifera Leaf Powder)
Zakaria 2020 (567)	Wrong intervention (Moringa Oleifera Leaf Powder)
Zavaleta 2011 (568)	Wrong intervention (milk with protein)

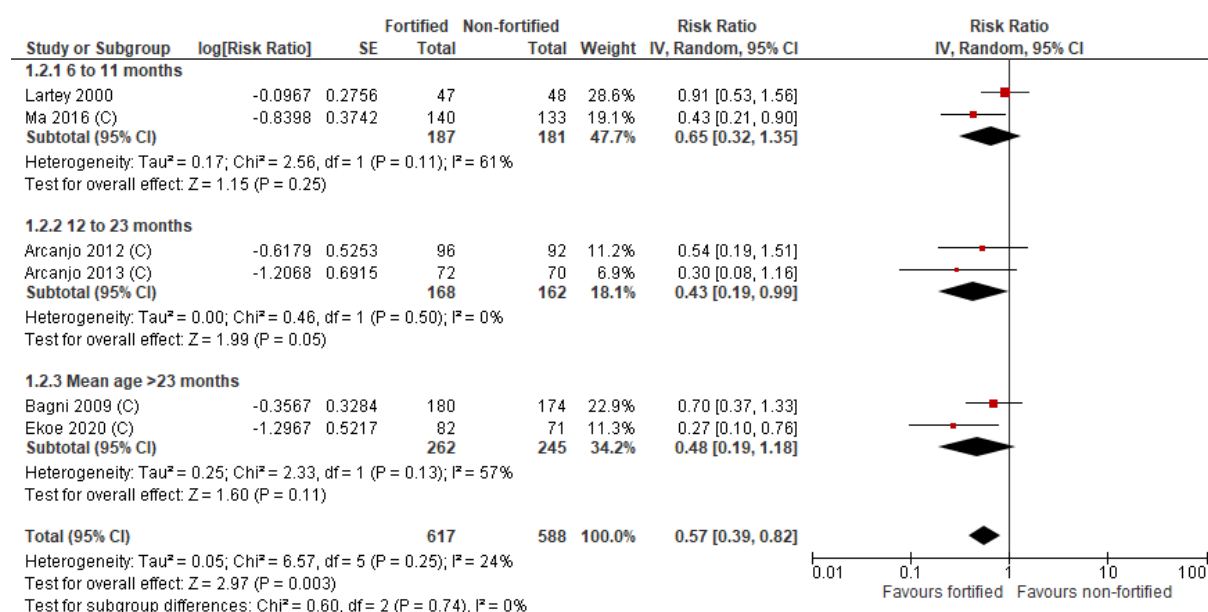
Zhang 2016 (569)	Wrong intervention (food supplement+health education)
Zhichien 1956 (570)	Wrong intervention (fortification with lysine)
Ziegler 2009 (571)	Wrong comparator
Ziegler 2011 (572)	Wrong study design
Ziegler 2011 (25)	Wrong comparator
Zyba 2019 (573)	Wrong intervention (lipid-based nutrient supplement)

Appendix 6. DATA AND ANALYSES

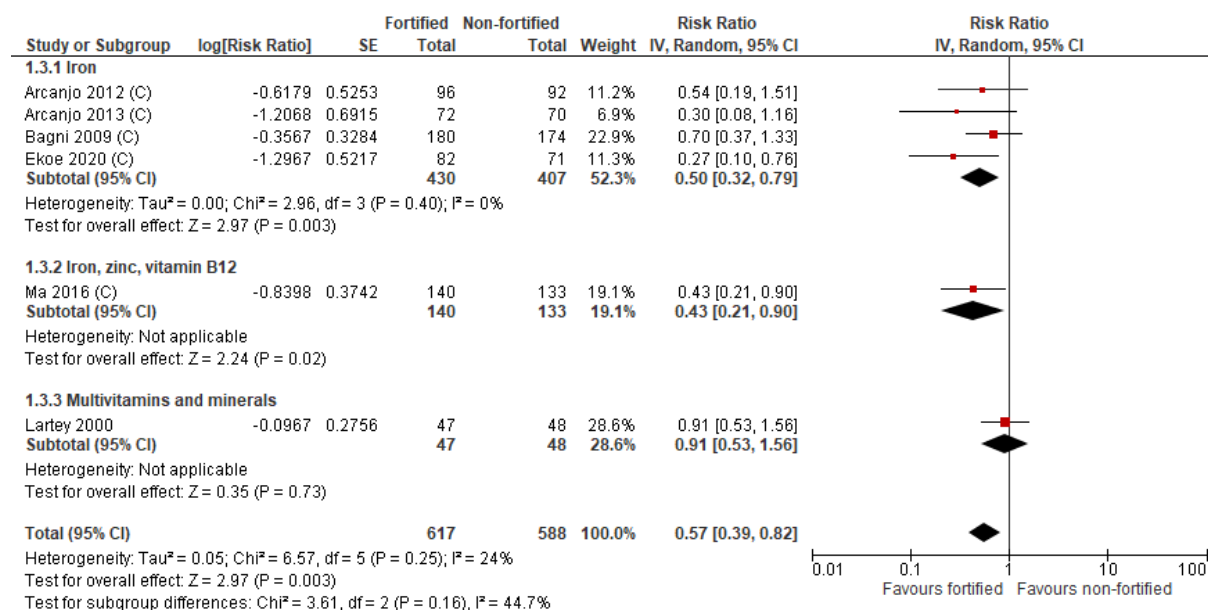
Analysis 1.1 Fortified versus non-fortified complementary food. Outcome: Anaemia



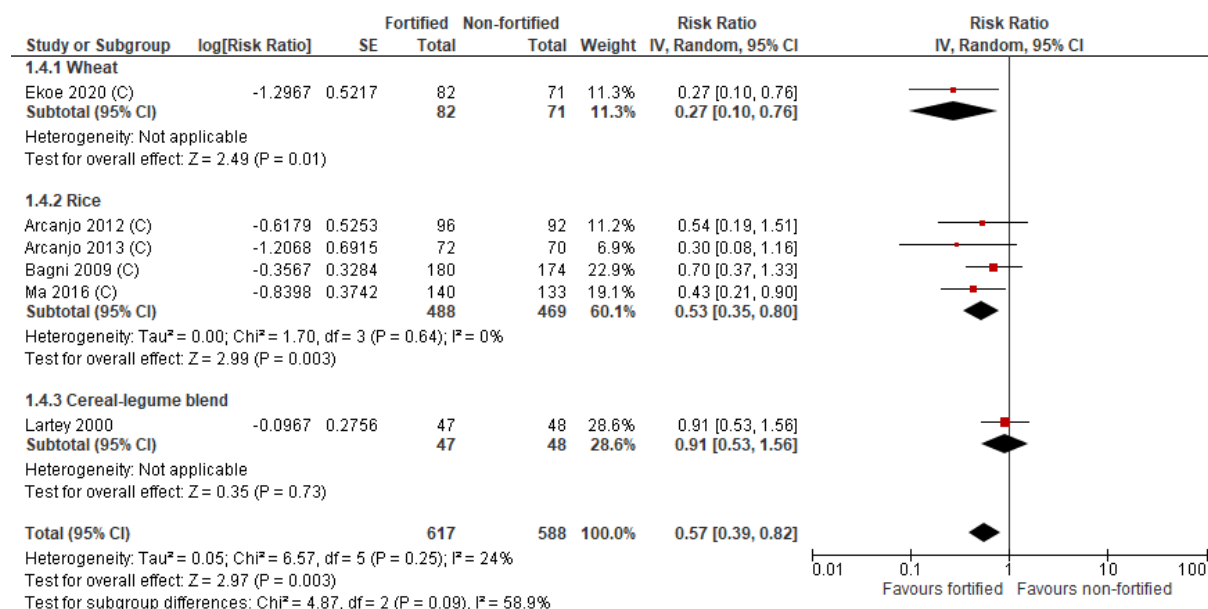
Analysis 1.2 Fortified versus non-fortified complementary food. Outcome: Anaemia by age at the start of the intervention



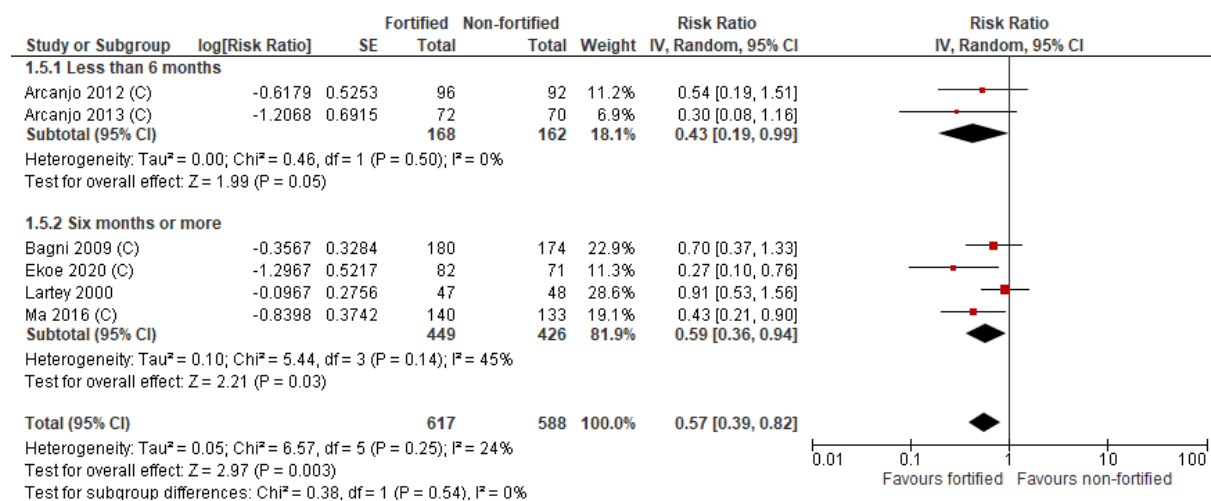
Analysis 1.3 Fortified versus non-fortified complementary food. Outcome: Anaemia by types of nutrients added through fortification



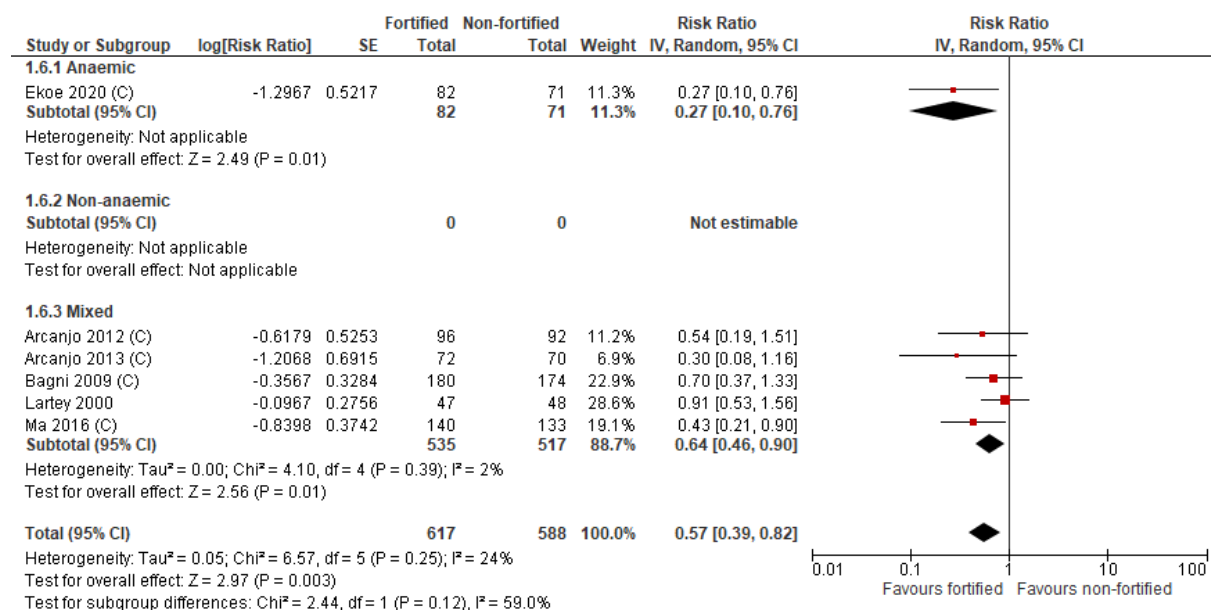
Analysis 1.4 Fortified versus non-fortified complementary food. Outcome: Anaemia by types of products fortified



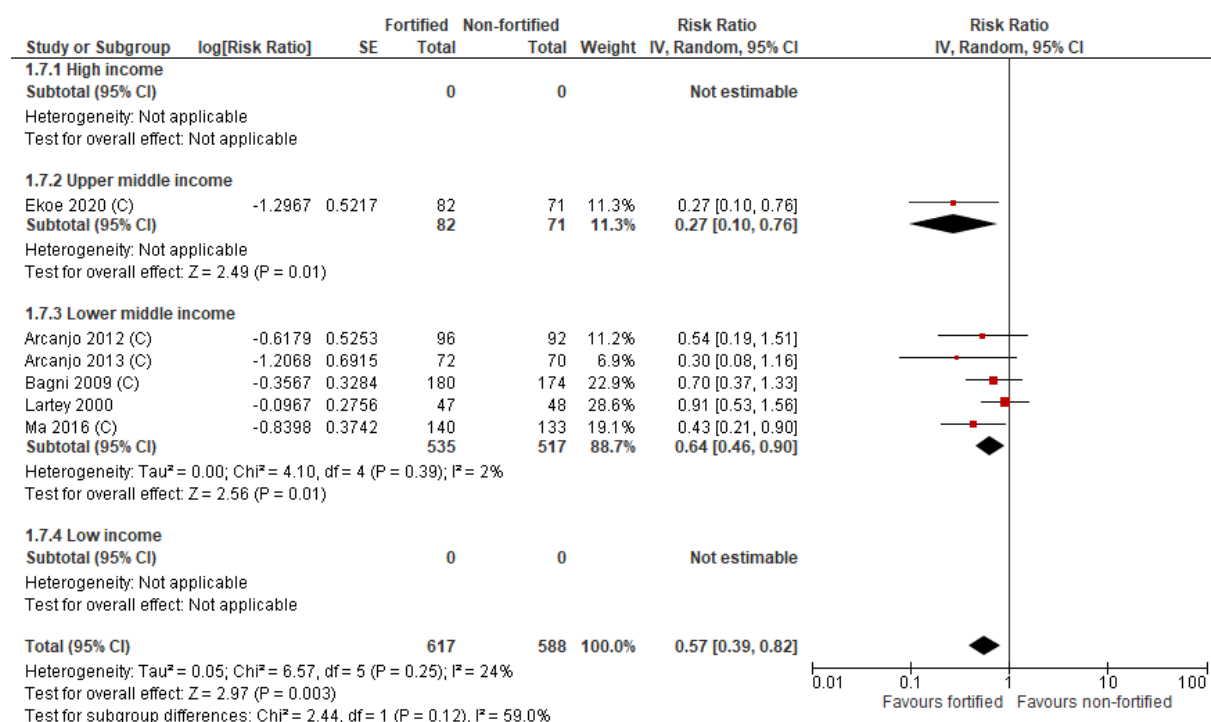
Analysis 1.5 Fortified versus non-fortified complementary food. Outcome: Anaemia by duration of intervention



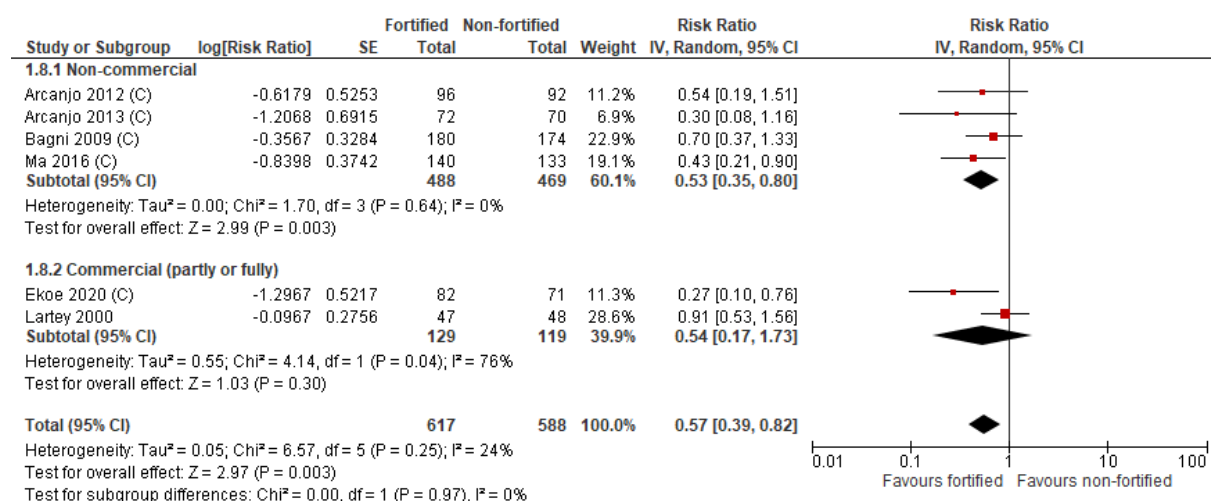
Analysis 1.6 Fortified versus non-fortified complementary food. Outcome: Anaemia by baseline anaemia status



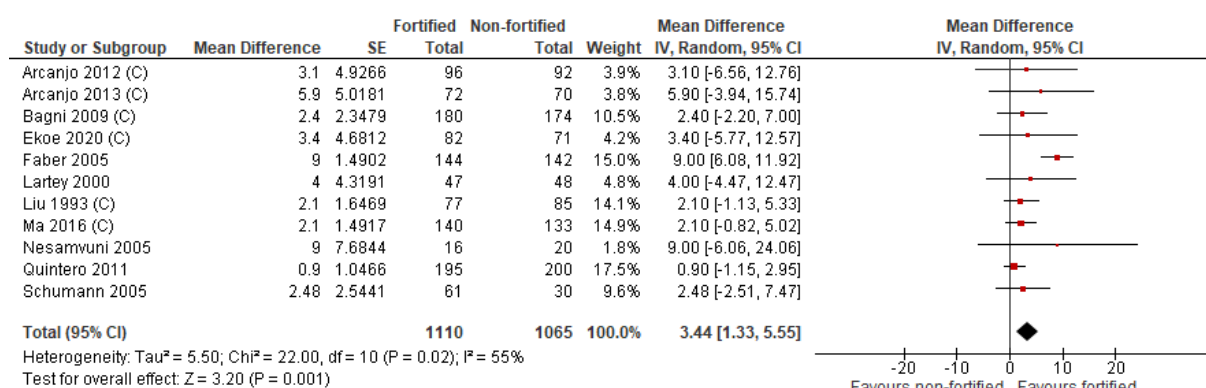
Analysis 1.7 Fortified versus non-fortified complementary food. Outcome: Anaemia by country income classification



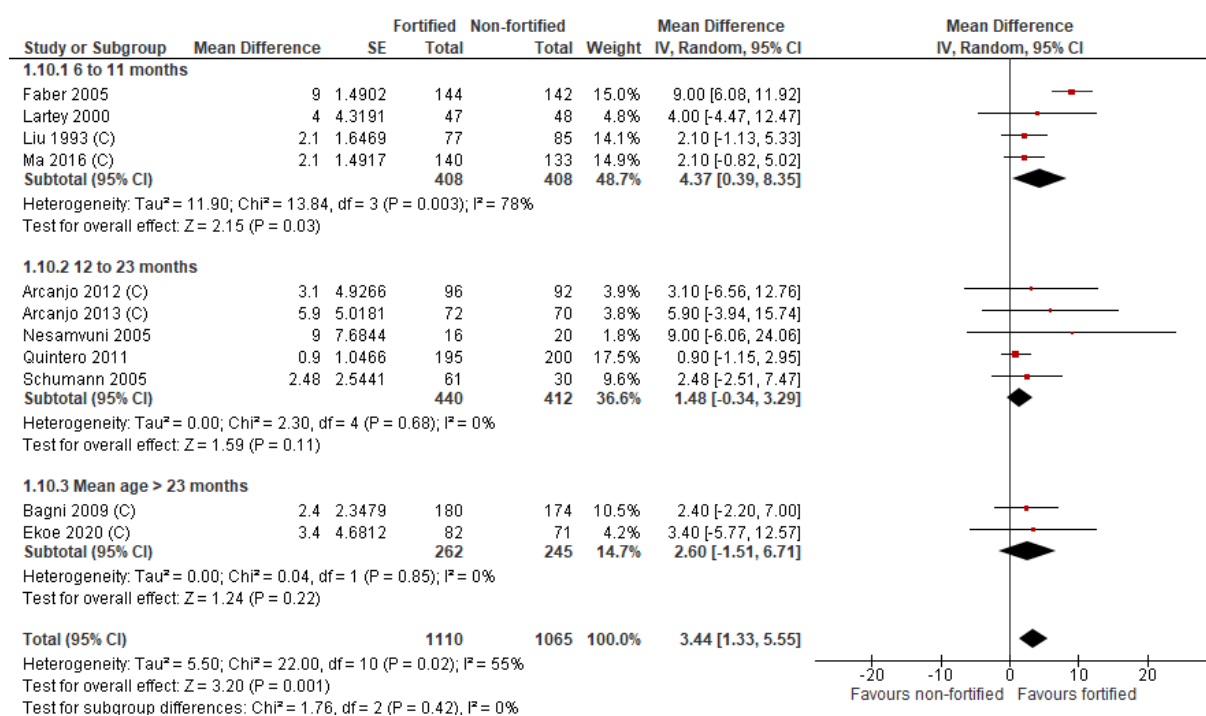
Analysis 1.8 Fortified versus non-fortified complementary food. Outcome: Anaemia by study funding



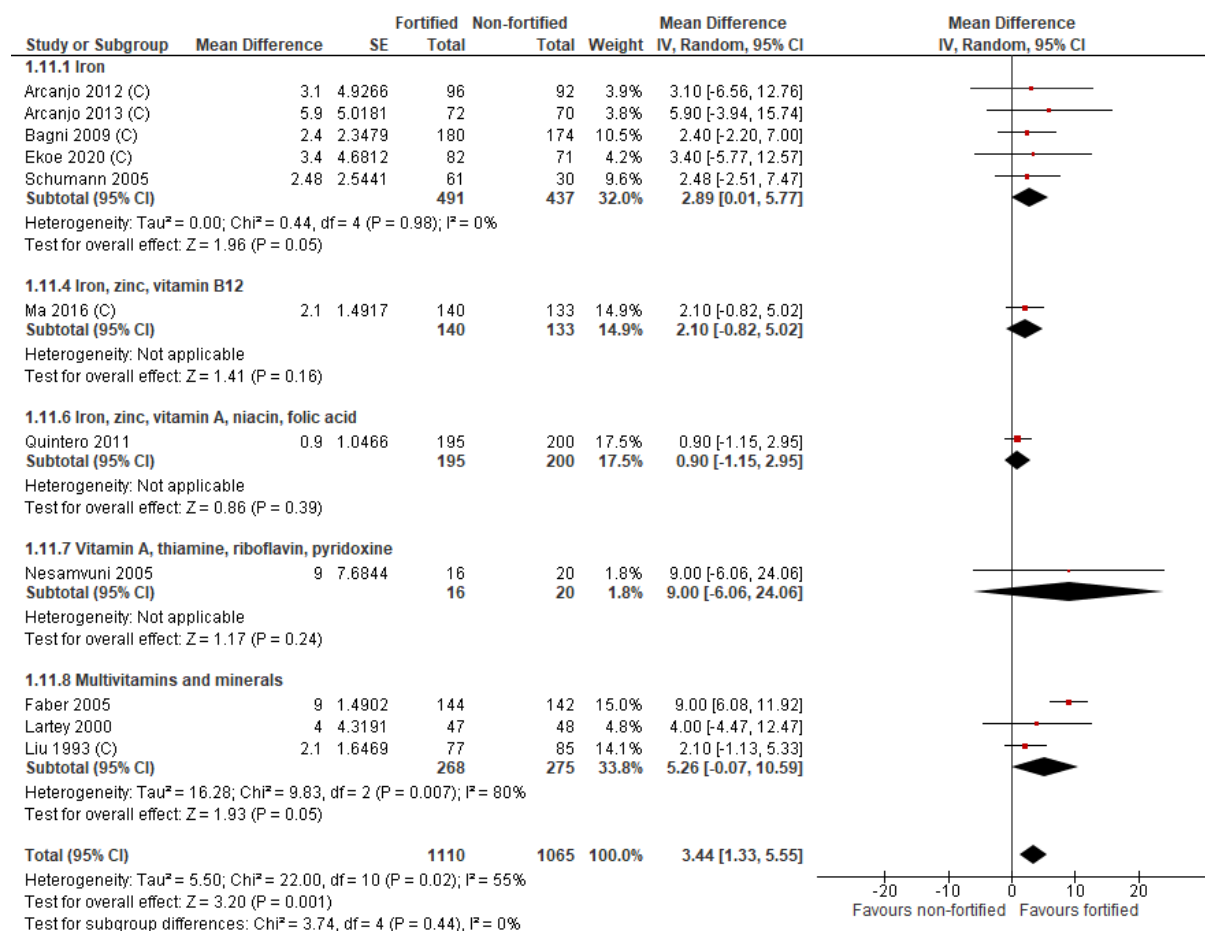
1.9 Fortified versus non-fortified complementary food. Outcome: Haemoglobin (g/L)



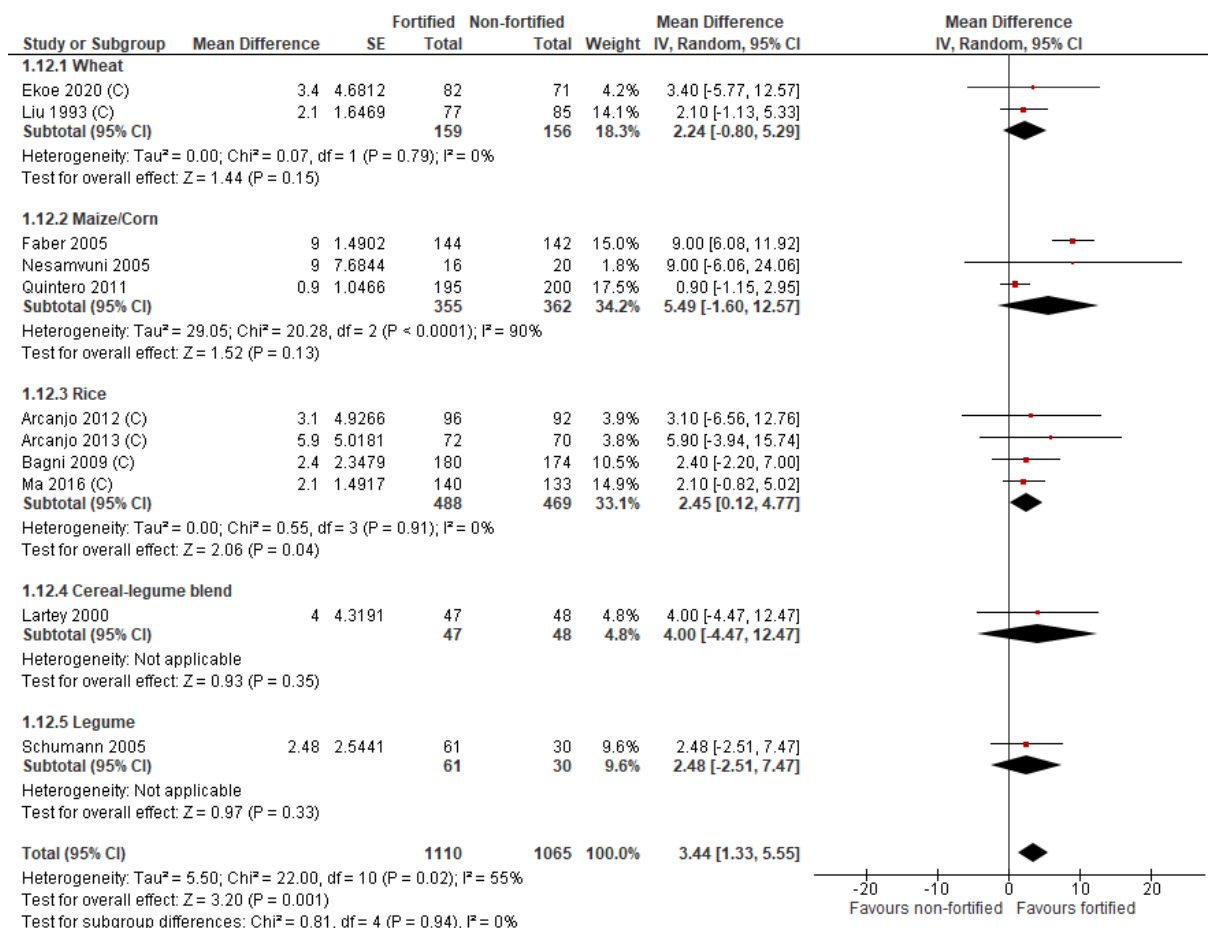
1.10 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by age at the start of the intervention



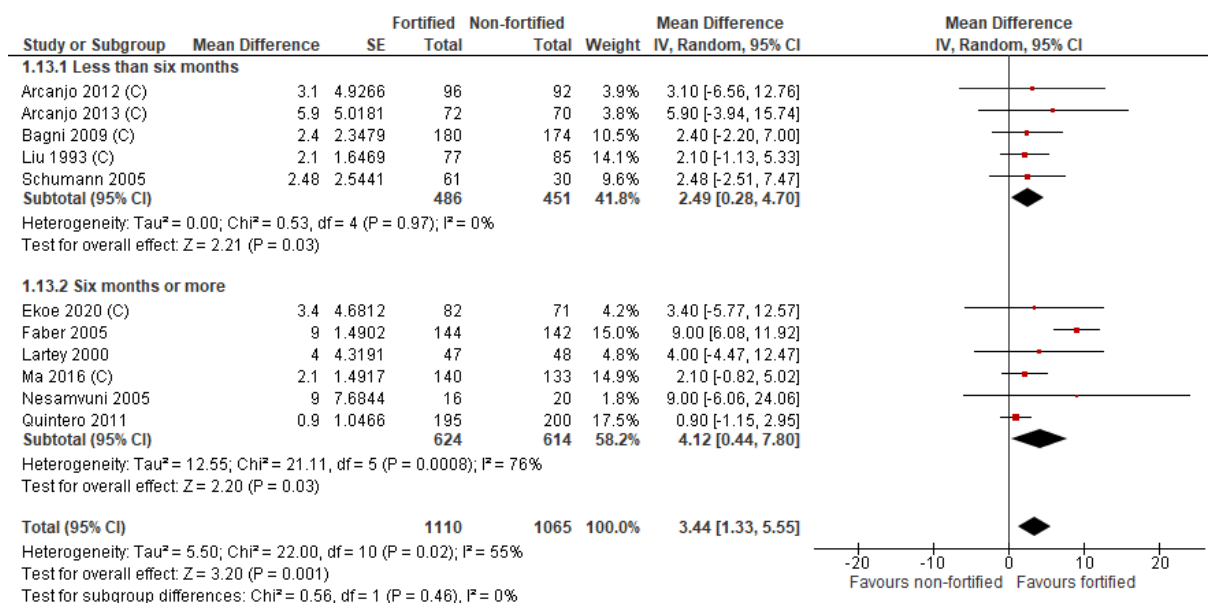
1.11 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by types of nutrients added through fortification



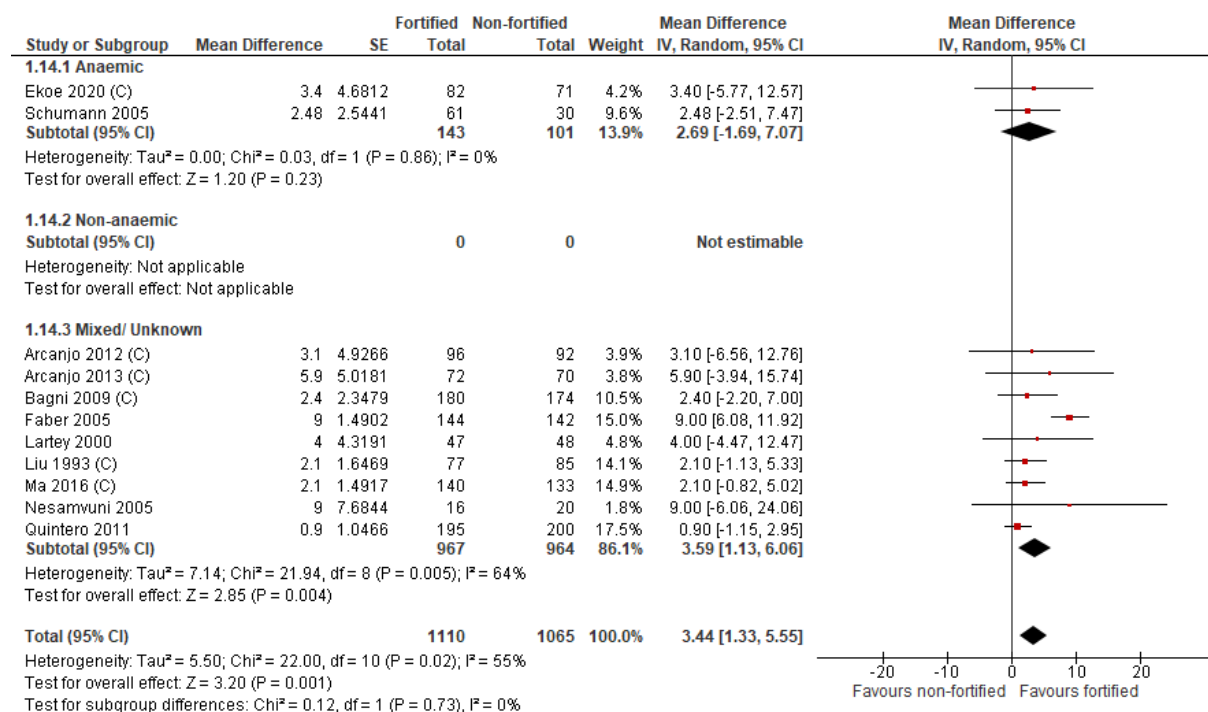
1.12 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by types of products fortified



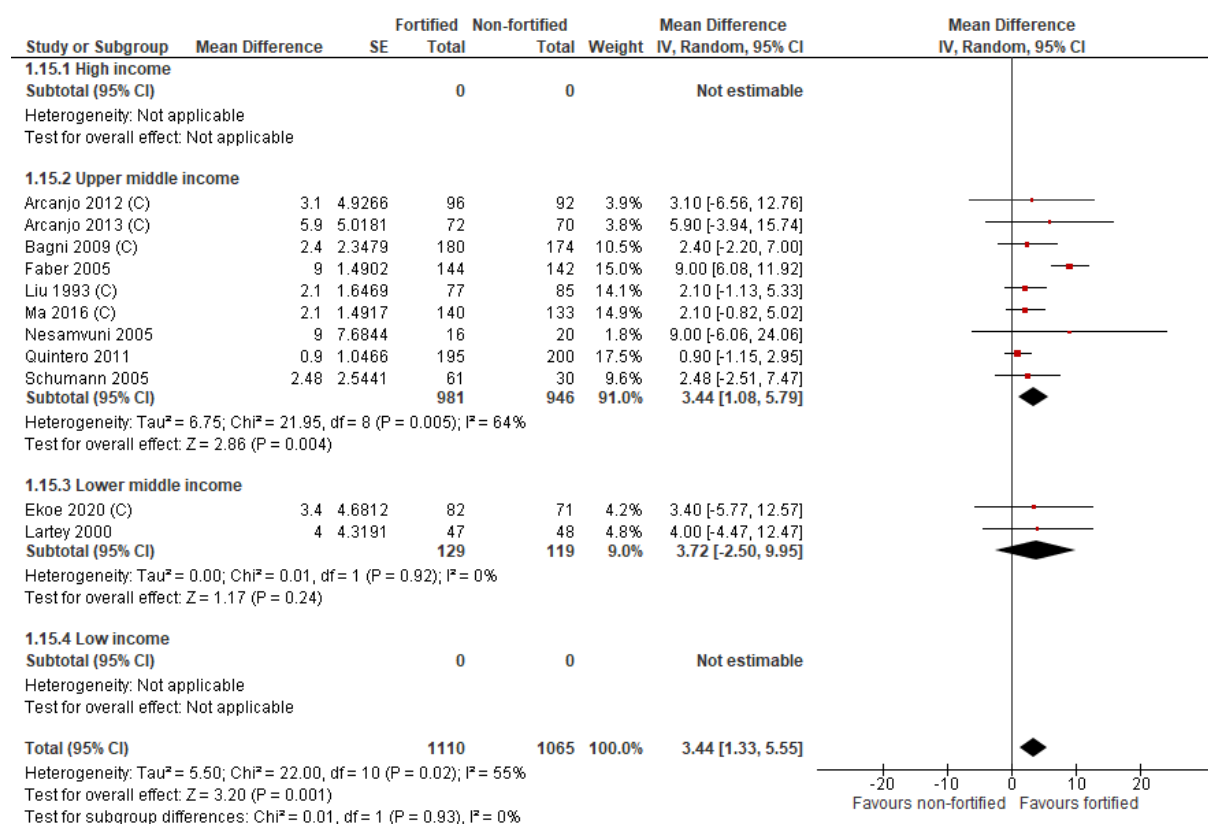
1.13 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by duration of intervention



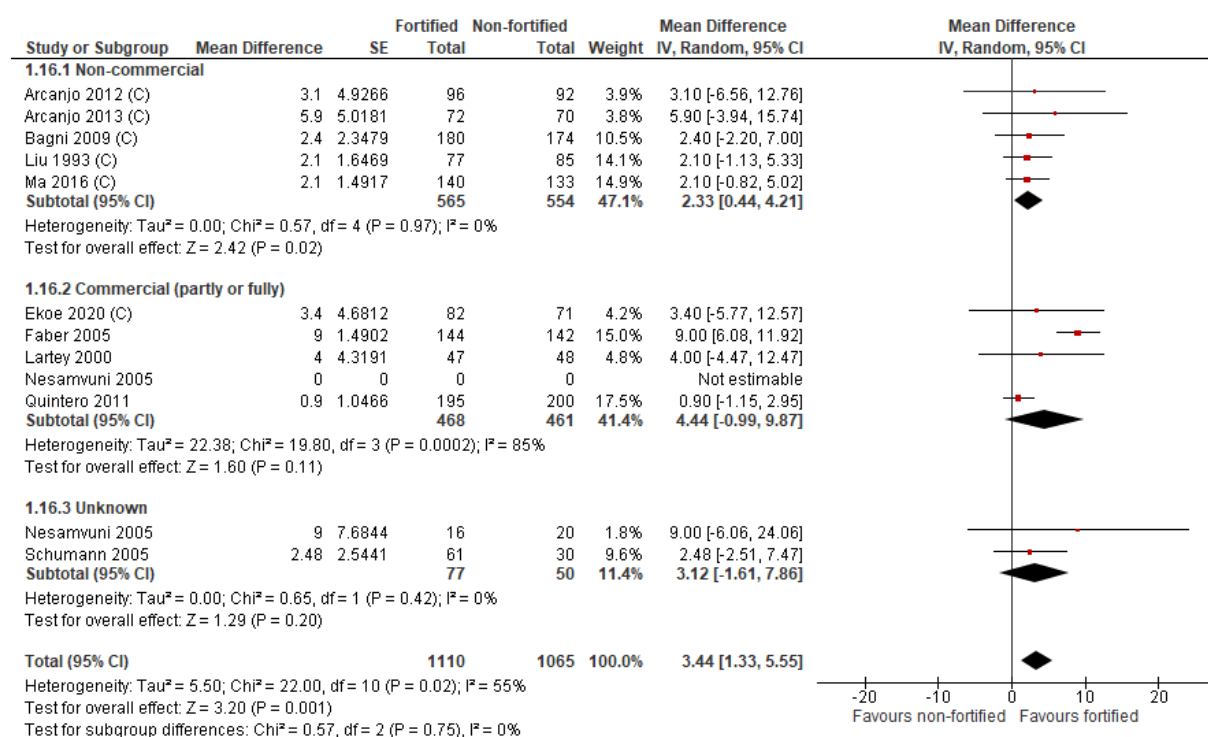
1.14 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by baseline anaemia status



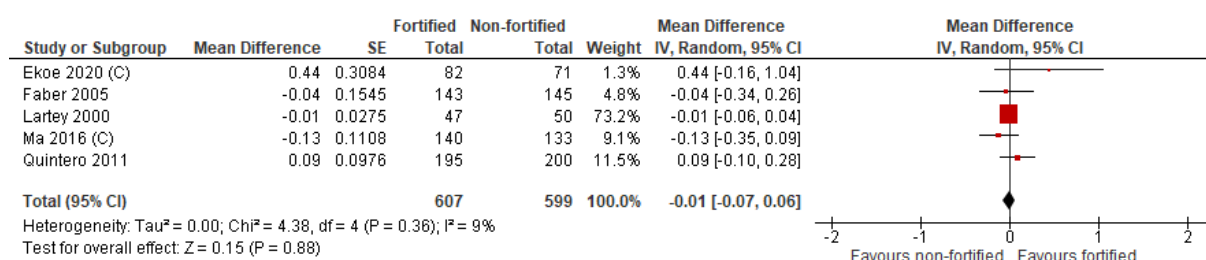
1.15 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by country income classification



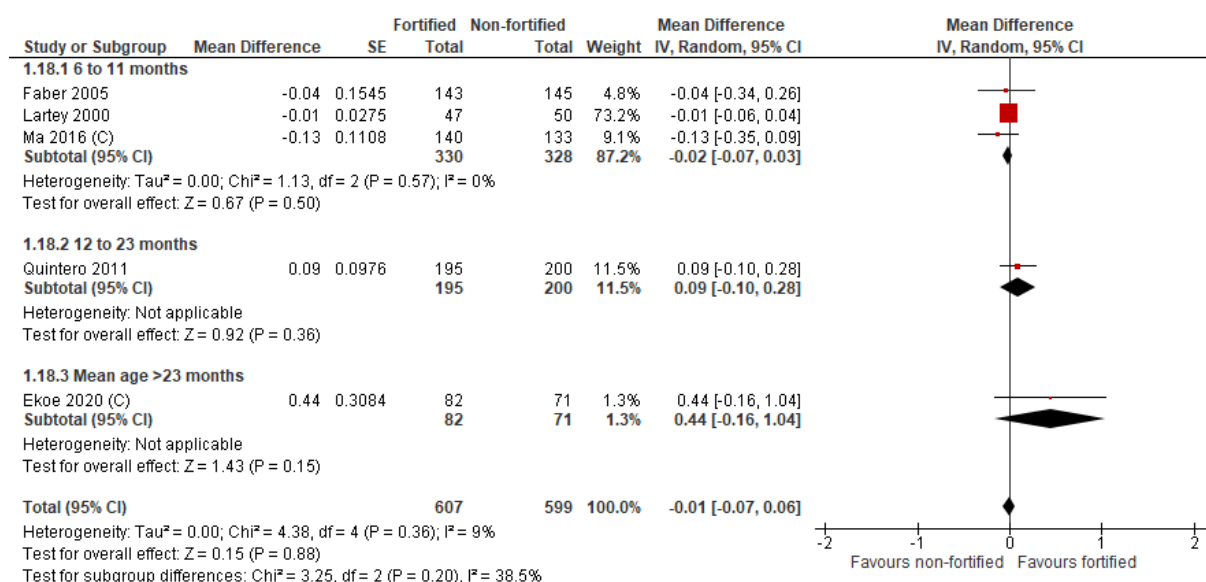
1.16 Fortified versus non-fortified complementary food. Outcome: Haemoglobin by study funding



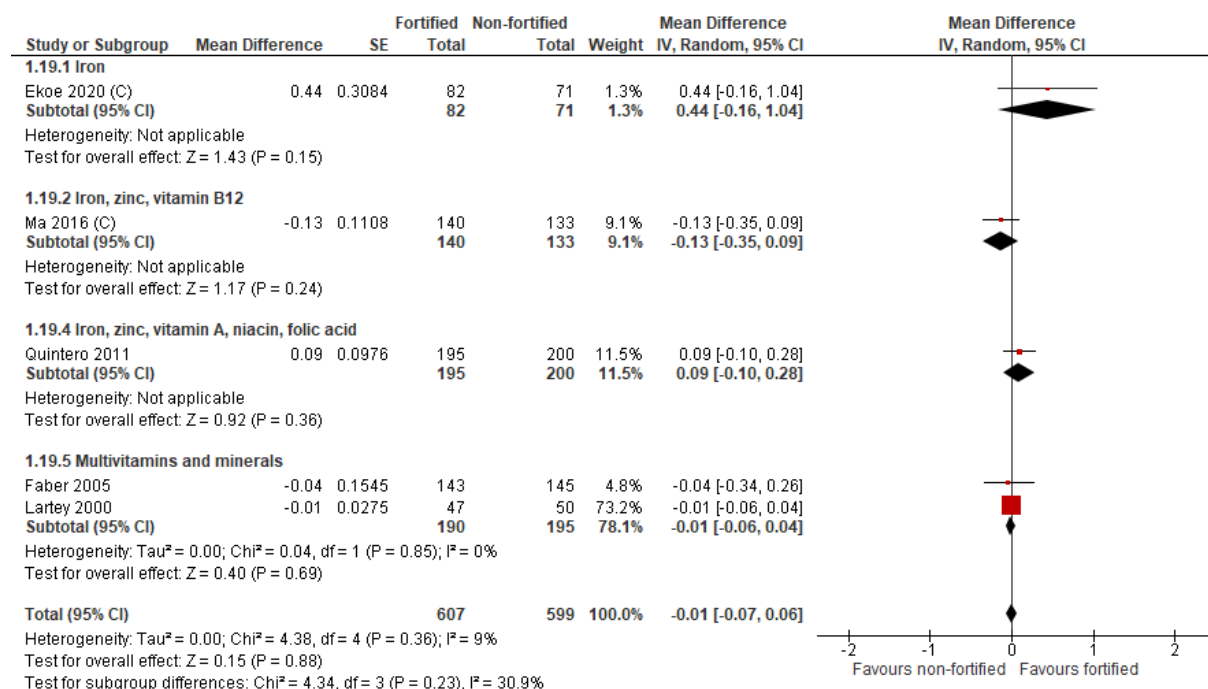
1.17 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores)



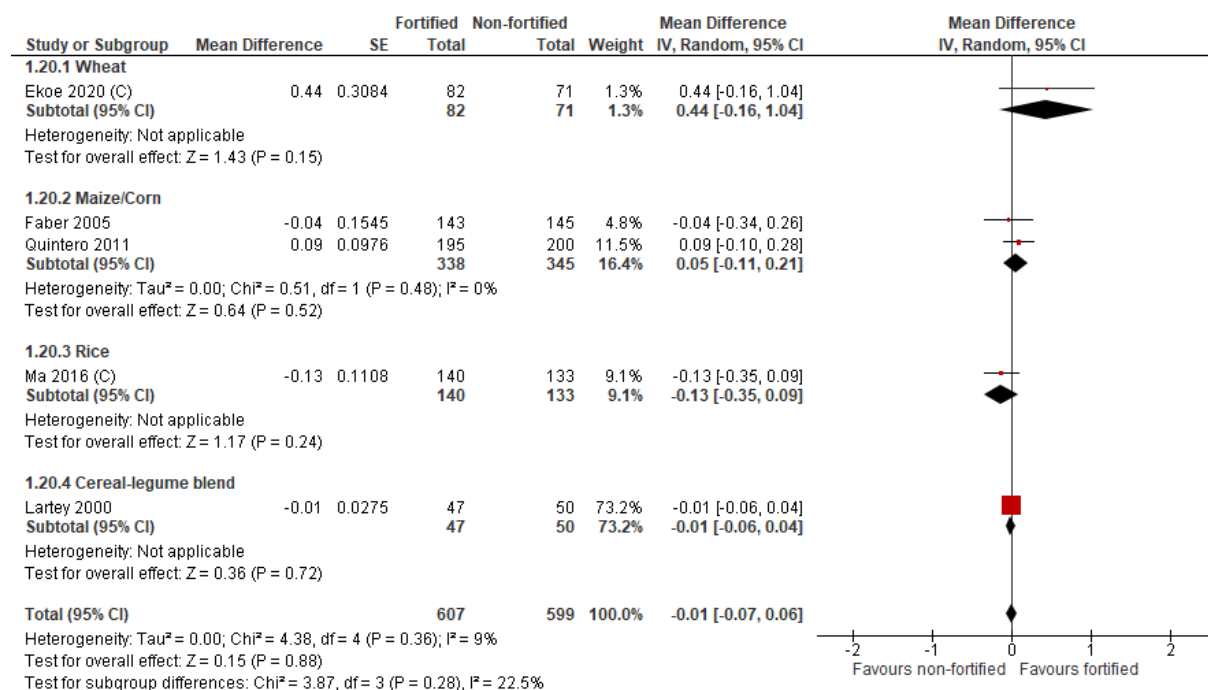
1.18 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by age at the start of the intervention



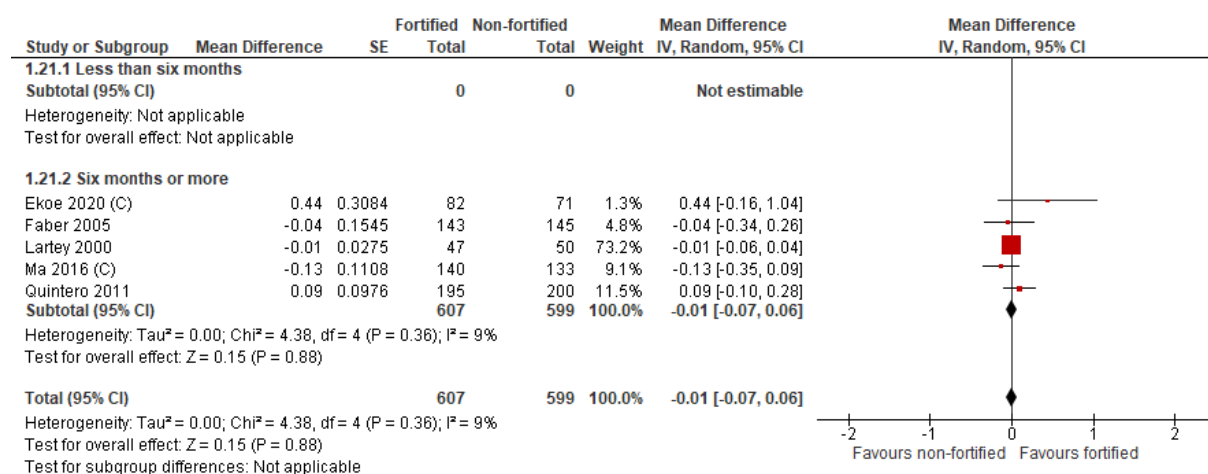
1.19 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by types of nutrients added through fortification



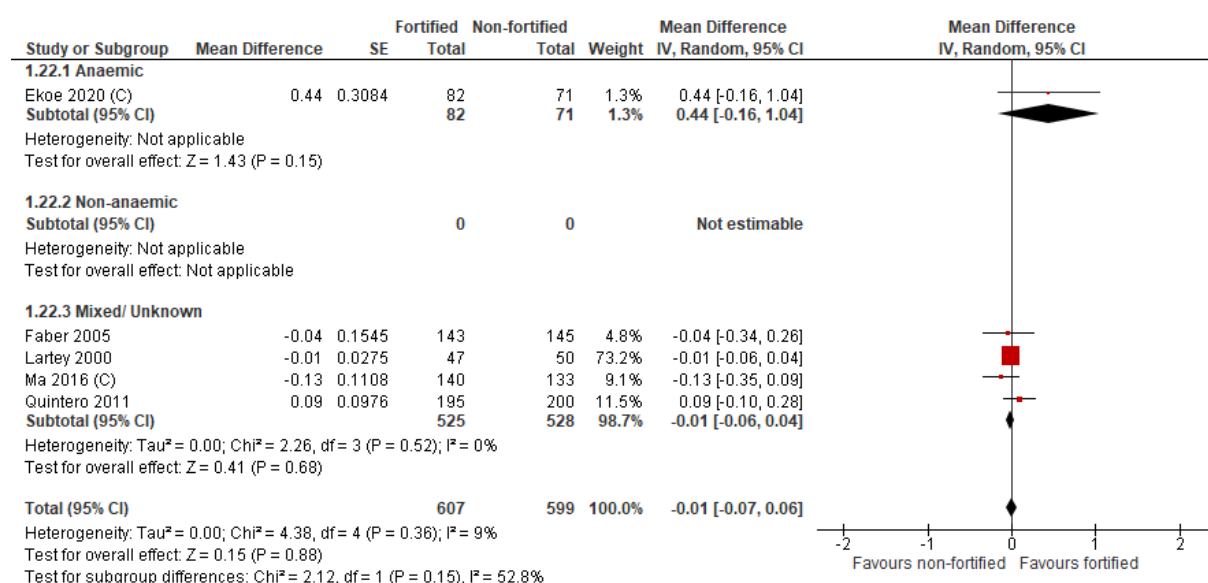
1.20 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by types of products fortified



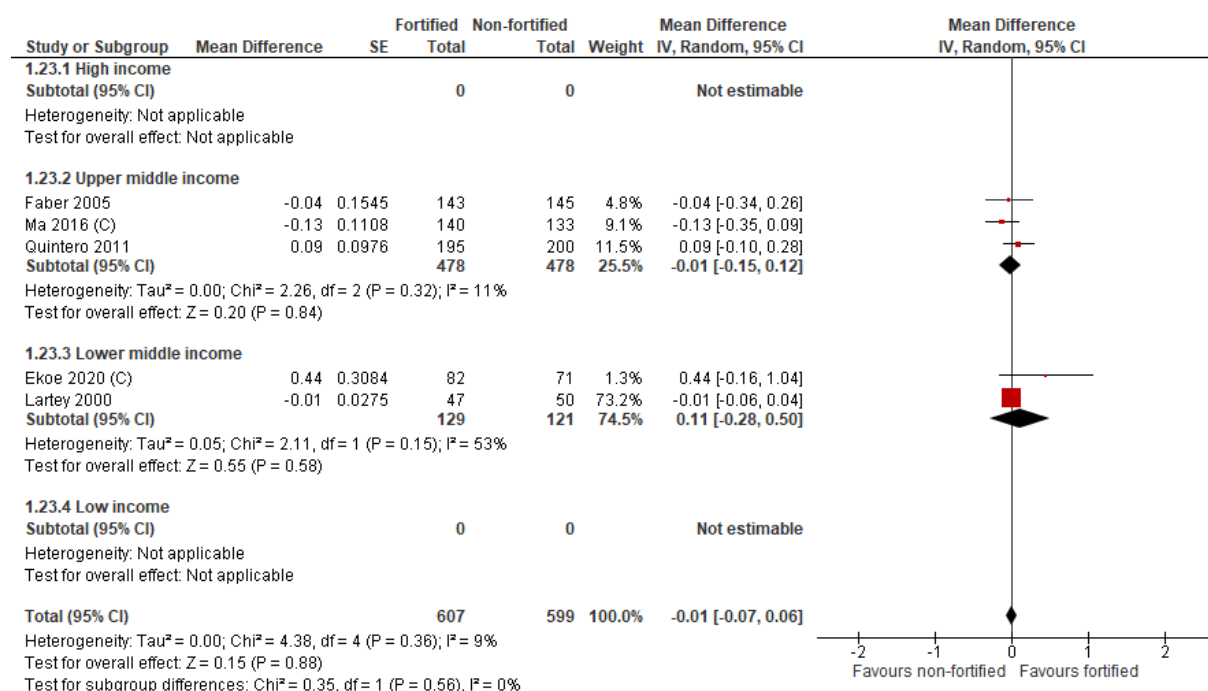
1.21 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by duration of intervention



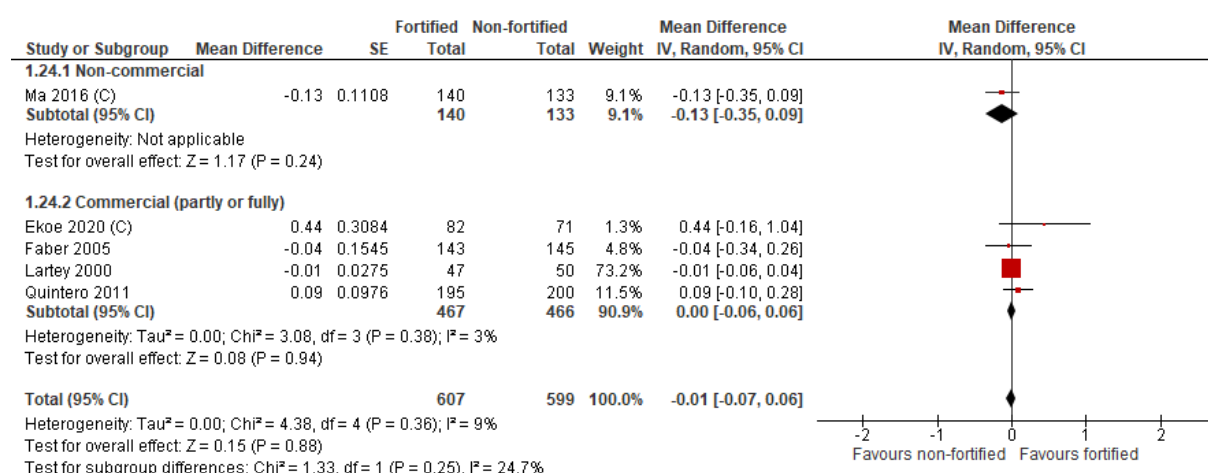
1.22 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by baseline anaemia status



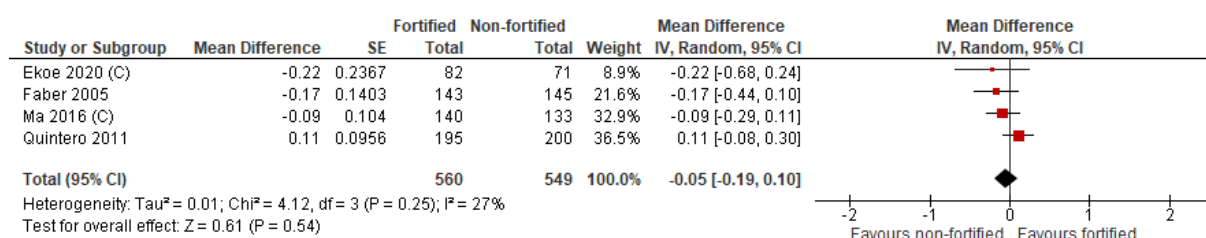
1.23 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by country income classification



1.24 Fortified versus non-fortified complementary food. Outcome: Weight-for-age (in z-scores) by study funding

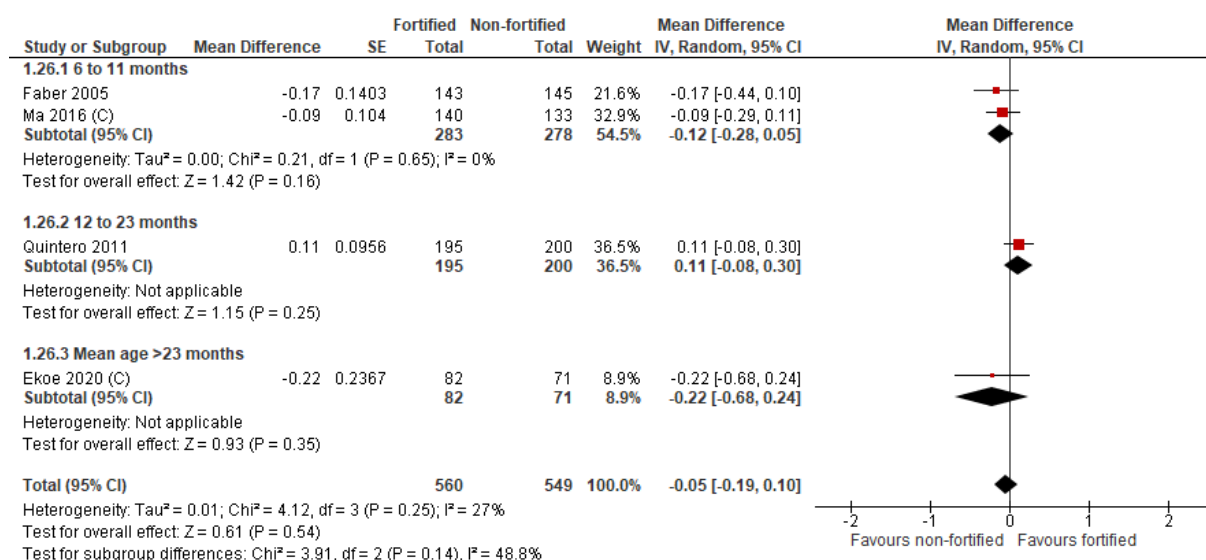


1.25 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)



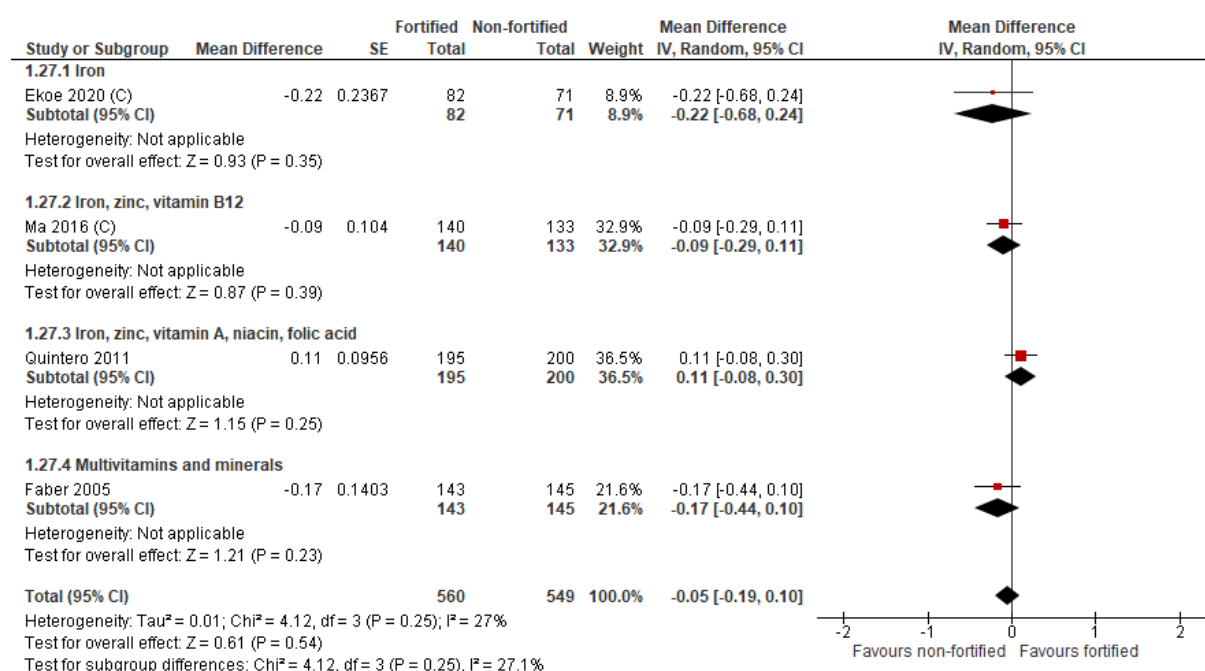
1.26 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by age at the start of the intervention



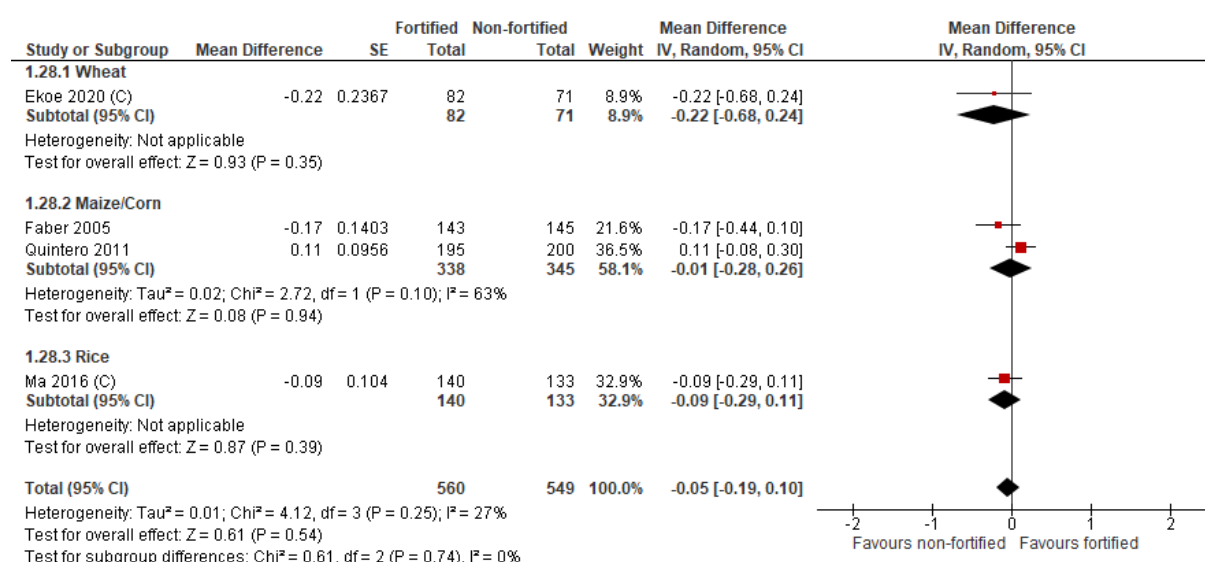
1.27 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by types of nutrients added through fortification



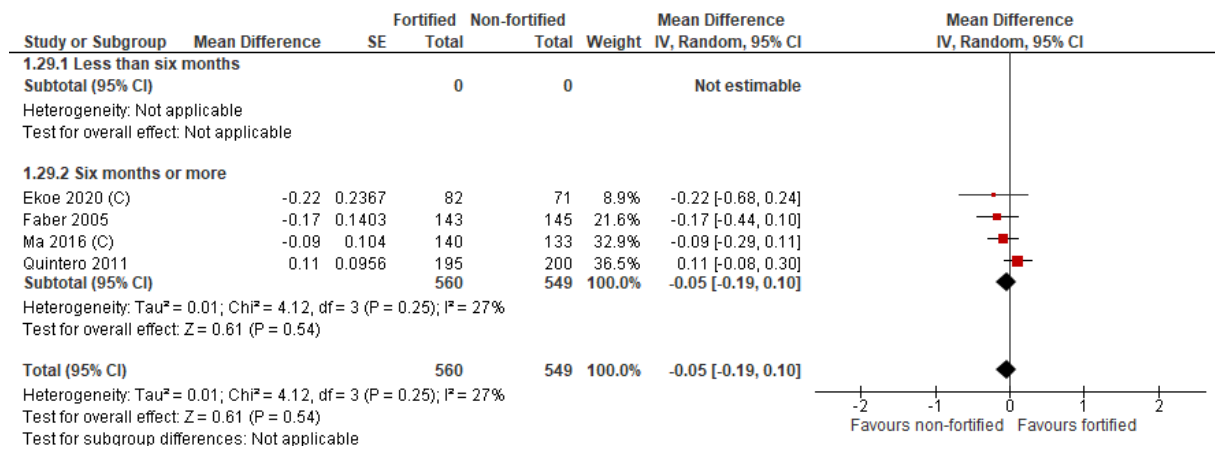
1.28 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by types of products fortified



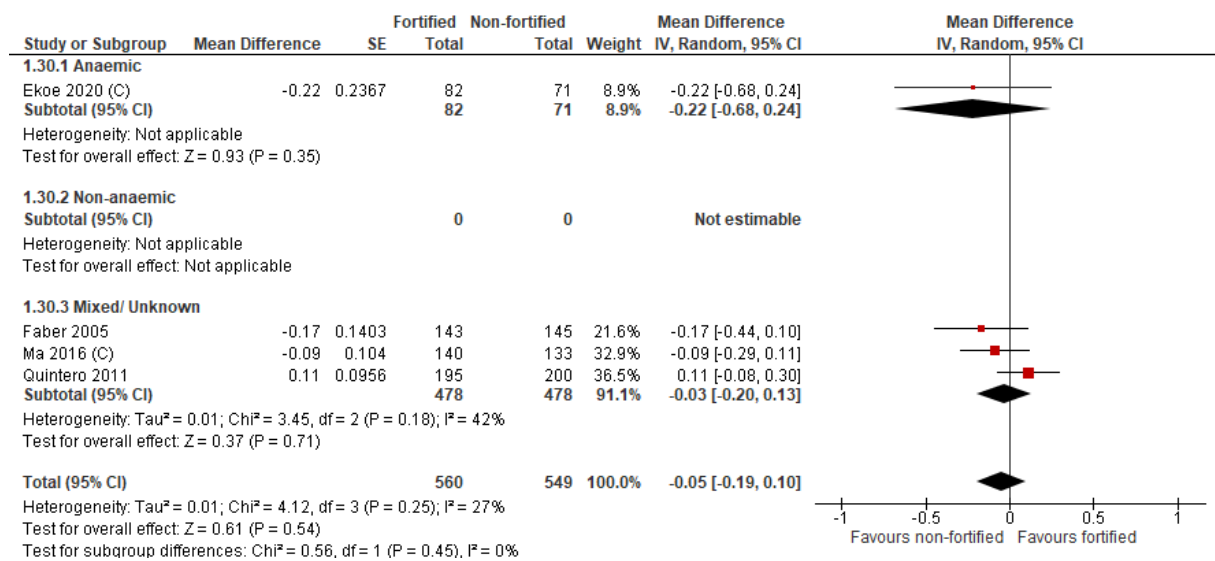
1.29 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by duration of intervention



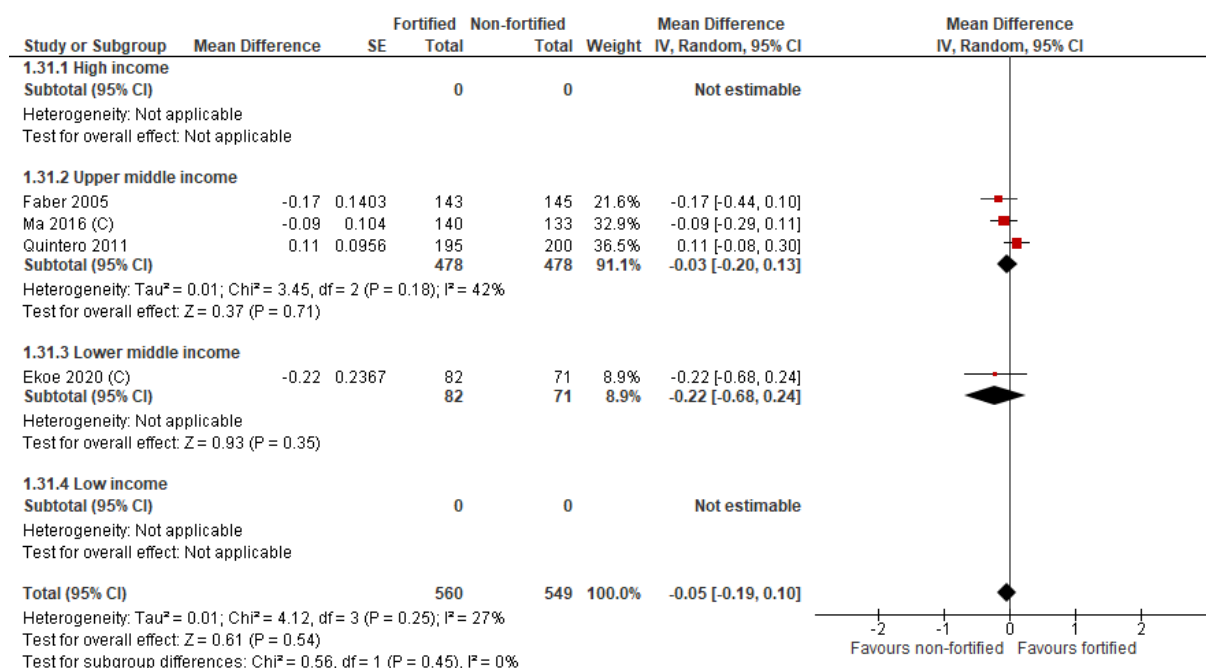
1.30 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by baseline anaemia status



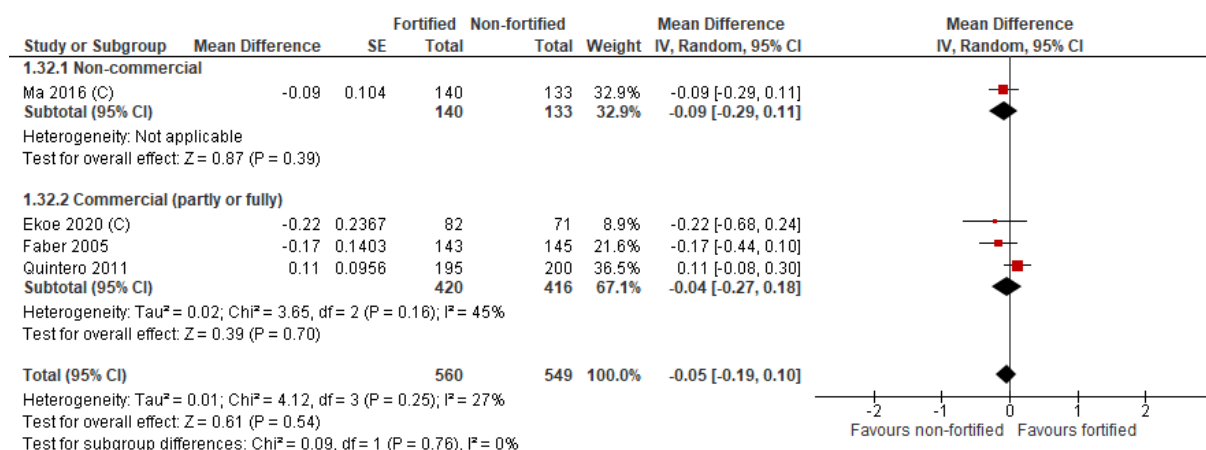
1.31 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

by country income classification

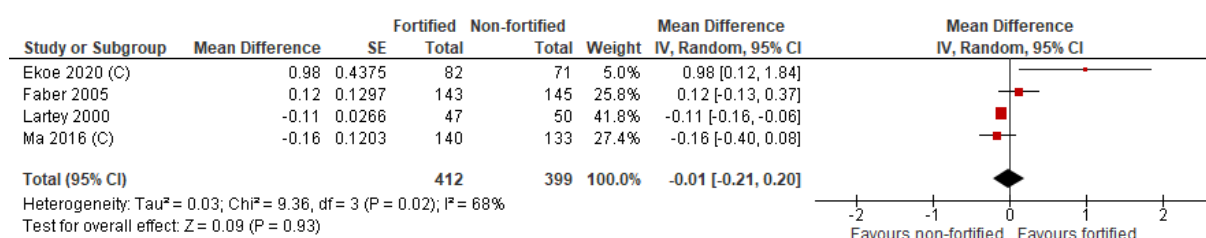


1.32 Fortified versus non-fortified complementary food. Outcome: Weight-for-length (in z-scores)

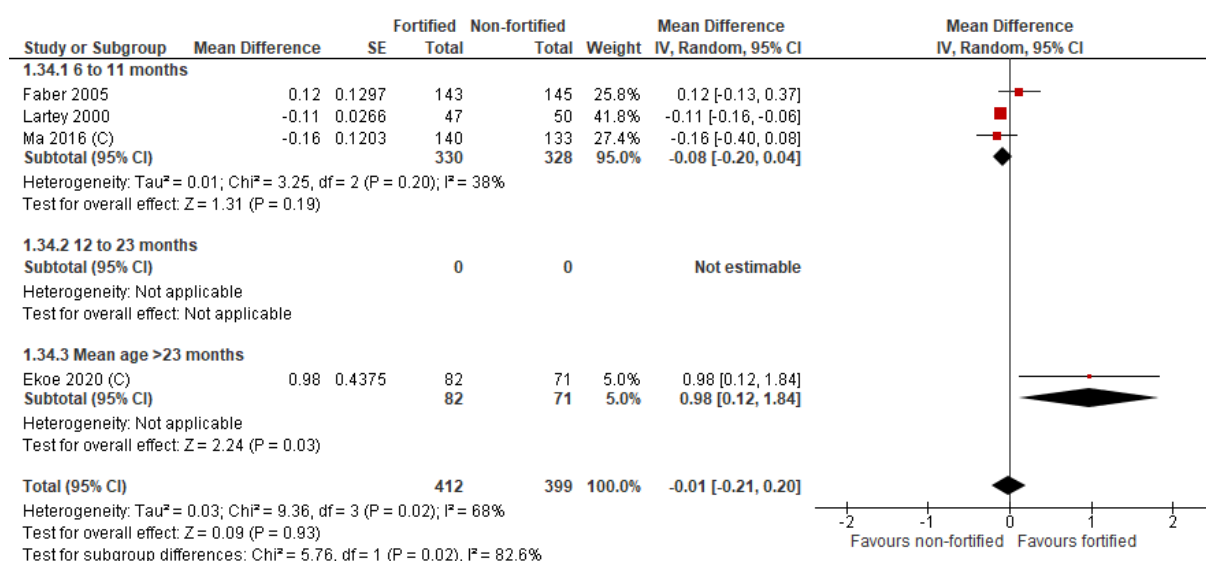
by study funding



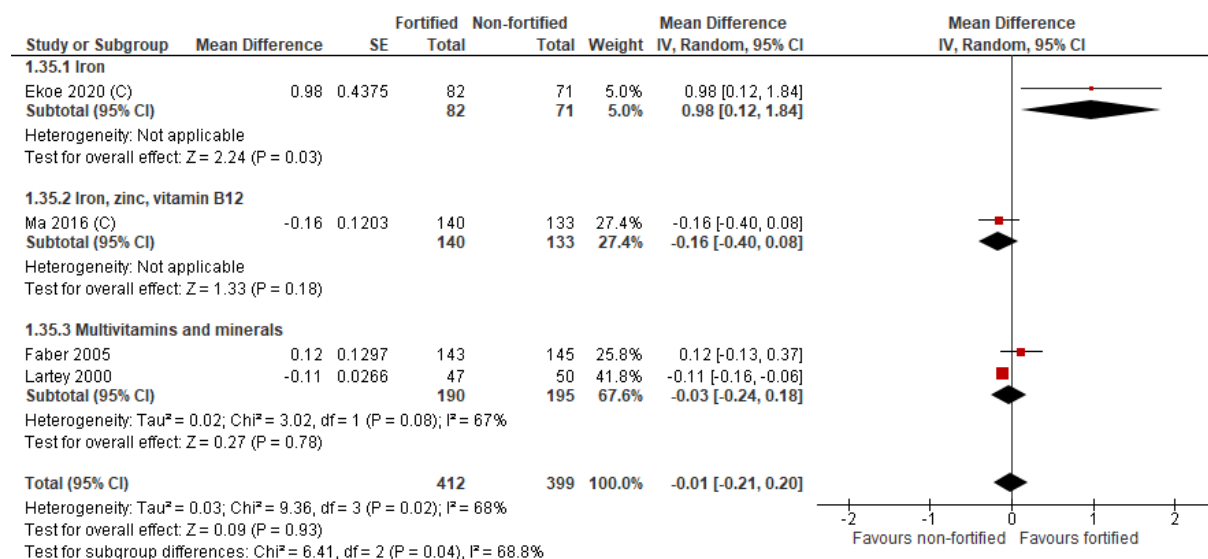
1.33 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores)



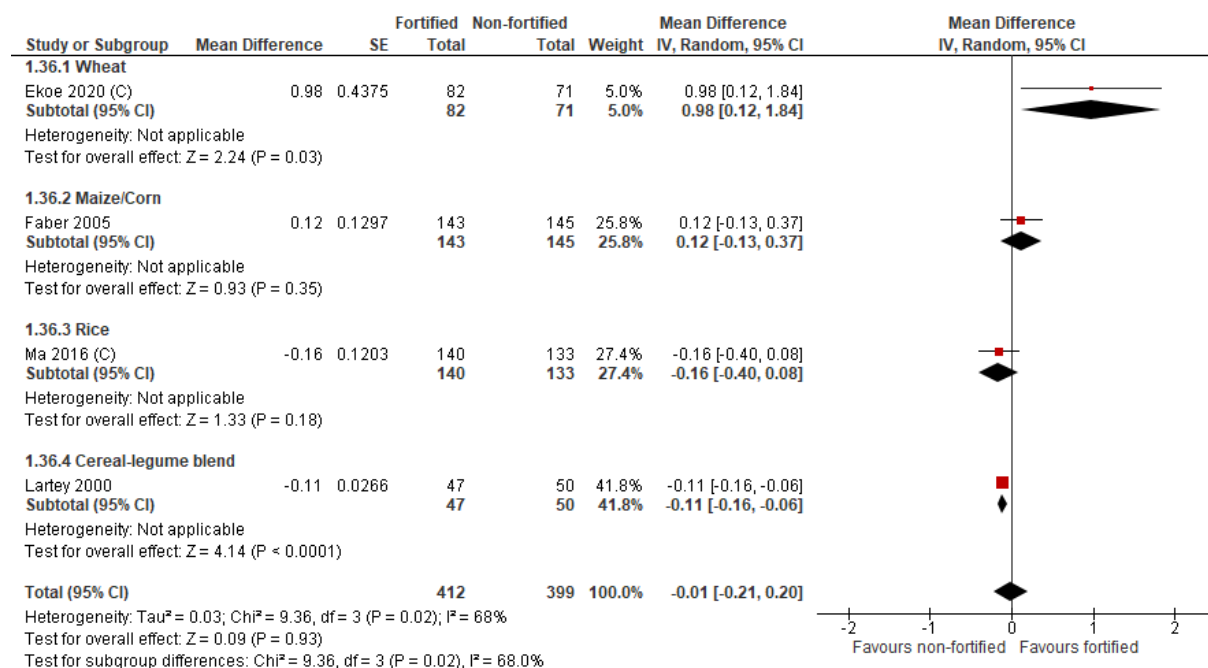
1.34 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by age at the start of the intervention



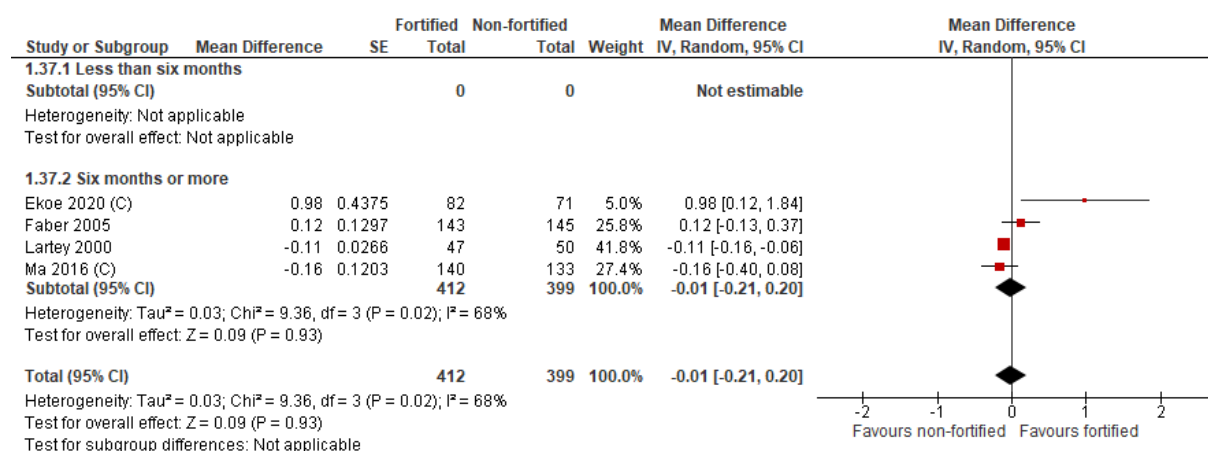
1.35 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by types of nutrients added through fortification



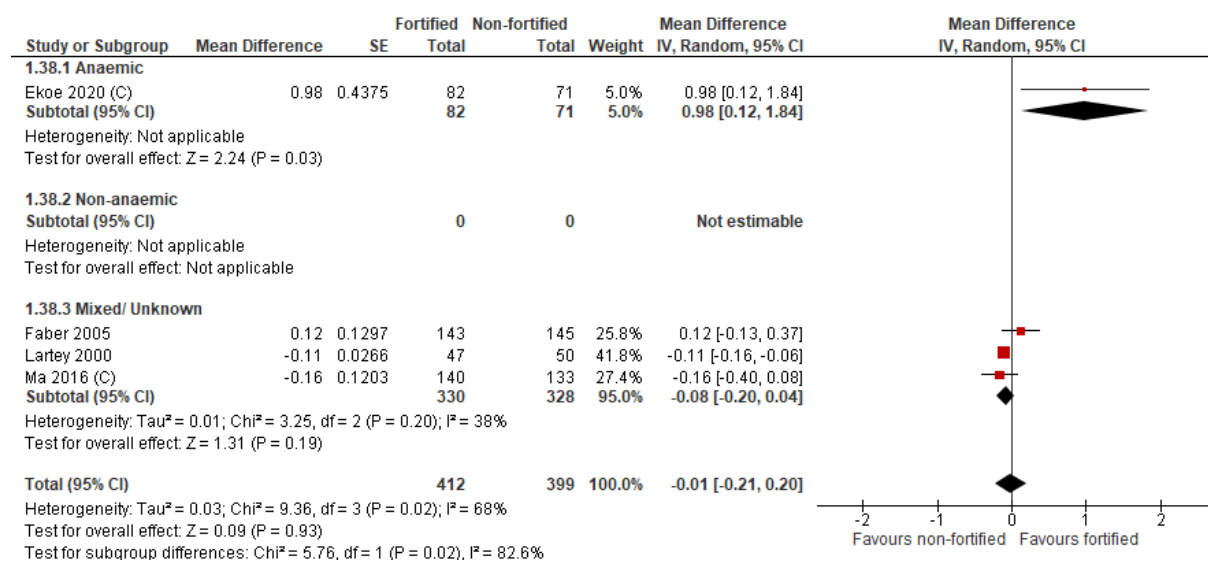
1.36 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by types of products fortified



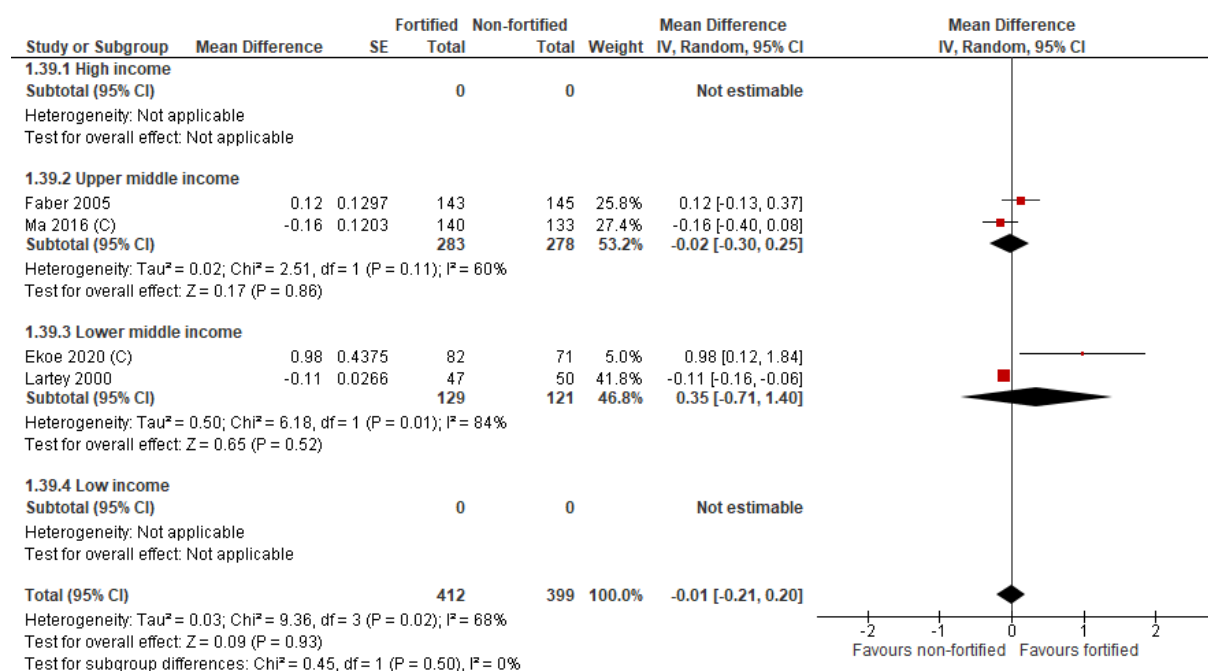
1.37 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by duration of intervention



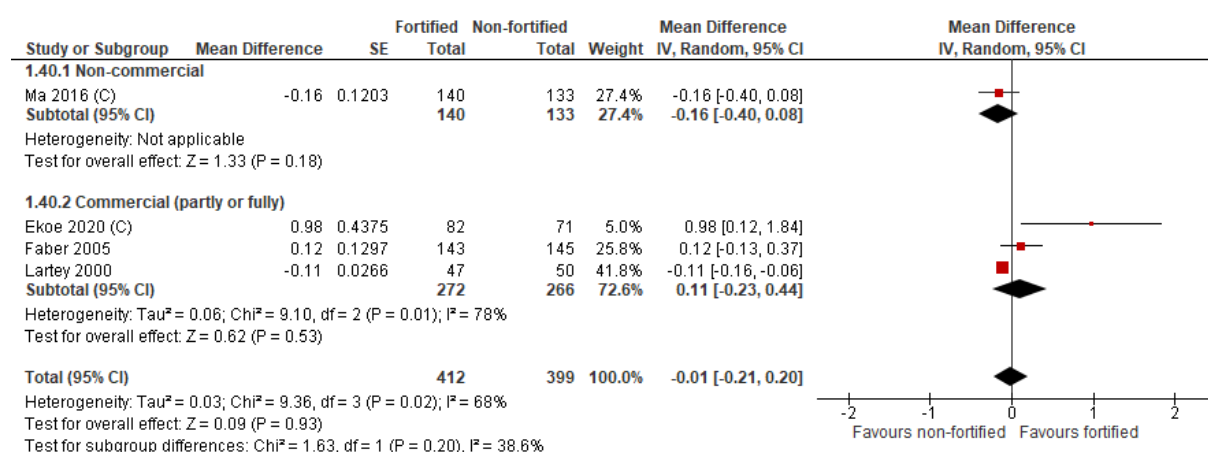
1.38 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by baseline anaemia status



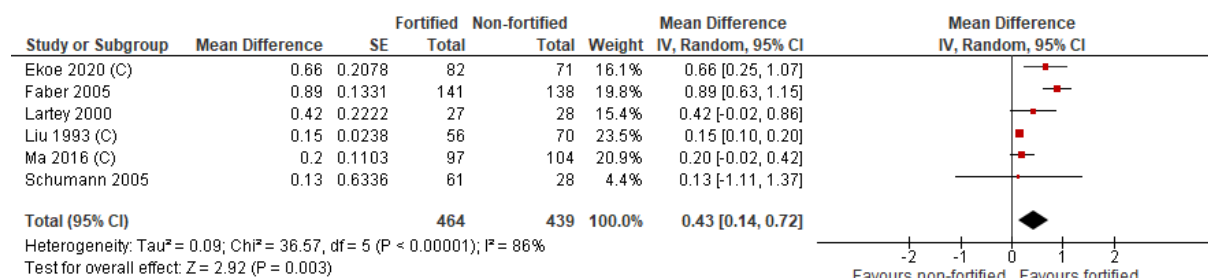
1.39 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by country income classification



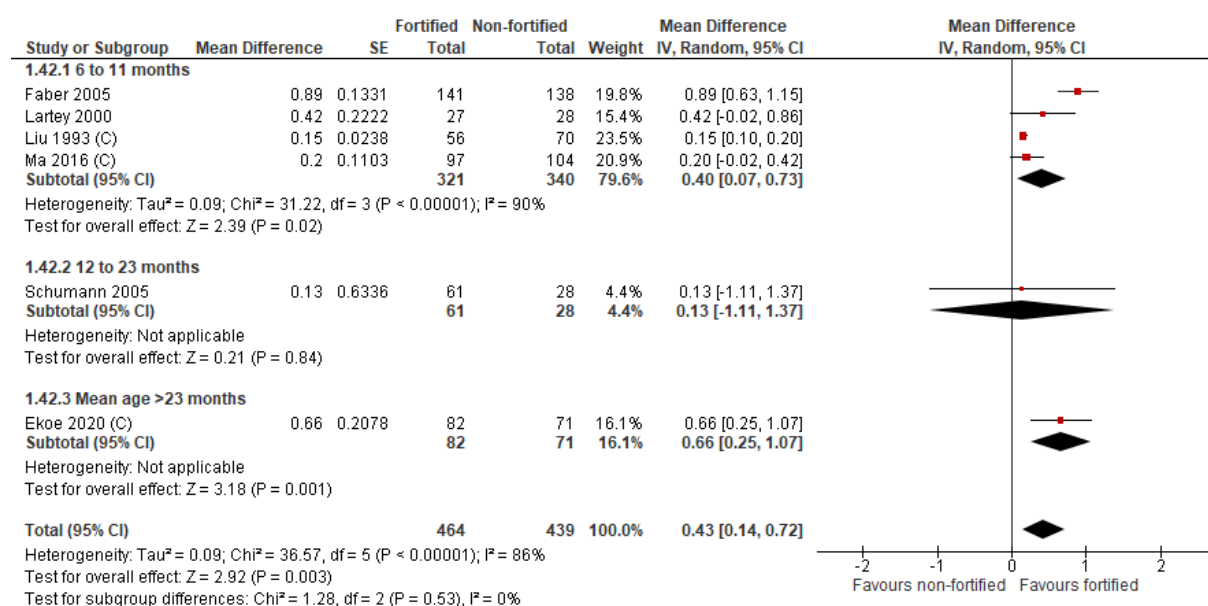
1.40 Fortified versus non-fortified complementary food. Outcome: Length-for-age (in z-scores) by study funding



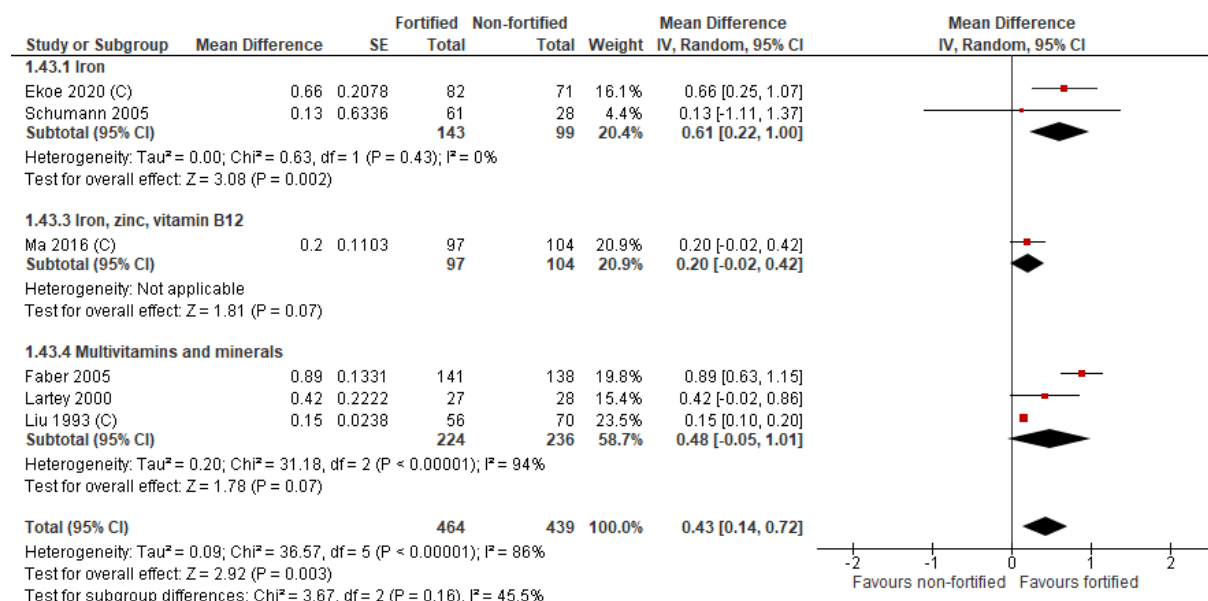
1.41. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin concentrations in µg/L)



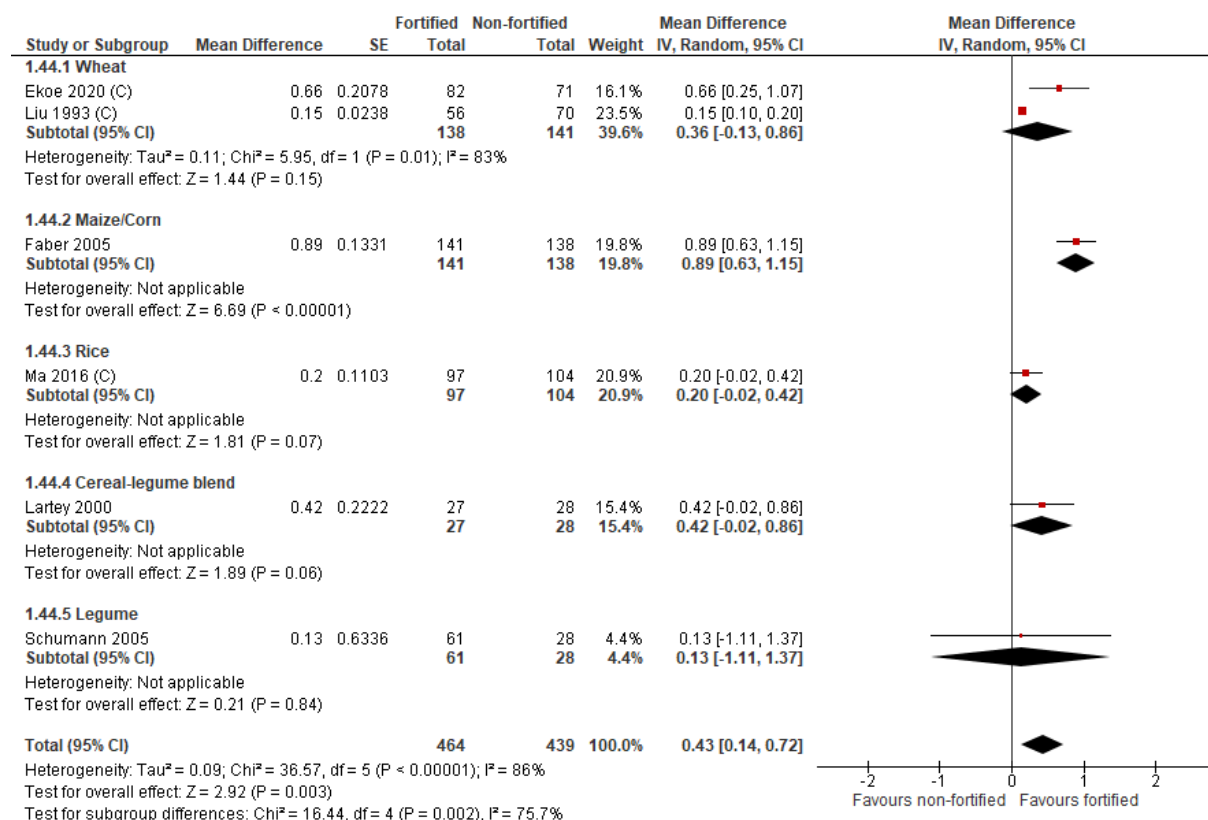
1.42. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by age at start of the intervention



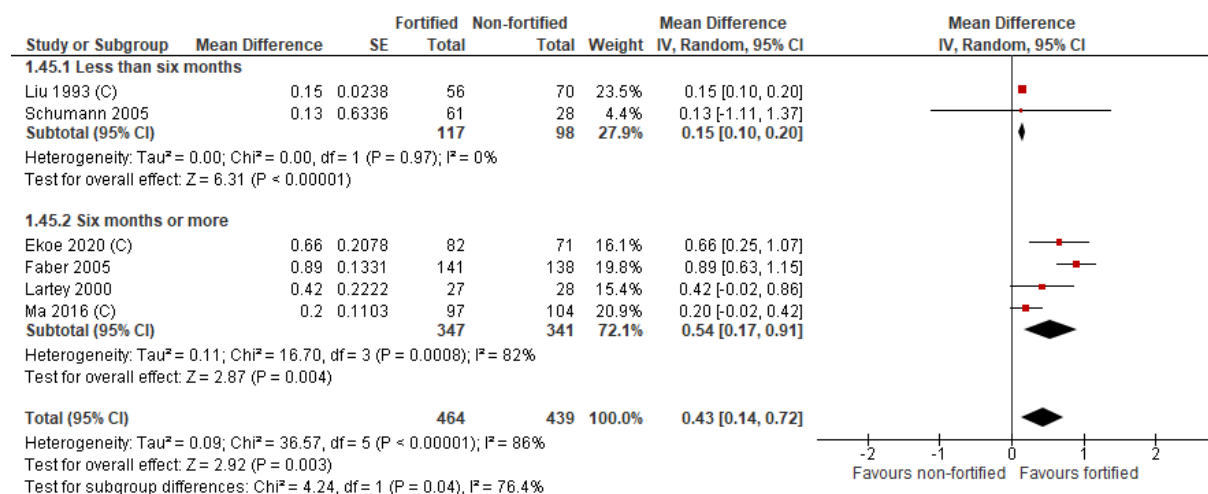
1.43. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by types of nutrients added through fortification



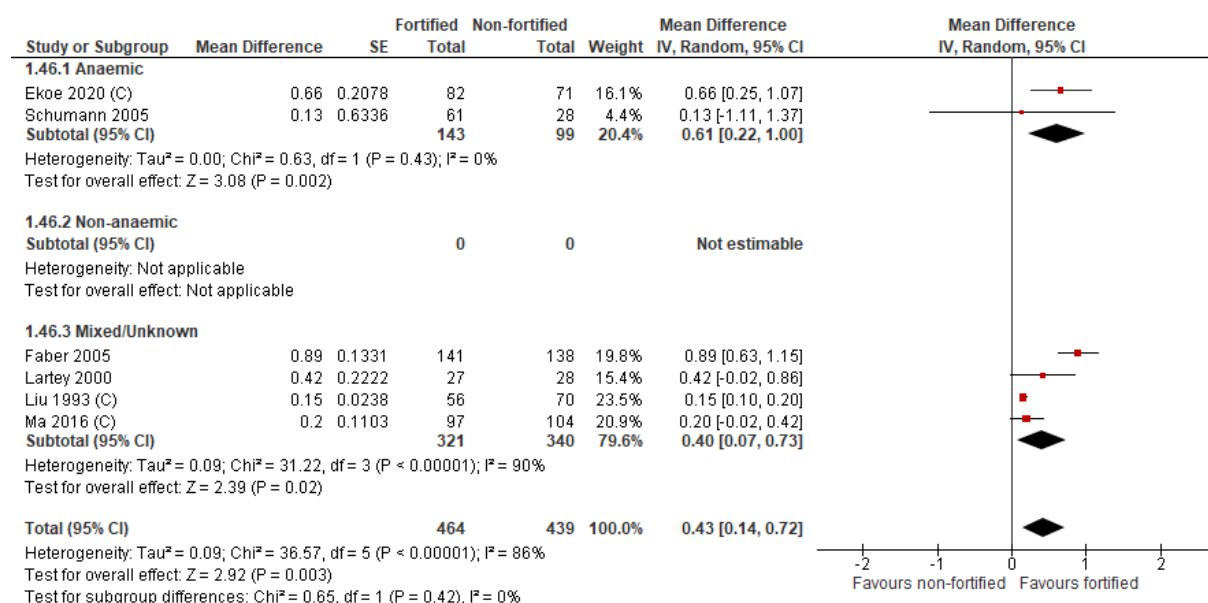
1.44. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by types of products fortified



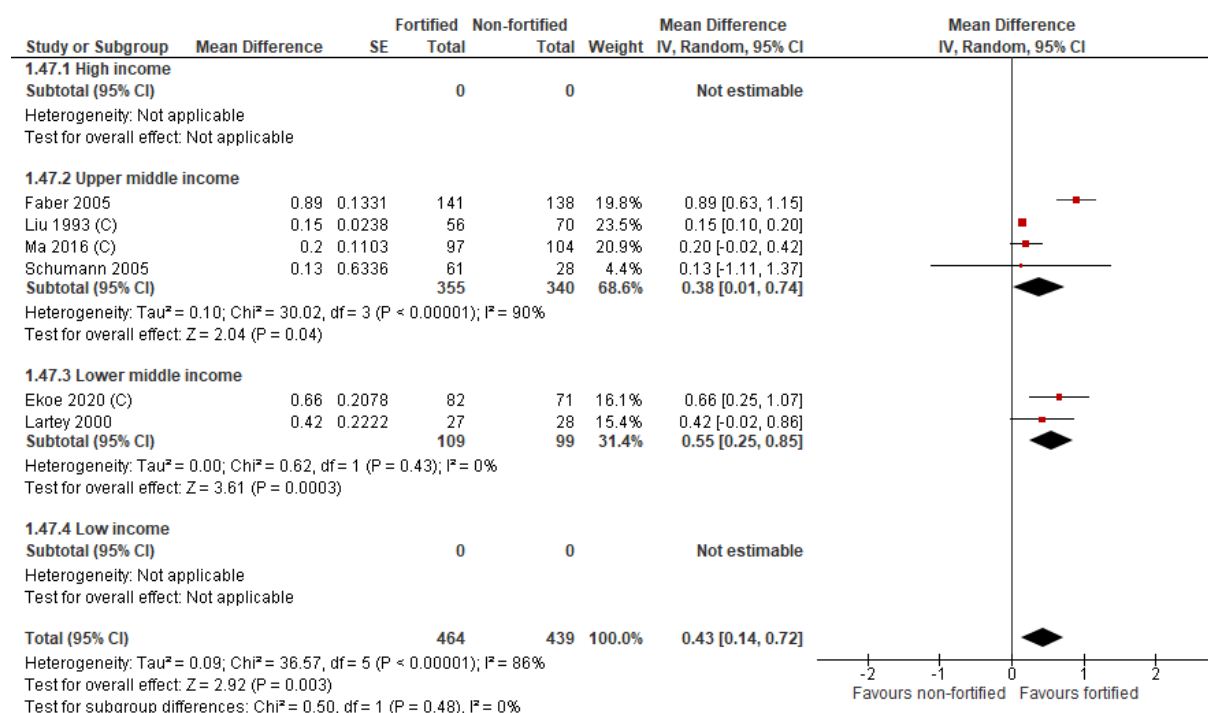
1.45. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by duration of intervention



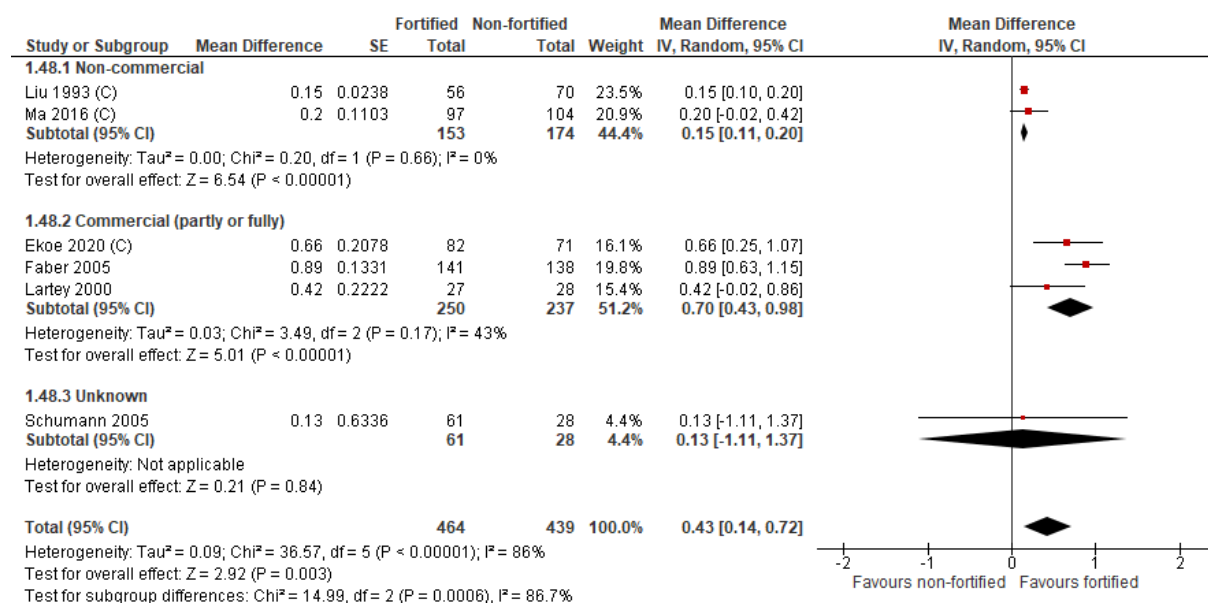
1.46. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by baseline anaemia status



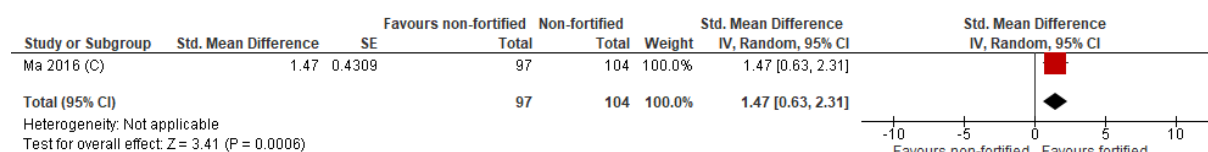
1.47. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by country income classification



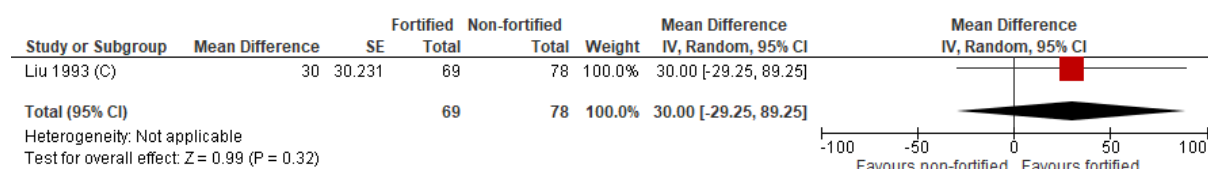
1.48. Fortified versus non-fortified complementary food. Outcome: Iron status (ferritin) by study funding



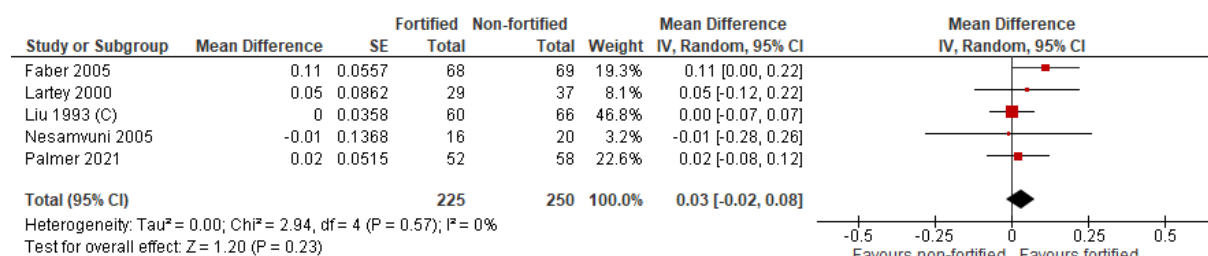
1.49. Fortified versus non-fortified complementary food. Outcome: Iron status (body iron in mg/kg)



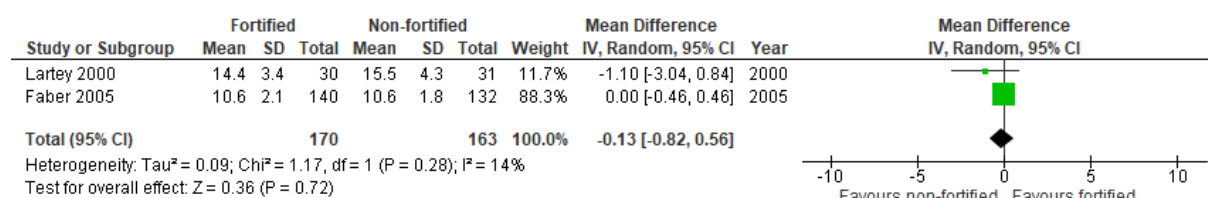
1.50. Fortified versus non-fortified complementary food. Outcome: Iron status (free erythrocyte porphyrin in µg/L)



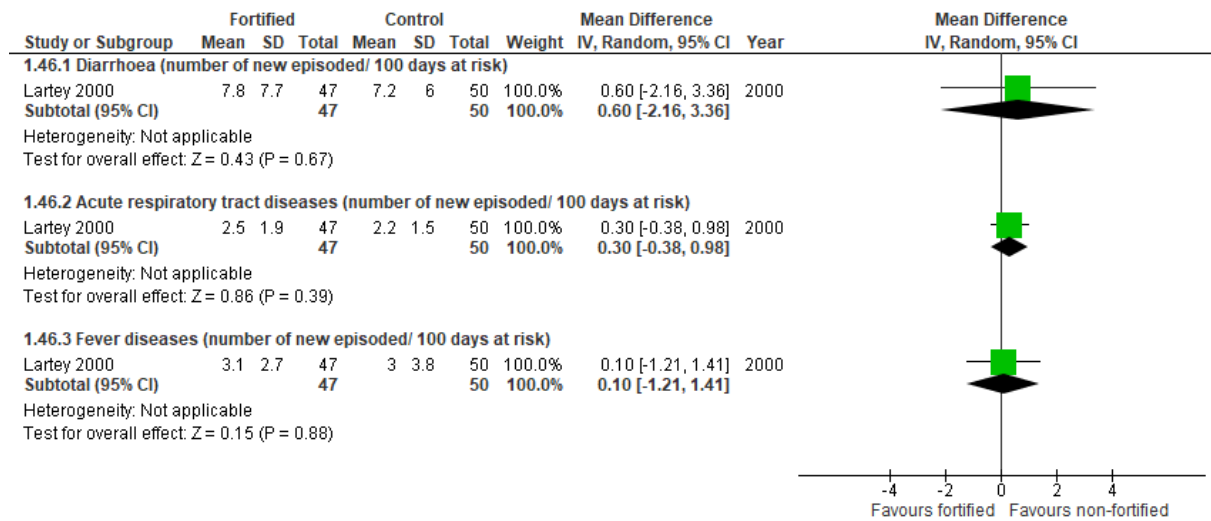
1.51. Fortified versus non-fortified complementary food. Outcome: Serum retinol (µmol/L)



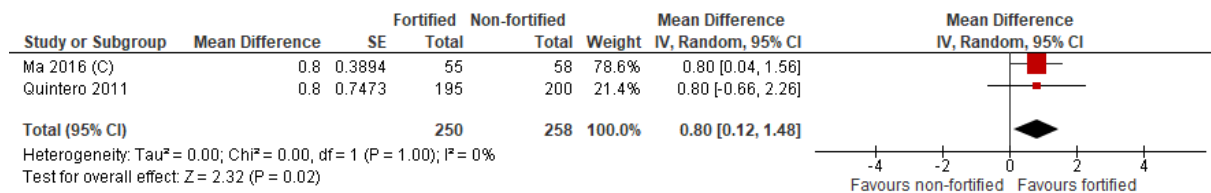
1.52. Serum zinc concentration



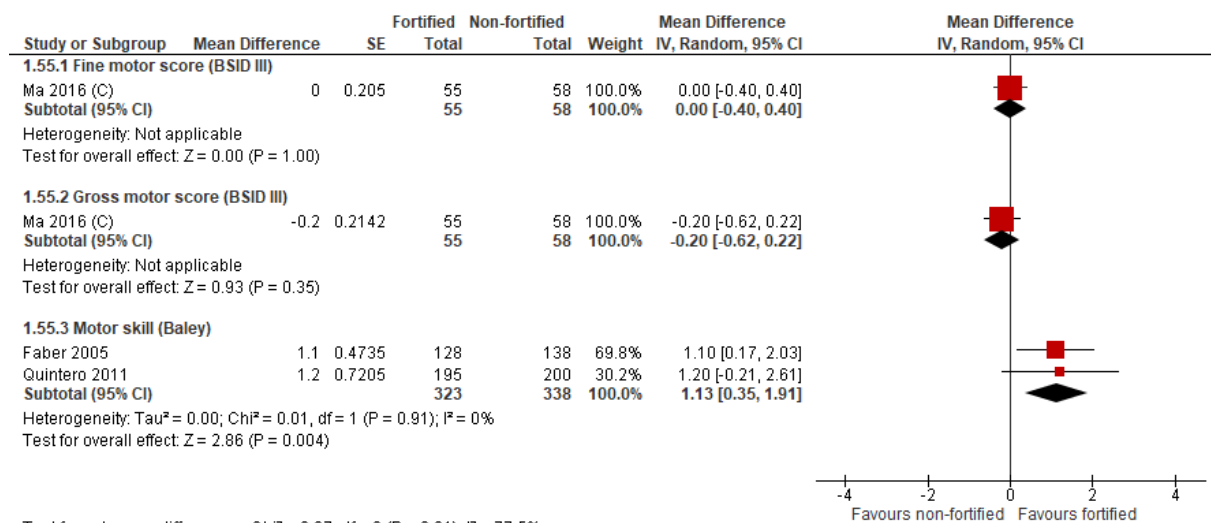
1.53. Fortified versus non-fortified complementary food. Outcome: Morbidity



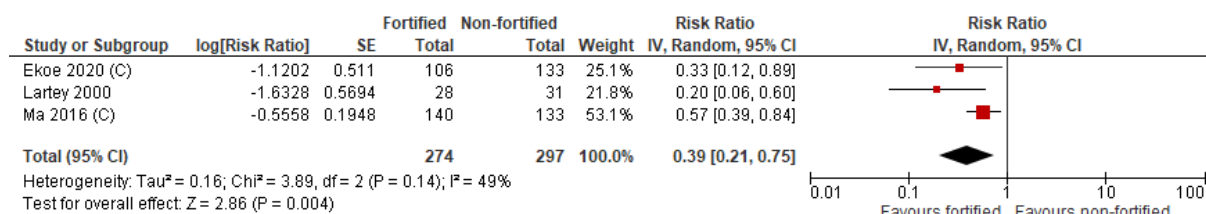
1.54. Fortified versus non-fortified complementary food. Outcome: Mental skill development



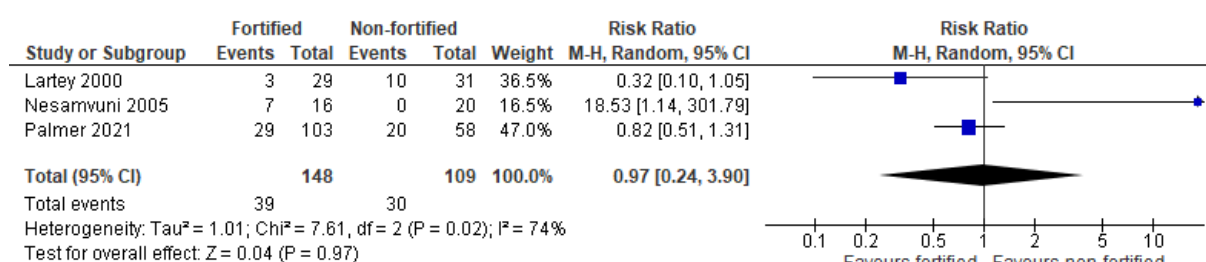
1.55. Fortified versus non-fortified complementary food. Outcome: Motor skill development



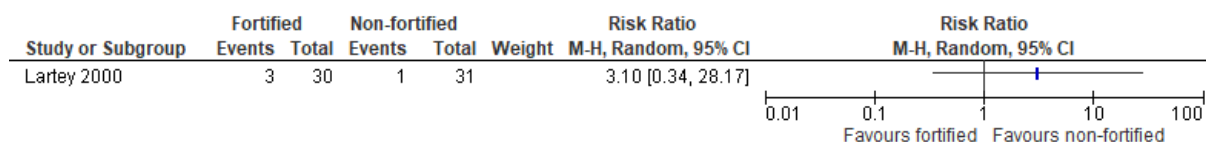
1.56. Fortified versus non-fortified complementary food. Outcome: Iron deficiency



1.57. Fortified versus non-fortified complementary food. Outcome: Vitamin A deficiency



1.58. Fortified versus non-fortified complementary food. Outcome: Zinc deficiency



Appendix 7. Information about malaria in the area of the trial

Study	Country	Malaria presence in the region mentioned in the manuscript	Children with malaria included	Malaria endemic country *
Palmer 2021	Zambia	yes	yes	yes
Lartey 2000	Ghana	yes	yes	yes
Ma 2016	China	no	-	no
Arcanjo 2012	Brazil	no	-	yes
Schumann 2005	Guatemala	yes	yes	yes
Huey 2018	India	no	-	yes
Faber 2005	South Africa	no	-	yes
Liu 1993	China	no	-	no
Nesamvuni 2005	South Africa	no	-	yes
Bovell-Benjamin 1999	USA	no	-	no
Gershoff 1977	Thailand	no	-	yes
Gannon 2019	India	yes	no	yes
Arcanjo 2013	Brazil	no	-	yes
Bagni 2009	Brazil	no	-	yes
Eko 2020	(East) Cameroon	yes	yes**	yes
Quintero 2011	Mexico	no	-	yes

*based on: World Malaria Report, 10 years of Global Progress & Challenges, 2020

**severe malaria cases were excluded

Appendix 8. GRADE Assessment

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		

Anaemia (follow-up: 3 to 12 months)

6 ^{1,2,3,4,5,6}	randomised trials	serious ^a	not serious	not serious	not serious ^b	none	51/617 (8.3%)	90/588 (15.3%)	RR 0.57 (0.39 to 0.82)	66 fewer per 1 000 (from 93 fewer to 28 fewer)	⊕⊕⊕○ Moderate	CRITICAL
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Haemoglobin (follow-up: 3 to 12 months; assessed with: g/L)

11 ^{1,2,3,4,6,7,8,9,10,11,12}	randomised trials	serious ^c	not serious ^d	not serious	not serious ^e	none	1110	1065	-	MD 3.43 g/L higher (1.34 higher to 5.52 higher)	⊕⊕⊕○ Moderate	CRITICAL
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Weight-for-age (follow-up: 6 to 12 months; assessed with: z-scores)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
5 ^{1,4,8,11,12}	randomised trials	serious ^f	not serious	not serious	not serious ^e	none	607	599	-	MD 0.01 z-score lower (0.07 lower to 0.06 higher)	⊕⊕⊕○ Moderate	CRITICAL

Weight-for-length (follow-up: 6 to 12 months; assessed with: z-scores)

4 ^{1,4,8,12}	randomised trials	serious ^g	not serious	not serious	not serious ^e	none	560	549	-	MD 0.05 z-score lower (0.19 lower to 0.1 higher)	⊕⊕⊕○ Moderate	CRITICAL
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Length-for-age (follow-up: 6 to 12 months; assessed with: z-scores)

4 ^{1,4,5,12}	randomised trials	serious ^g	serious ^h	not serious	not serious ^e	none	412	399	-	MD 0.01 z-score lower (0.21 lower to 0.2 higher)	⊕⊕○○ Low	CRITICAL
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Iron status (follow-up: 3 to 12 months; assessed with: ferritin concentrations in ug/L)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
6 ^{1,4,5,7,10,12}	randomised trials	serious ⁱ	serious ⁱ	not serious	not serious ^e	none	464	439	-	MD 0.43 ug/L higher (0.14 higher to 0.72 higher)	⊕⊕○○ Low	CRITICAL

Iron status (follow-up: 12 months; assessed with: body iron in mg/kg)

1 ⁴	randomised trials	serious ^k	not serious ^l	not serious	serious ^m	none	97	104	-	MD 1.47 mg/kg higher (0.63 higher to 2.31 higher)	⊕⊕○○ Low	CRITICAL
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Iron status (follow-up: 3 months; assessed with: free erythrocyte porphyrin in µg/L)

1 ¹⁰	randomised trials	very serious ⁿ	not serious ^l	not serious	serious ^m	none	69	78	-	MD 30 higher (26.06 lower to 86.06 higher)	⊕○○○ Very low	CRITICAL
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Serum retinol (follow-up: 3 to 12 months; assessed with: µmol/L)

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
5 ^{5,9,10,12,13}	randomised trials	serious ^o	not serious	not serious	not serious ^e	none	225	250	-	MD 0.03 umol/L higher (0.02 lower to 0.08 higher)	⊕⊕⊕○ Moderate	CRITICAL

Serum zinc (follow-up: 6 months; assessed with: g/dL)

2 ^{5,12}	randomised trials	serious ^p	not serious	not serious	serious ^m	none	170	163	-	MD 0.13 lower (0.82 lower to 0.56 higher)	⊕⊕○○ Low	CRITICAL
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Diarrhoea (follow-up: 6 months; assessed with: number of new episoded/ 100 days at risk)

1 ⁵	randomised trials	serious ^k	not serious ^l	not serious	very serious ^q	none	47	50	-	MD 0.6 higher (2.16 lower to 3.36 higher)	⊕○○○ Very low	IMPORTANT
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Acute respiratory tract diseases (follow-up: 6 months; assessed with: number of new episoded/ 100 days at risk)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
1 ⁵	randomised trials	serious ^k	not serious ^l	not serious	very serious ^q	none	47	50	-	MD 0.3 higher (0.38 lower to 0.98 higher)	⊕○○○ Very low	IMPORTANT

Fever diseases (follow-up: 6 months; assessed with: number of new episoded/ 100 days at risk)

1 ⁵	randomised trials	serious ^k	not serious ^l	not serious	very serious ^q	none	47	50	-	MD 0.1 higher (1.21 lower to 1.41 higher)	⊕○○○ Very low	IMPORTANT
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Mental skill development (follow-up: 10 to 12 months; assessed with: BSID I-III)

2 ^{4,8}	randomised trials	serious ^r	not serious	not serious	not serious ^e	none	250	258	-	MD 0.8 higher (0.12 higher to 1.48 higher)	⊕⊕⊕○ Moderate	IMPORTANT
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Fine motor score (follow-up: 12 months; assessed with: BSID III)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
1 ⁴	randomised trials	serious ^k	not serious ^l	not serious	serious ^m	none	55	58	-	MD 0 (0.4 lower to 0.4 higher)	⊕⊕○○ Low	IMPORTANT

Gross motor score (follow-up: 12 months; assessed with: BSID III)

1 ⁴	randomised trials	serious ^k	not serious ^l	not serious	serious ^m	none	55	58	-	MD 0.2 lower (0.62 lower to 0.22 higher)	⊕⊕○○ Low	IMPORTANT
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Psychomotor development (follow-up: 6 to 10 months; assessed with: BSID I-III)

28.12	randomised trials	serious ^p	not serious	not serious	not serious ^e	none	323	338	-	MD 1.13 higher (0.35 higher to 1.91 higher)	⊕⊕⊕○ Moderate	IMPORTANT
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Acceptability (follow-up: 3 days; assessed with: 9-point hedonic scale)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
3 ^{14,15,16}	randomised + non-randomised trials	very serious ^s	not serious	not serious	serious ^m	none	Acceptability of fortified as compared to unfortified complementary food was measured in three acute studies with a total of 215 children. All described that there were no significant differences between the ratings of children allocated to the two groups				⊕○○○ Very low	IMPORTANT

Iron deficiency (follow-up: 6 to 12 months)

3 ^{1,4,5}	randomised trials	serious ^t	not serious	not serious	not serious ^u	none	48/274 (17.5%)	120/297 (40.4%)	RR 0.39 (0.21 to 0.75)	246 fewer per 1 000 (from 319 fewer to 101 fewer)	⊕⊕⊕○ Moderate	CRITICAL
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Vitamin A deficiency (follow-up: 3 to 12 months)

3 ^{5,9,13}	randomised trials	very serious ^v	serious ^w	not serious	serious ^x	none	39/148 (26.4%)	30/109 (27.5%)	RR 0.97 (0.24 to 3.90)	8 fewer per 1 000 (from 209 fewer to 798 more)	⊕○○○ Very low	CRITICAL
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Zinc deficiency (follow-up: 6 months)

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fortified complementary food	Non-fortified complementary food	Relative (95% CI)	Absolute (95% CI)		
1 ⁵	randomised trials	serious ^y	not serious ^l	not serious	very serious ^z	none	3/30 (10.0%)	1/31 (3.2%)	RR 3.10 (0.34 to 28.17)	68 more per 1 000 (from 21 fewer to 876 more)	⊕○○○ Very low	CRITICAL

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Explanations

a. Downgraded by one level for risk of bias (RoB) since 1 out of 6 studies was rated with a high RoB, and none of the included studies was rated with a low RoB.

b. Not downgraded for imprecision. Although the number of events was low (<400), the outcome was a common event (occurred >1/100), and there were 6 studies with a median sample size of 170 children included. The 95% confidence interval (CI) for the pooled estimate is narrow and is consistent with benefit.

c. Downgraded by one level for RoB since 5 out of 11 studies were rated with a high RoB, and none of the included studies was rated with a low RoB.

d. Not downgraded for inconsistency although I^2 was 55% (driven by the study of Faber et al. 2005), since 95% CI overlaps mainly between studies. In all sub-group analyses heterogeneity was present only in those sub-groups which contained the study Faber et al. 2005, while no heterogeneity was observed in other sub-groups.

e. Not downgraded for imprecision since number of participants was >400.

f. Downgraded by one level for RoB since 1 out of 5 studies were rated with a high RoB, and none of the included studies was rated with a low RoB.

g. Downgraded by one level for RoB since 1 out of 4 studies were rated with a high RoB, and none was rated as low RoB.

h. Downgraded by one level for inconsistency since I^2 was 68%, p-value for heterogeneity was 0.02, point estimates and 95% CI did not overlap between studies. Sub-group analyses did not fully explain heterogeneity.

i. Downgraded by one level for RoB since 3 out of 6 studies were rated with a high RoB, and none was rated as low RoB.

j. Downgraded by one level for inconsistency since I^2 was 86%, p-value for heterogeneity was <0.001, point estimates and 95% CI did not overlap between studies. Sub-group analyses did not fully explain heterogeneity.

k. Downgraded by one level for RoB since the included study was rated with some concerns of RoB.

l. This is a single study so inconsistency cannot be judged.

- m. Downgraded by one level for imprecision since total sample size was low (<400).
- n. Downgraded by two levels for RoB since the included study was rated with a high RoB.
- o. Downgraded by one level for RoB since 3 out of 5 studies were rated with a high RoB, and 1 study was rated as low RoB.
- p. Downgraded by one level since 1 out of 2 included studies was rated with a high RoB, and none of the included studies was rated with a low RoB.
- q. Downgraded by two levels for imprecision since sample size was very low (<100).
- r. Downgraded by one level for RoB since both included studies were rated with some concerns for RoB.
- s. Downgraded by two levels for RoB since 2 out of 3 included studies was rated with high RoB, and none of the included studies was rated with a low RoB.
- t. Downgraded by one level for RoB since all included studies were rated with some concerns for RoB.
- u. Not downgraded for imprecision. Although the number of included studies is low (n=3), studies had an intermediate sample size with a median of 239 participants, and the outcome was a common event (occurred >1/100).
- v. Downgraded by two levels for RoB, as for this outcome 1 out of the 3 included studies was rated with high RoB, and none of the included studies was rated with a low RoB. There were large baseline between-group differences in the number of vitamin A deficient participants in two studies (Nesamvuni 2005: 7 out of 16 in the experimental and 0 out of 20 in the control group; Palmer 2021: 10 out of 51 in the biofortified, 11 out 52 in the fortified and 18 out of 58 in the control group)
- w. Downgraded by one level for inconsistency as point estimates did vary widely, 95% CI did not overlap between studies, the direction of effect was not consistent. and the magnitude of heterogeneity was high (I^2 was 74%, p-value for heterogeneity was 0.02). Due to the low number of studies subgroup analyses were not possible.
- x. Downgraded by one level for imprecision since total sample size was low (<400).
- y. Downgraded by one level for RoB since the included study was rated with some concerns of RoB.
- z. Downgraded by two levels for imprecision since results are derived from one study, where total sample size was very low (n<100).

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