Health effects of commercially-available complementary foods: a systematic review

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Conflict of interest statement

The authors are faculty (LA) or PhD students (ET, MK, MW) in the Department of Nutrition at the Gillings School of Global Public Health. In 2012-14, the Department of Nutrition received an educational grant from Pfizer Nutrition, which supported graduate student stipends for students with a research focus on pediatric nutrition (including the co-authors of this report), and an educational seminar series. In this time frame, Pfizer's nutrition division was acquired by Nestlé who continued support of the educational program. Under provisions of the agreement with the company, students were free to select and pursue research topics of their choice, and to publish their work without any influence of the company. Funding ended in August 2014, prior to the commissioning of this review.

Abstract

With the broad goal of informing WHO's consideration of inappropriate promotion of foods for infants and young children, this systematic review aimed to locate and synthesize results of scientific literature on the health effects of commercially-available complementary foods (CACF) for infants and young children under 2 years of age. The review addresses 5 specific research questions:

Q1. To what degree do commercially-available products replace, rather than complement, the intake of breast milk in children 6-23 months of age?
Q2. To what degree do commercially-available products consumed by children 6-23 months of age increase the risk of childhood obesity or chronic disease risk factors?
Q3. Are commercially-available products nutritionally inferior or superior to home-prepared and/or local foods? Do they contain higher or lower amounts of trans fat, saturated fat, free sugars, or salt? Do they contain higher or lower amounts of essential micronutrients? Do commercially-available products provide nutrients that are generally lacking in the diets of young children?
Q4. Are the portion sizes of commercially-available products greater than would be appropriate based on age?
Q5. Do commercially-available products reduce the risk of stunting, anemia, or micronutrient deficiencies?

We searched the following data bases: PubMed, CINAHL plus, EMBASE, Agricola, CAS (Clinicaltrials.gov), Cochrane, Global Health, WHO Global Library, Business Source Premier, AgEcon, Mintel Oxygen, as well as relevant conference proceedings, and sources of grey literature and reviewed reference lists from highly relevant reviews and articles. Titles and abstracts were extracted and reviewed for relevance. Inter-rater reliability was assessed using Kappa statistics. Outcomes included breastfeeding duration or frequency or breast milk intake for Q1; anthropometric indicators of weight status or biomarkers of chronic disease risk for Q2; nutritional composition of foods or infant intake of nutrients for Q3; portion sizes of complementary foods (CFs) for Q4, and stunting, anemia, and micronutrient deficiencies for Q5.

The Population-Intervention-Comparison-Outcome (PICO) for each question was narrowly defined to compare CACFs to home-prepared or locally-available CFs. CACFs were defined as commercial products developed and marketed for infant consumption, or products developed for studies to closely mimic CACFs. We also included investigator-prepared local foods that mimicked home-prepared foods. For feeding trials, these were necessary to allow for blinding, quality control and safety.

We found very few studies that met the PICO criteria, most often because they did not report on direct comparisons of CACFs with similar home-prepared foods. For all of the research questions, the evidence was judged to be of low or very low quality. For Q1, we found limited evidence that CACFs did not displace breast milk intake, but their consumption was associated with shorter duration of breastfeeding. For Q2, limited evidence suggests that high protein intake and intake of milk-cereal drinks are associated with higher child BMI. For Q3, results were highly heterogeneous given the wide variety of CACFs and home-prepared foods that were assessed: some CACFs were nutritionally superior to home-prepared or local foods, while the converse was true for others. We found no studies that addressed Q4. For Q5, we found no evidence that CACFs improved infant nutritional status.

More evidence is needed to identify the benefits and potential harms of CACFs. Additional evidence might be brought to bear on the research questions by comparing CACFs and home-prepared foods to reference data rather than to each other.

List of abbreviations

AHRQ	Agency for Health Care Research and Quality
BF	Breastfed, breastfeeding
CACF	Commercially-available complementary food
CF	Complementary food
GRADE	Grading of Recommendations Assessment, Development and Evaluation
LMIC	Low and middle income countries
RCT	Randomized controlled trial
LNS	Lipid Nutrition Supplement

PART 1. RESEARCH QUESTION 1

To what degree do commercially-available products replace, rather than complement, the intake of breast milk in children 6-23 months of age?

1.1 Background

Owing to the high quality of nutrients and other beneficial aspects of breastfeeding, it is desirable, starting at 6 months, to ***add*** high nutritional quality foods to the infant's diet ***without displacing*** breast milk intake. Infants have the ability to self-regulate their intake to maintain energy balance. [1] Thus, concern has been raised that in response to feeding of complementary foods (CF) --- particularly those high in energy density --- infants will consume less breast milk. If the foods displacing breast milk are of lower nutritional quality than breast milk, the infant's nutritional status may suffer.

Evidence on whether breast milk is displaced by CFs should ideally come from experimental studies with accurate and precise quantification of breast milk intake before and after feeding of CFs. Since CFs are recommended for infants 6 months and older,[2] it would not be ethical to assign infants to a no-CF food (exclusively breast-fed) comparison group. Thus, relevant studies allowing causal inference are those that examine how different amounts, forms, and composition of CFs provided as part of an experimental protocol influence breast milk intake. No-supplement control groups would be consuming their usual diet, which would need to be carefully quantified. A relatively small number of studies have used this ideal design.

The "gold standard" method of quantifying breast milk intake is estimation using deuterium dose to the mother. [3,4] Less accurate methods include test weighing of infants before and after breastfeeding,[5] estimation from mother's report of feeding frequency and duration, and estimation based on usual intakes of infants of given size, age, and growth rate. Respondent burden for test weighing is high, and estimated intakes require researchers to make assumptions that may not be valid for individual infants. In particular, breast milk intake modeled as the difference of estimated total intake and quantitated intake from CFs would not allow investigators to examine how breast milk intake is influenced by CF.

Other insights can be obtained by comparing duration of breastfeeding or age-specific prevalence of breastfeeding associated with different amount, type, or composition of CFs. However, no causal inferences can be derived from these types of studies. Such studies would have high potential for endogeneity bias, since mothers make simultaneous decisions about breastfeeding and choice of complementary foods.

1.2 Objective

The objective for Q1 is to review evidence on the degree to which commercially-available products replace, rather than complement, the intake of breast milk in children 6-23 months of age.

1.3 Methods

1.3.1 Criteria for considering studies.

We did not restrict our search by study design: randomized-controlled trials (RCTs) and observational studies were included. For inclusion, studies had to present evidence on infants and young children, ages 6-23 months, who were still breastfed. The main exposure was consumption of commercially-available complementary food products (CACFs) compared to home-prepared or local CF products. We included studies with a quantifiable aspect of breastfeeding as an outcome variable, including quantification of infant milk intake by one of the methods described in the background, or mother's reports of duration and/or frequency of breastfeeding.

1.3.2 Search method strategies for identification of studies

1.3.2.1 Electronic searches

The following electronic databases were searched to identify relevant studies:

- PubMed (2000 – 30 Mar 2015)
- CINAHL plus (2000 – 31 Mar 2015)
- EMBASE (2000 – 30 Mar 2015)
- Agricola (2000 – 31 Mar 2015)
- CAS (2000 – 31 Mar 2015)
- Clinicaltrials.gov (2000 – 31 Mar 2015)
- Cochrane (2000 – 31 Mar 2015)
- Global Health (2000 – 31 Mar 2015)
- WHO Global Library (2000 – 2 Apr 2015)
- Business Source Premier (2000 – 6 Apr 2015)

1.3.2.2 Searching other resources

We searched other economics databases (AgEcon, Mintel Oxygen), relevant conference proceedings (Association for Consumer Research, International Health Economics Association), and sources of grey literature (New York Academy of Medicine's Grey Literature Report, Open Grey, PH Partners). We also reviewed reference lists from highly relevant reviews and articles.

1.3.2.3 Search strategy

The search strategy was created using a combination of subject headings and free-text keywords to identify publications (see **Appendix 1.1**). We did not restrict by language or study design. We restricted to studies published after 2000, to ensure that the CACFs analyzed would provide relevant and contemporary evidence. References were extracted and imported into EndNote. Duplicate articles were identified and removed. All articles were assigned a unique record number.

1.3.3 Data collection and analysis

1.3.3.1 Selection of studies

Two reviewers independently screened titles and abstracts from electronic databases to identify potentially eligible studies. Prior to starting the work, inter-rater agreement was assessed by screening a subset of titles and abstracts and calculating Cohen's Kappa. Discrepancies were resolved by discussion with a third reviewer. One reviewer screened titles and summaries from the other resources. Full-text articles were obtained, and were independently reviewed by two reviewers according to the inclusion criteria. Discrepancies were resolved with discussion. When the full-text was not available in English it was excluded.

1.3.3.2 Data extraction

Excel workbooks created for systematic review data management were utilized for abstract screening and full-text reviews. [6] Record numbers, titles, and abstracts were exported from EndNote into the Excel workbook, and all title and abstract screening and full-text review took place within Excel. Comments on reasons for full-text exclusions were noted in a separate file. Each reviewer had her own Excel workbook, to keep the review process blinded.

Two reviewers extracted data into standardized tables. Information was extracted on: general study characteristics (design, location/setting, recruitment strategy), participant characteristics (sample size, age, inclusion/exclusion criteria), description of the commercially-available complementary food and comparison foods, outcome, and results. Two separate risk of bias assessment tables were created (for RCTs vs. observational studies).

1.3.3.3 *Assessment of risk bias and quality in included studies*

Articles included in the review were assessed for quality using AHRQ tools for observational studies, [7,8] and the Cochrane tools for Interventions. [9] The studies included in the final review were highly heterogeneous in design, CFs, and settings, and were not amenable to a meta-analysis of results. Overall quality of the evidence from the final studies was assessed using GRADE evidence profiles. [10]

1.4 Results

1.4.1 Literature search

We identified 3038 abstracts for initial screening, from which 88 were referred for full-text review. Of these, 8 were included in the final review. **Figure 1.1** shows the flowchart of the screening and eligibility evaluation phases. Main reasons for exclusion were that the study did not include CACFs, breastfeeding was not a quantifiable outcome of the study, the comparison group was not infants consuming home-prepared CFs, and the full-text was not available in English (see **Appendix 1.2** for a full description of full-texts that were reviewed and excluded from the final set).

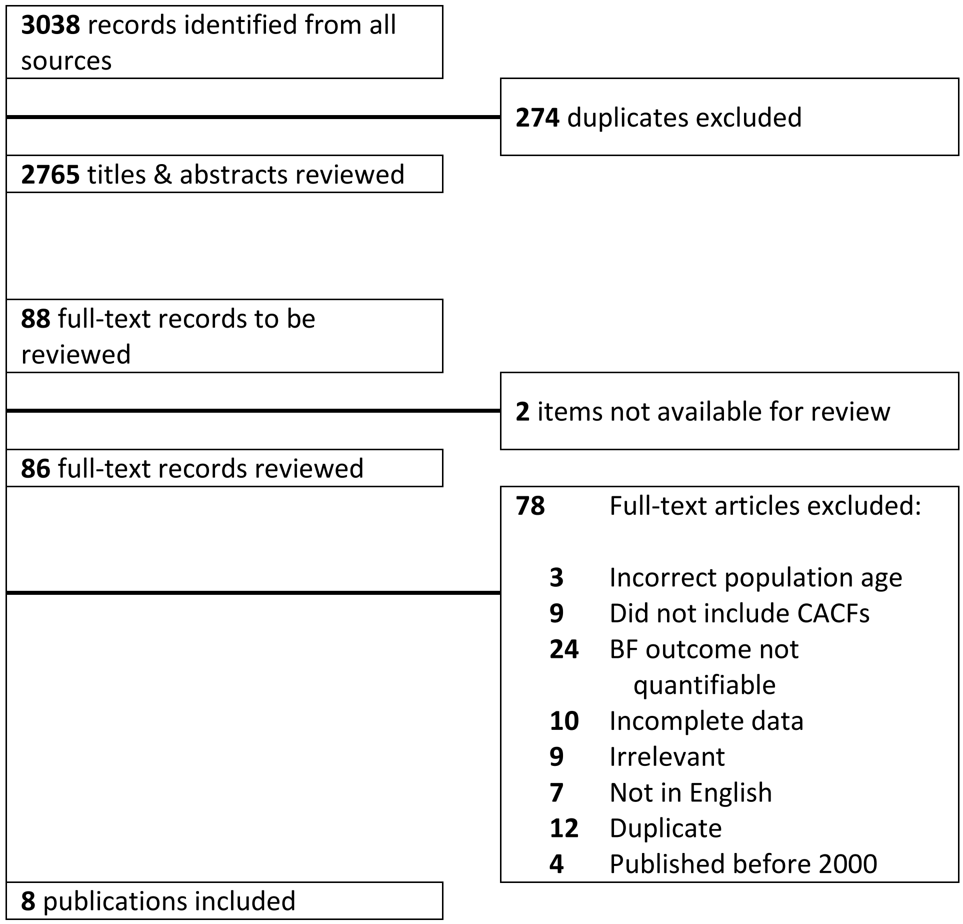


Figure 1.1 Flowchart of review process

1.4.2 Characteristics of included studies

Of the eight papers included in the review, four were RCTs that assigned alternate CFs to infants and compared their breast milk intake. All were done in LMIC (1 in India, 1 in the Democratic Republic of the Congo (DRC), and 2 in Malawi). Of the four, three used deuterium dose to the mother to quantify breast milk intake, while the fourth relied on mother's reports of breastfeeding frequency and duration of each feeding episode. Three observational studies, one each in Italy, Germany and Guatemala, related breastfeeding to CFs. An additional paper was a secondary analysis of data from a RCT designed for obesity prevention in Australia. The studies differ markedly in the CFs given to infants and in their comparison groups, as well as methods of quantifying CF intakes. Qualitative summaries of the studies are therefore presented. Detailed descriptions of each included study and their results are included in **table 1.1** (RCTs) and **table 1.2** (observational studies). Owing to the vast differences in the design and quality of RCTs and observational studies, they are separately evaluated.

1.4.3 Substantive findings from RCTs (Table 1.1)

Bhandari et al. [11] provided a milk-cereal supplement produced by a local dairy to Indian infants from 4 to 12 months in a 4-arm study whose primary outcome was infant growth. Investigators also compared the proportion breastfed, and mean breastfeeding frequency in the CF supplement group to that of infants in a nutrition counseling group, a visitation only, and a control group. The proportion of infants breastfed was significantly lower in the CF supplement compared to the visitation only group at 38 (-5%) and 52 weeks (-12.8%). Mean breastfeeding frequency was also lower in the food supplement group compared to the visitation group at 26 (-1.7 feedings/d) and 38 weeks (-1.2 feedings per day).

The other RCTs aimed to determine whether infant CFs displace breast milk. Three studies quantified breast milk intake by deuterium dose to the mother after varying periods of feeding CFs in different amounts or energy density. These studies were carried out in the context of high rates of infant stunting in Malawi and the DRC, and were aimed at determining how to optimize infant nutrition with CFs without displacing breast milk. Two studies in Malawi [12,13] used lipid-based fortified spreads given in different daily doses to either a no-supplement group,[12] or to a corn-soy blend porridge. [13] The study by Galpin et al. [13] used a product produced by a local NGO, which while not commercially sold, is directly comparable to a commercial product, and was therefore included in our analysis. The third study, done in the DRC [14] compared a ready-to-use mix of locally available foods to UNIMIX porridge. None of these studies found intergroup differences in mean breast milk intake. Only 1 study assessed change in breast milk intake in response to one month of feeding of the alternate CFs, and found that breast milk intake per kg infant body weight declined after 1 month of CF supplementation, but there was no difference between the fortified spread and corn-soy blend CF groups in the amount of change. [13]

1.4.3.1 Quality of included studies: RCTs

Only one study used the optimal design of comparing change in breast milk intake in individual children randomized to alternate CFs. [13] Two studies compared breast milk intake several months after randomization to alternate CFs, and were therefore unable to confirm that there were no initial intergroup differences in breast milk intake at the time of randomization. [12,14]

1.4.3.2 Quality of outcomes: RCTs (GRADE)

Overall, there is low quality evidence that CACFs do not displace breast milk.

Risk of bias. Owing to differences in the nature, amount, or physical characteristics of the CFs used in the RCTs, masking of treatment is not possible for participants and study personnel who deliver the supplements and this lack of blinding is a potential source of bias. Sequence generation was not judged to pose risk of bias. Sufficient information to judge bias associated with allocation concealment was not available for 3 of the 4 studies. There was no significant differential attrition across study groups in any of the RCTs nor was there evidence of selective outcome reporting.

Inconsistency. Heterogeneity in effects was not directly assessed across the studies, owing to substantial differences in recruitment strategies, participant populations, sample size, and CFs tested. The interventions varied in duration and in composition and dose of CFs. The outcome measures were similar in 3 of the 4 studies. However, the studies that used objective measures of breast milk intake were consistent in showing no clear evidence of displacement of breast milk by CFs.

Indirectness. The RCTs directly assessed the outcome of interest. It was not clear whether all of the CFs tested were commercially available, but we included them because of their direct comparability with CACFs. All of the trials were in LMIC where prevalence rates of child stunting and/or micronutrient deficiencies were high. Studies excluded severely malnourished children, but the results from these trials may not be generalizable to high income settings.

Imprecision. All studies had wide, overlapping confidence intervals when comparing alternate CFs. Sample size is small (<60) for 2 of the 4 studies.

Publication bias. It was not possible to formally assess publication bias.

1.4.4 Substantive findings from observational studies (Table 1.2)

The observational studies come from three high income countries (Italy, Germany, and Australia), and one LMIC (Guatemala). In all of these studies, data on breastfeeding and CF were collected at the same point in time, so ***no causal inferences*** can be drawn, but they may be useful to provide insights into how breastfeeding relates to intake of CACFs. In most cases, CACFs were consumed as part of mixed diets, and the studies varied in the extent to which it is possible to isolate differences in breastfeeding that are associated with CACFs versus other foods.

Pani et al. [15] in their study of Italian infants, found that at 6 months, total average daily energy intake was higher in infants who were not breastfed, owing to their higher intake of CFs, particularly CACFs which represented their main source of carbohydrates. Foterek [16] quantified breast milk intake of German infants in the DONALD study by weighing infants before and after feeding, and quantified CFs using 3-day records of weighed foods. Infants with high CACF consumption were fully breastfed for about 5 weeks less than those with lower CACF consumption, and also had significantly shorter duration (10 weeks) of any breastfeeding. Bell [17] analyzed data collected at 14 and 24 months, in participants in multisite RCTs of obesity prevention in Australia. They quantified breast milk intake by time sucking, assuming that the infant consumed 10 g per minute. In this study, longer breastfeeding duration was associated with a dietary pattern characterized by lower intake of CACFs. In Hernandez's Guatemala study [18], breast milk intake was estimated as the difference between the infant's estimated total energy requirement (based on age and weight) and intake from CFs. This method precludes drawing any conclusions about how CFs and breast milk intake are related.

1.4.4.1 Quality of included studies: observational studies

Owing to high risk of strong bias related to the simultaneous measurement of breastfeeding and CF, inaccurate and potentially biased estimates of breastfeeding outcomes based on maternal self-report, and inability to clearly differentiate CACFs from other CFs, the evidence from these studies is judged to be of very low quality. However, the observational studies suggest higher energy intake among infants consuming CACFs.

Considering the RCTs and observational studies together, there is low quality evidence for no displacement of breastfeeding by CACFs, but consumption of CACFs may be associated with higher total energy intake.

1.4.5 Other studies of potential relevance

We identified other RCTs that directly assess whether CFs influence breast milk intake, but these studies did not assess a specific CACF **(table 1.3)**. We include the presentation and discussion of these studies because of their potential to inform Q1. For example, one might be able to make inferences that CACFs with characteristics similar to the tested CFs would have similar effects on breast milk intake. In addition, these studies are cited in several of the included studies. Islam et al. [19] compared breast milk intake (by test weighing of infants) in groups of Bangladeshi infants randomized to CFs of 3 different energy densities fed either 3, 4 or 5 times per day. Each infant went through a sequence of different treatment assignments, allowing comparison of intra- and inter-individual differences in response to CF. Total time spent nursing fell by 13%, and total breast milk consumption decreased by 11% when energy density of CF was increased from 0.5 to 1.5 kcal/kg, $p<0.001$. Total breast milk intake fell by 8% when feeding frequency was increased from 3-5 times/d ($p=0.04$). For each additional kcal/d intake of CF, energy intake from breast milk diminished by 0.18 kcal/d.

Similarly, in a study of New Delhi infants, Singh and colleagues [20] found that breast milk intake (measured by test weighing) was lower when infants were fed CFs more frequently: 4 vs 3 times per day was associated with -61.2 g ($p=0.05$). A limitation of this study was the short duration of exposure to each feeding frequency, which may have allowed insufficient time for the infant to respond. In this same setting, the research team also found that breast milk intake was reduced by 121 g/d when consuming a high (35 kcal/100g) vs. low (20 kcal/100 g) energy density porridge. [21] They concluded that adding higher energy density CF to the infant diet does not translate into increased total intake because of breast milk displacement. Finally, Owino [22] randomized 9 month old Zambian infants to receive a CF prepared from local products, with the only difference being inclusion of alpha amylase in one of the mixes. These 2 CF groups were compared to controls. Breast milk intake, measured by deuterium dose to the mother, was not different across the groups.

Three of these studies thus provide some evidence that breast milk intake is sensitive to energy density of the CF's fed, and to feeding frequency, and suggest displacement of breast milk by CFs depending on CF characteristics and how often CFs are fed.

Table 1.1 Study Characteristics of Q1 Randomized Controlled Trials

Author, Year	Owino, 2011 [14]	Kumwenda, 2014 [12]	Galpin, 2007 [13]	Bhandari, 2001 [11]
Design	RCT subgroup analysis from cluster RCT efficacy trial of RUCF from local ingredients vs. CSB: assessed differences in breast milk intake after about 3 months of receiving CF supplement	RCT sub-study of iLiNS DOSE trial: assessed differences in breast milk intake after about 3 months of receiving CF supplement	RCT, prospective, parallel group trial of 3 complementary feeding regimens: assessed breast milk intake before and 1 month after beginning of CF supplement	RCT. Stratified by infant weight-for-height (80% of NCHS median), then assigned to 1 of 4 groups followed over time: Food supplement (FS), nutrition counseling, no intervention, and visitation (for assessment of morbidity).
Location/year/setting	Lwiro Pediatric Hospital, South Kivu, Democratic Republic of Congo, October 2009-November 2010	Mangochi, Malawi. 12 month intervention. March 2010-Nov 2011	Lungwena, Malawi. Study dates not given	Urban slums of Delhi, India. Dates of study not given.
Recruitment strategy	Ensured equal number of males and females; systematic sample of large cluster randomized trial assessing the efficacy of RUCF compared with "UNIMIX"	Participants identified by community surveys	All children in 11 villages invited to participate	Community survey identified all pregnant women and infants < 4 months, participants enrolled when infant reached 4 months
Sample size (n) (recruited vs. final)	Of the 1400 infants in the larger RCT, 420 were in the RUCF and 330 in the UNIMIX arm. 58 infants were included in the smaller breast milk intake sub-study.	n=359 as final sample in 4 groups (control=79, 10g=75, 20g=98, 40g=107); study powered for 10% difference in total breast milk intake (55-60 Kcal)	Planned enrollment was 15/group for 3 groups. Enrolled 44, 41 completed.	418 enrolled at 4 months, 368 (88%) had complete data at 12 months
Age (age at recruitment and duration of study)	8.5 - 10.5 months. Duration: 14 days	Assessed at 9-10 months in study where CF supplement is given from 6 to 18 months	Enrolled at 5.5-6.5 months, study duration = 1 month	4 months at enrollment, followed until 12 months
Inclusion/exclusion criteria	Larger RCT: Inclusion: gestational age of 37+ weeks, birth weight 2500g+ informed consent. Exclusion: bottle-fed children, malformations and neurological impairment. Smaller, nested study: Inclusion: informed consent to participate in the breast milk study, drink the deuterium oxide, allow saliva sampling of mother and infant and allow anthropometric measure of mother. Exclusion: Infant illness at the beginning of the study.	At recruitment (5.5-6.49 mo), mom is breastfeeding only 1 child, excluded if severe illness or anemia in mother or infant, or participating in any other trial	Excluded HAZ<-2, edema, severe illness, peanut allergy, multi-births, participants in other trials	Congenital malformations, those unlikely to remain in study area

Table 1.1 Study Characteristics of Q1 Randomized Controlled Trials, con't

Author, Year	Owino, 2011 (14)	Kumwenda, 2014 (12)	Galpin, 2007 (13)	Bhandari, 2001 (11)
Commercial food studied/comparison group (how CF intake was measured)	RUCF=cooked maize, soybeans, sorghum, milk powder, veg. oil, sugar, 3% micronutrient powder that met RDAs for 6-12 mo-old infants, energy density of 5.5 kcal/g. Recommended intake: 50g/day in 2 meals- no mixing with other foods/water. UNIMIX= maize, soybean, vitamin-mineral pre-mix. Required cooking with 3 spoonsful of flour (35g) to achieve desired consistency. 280 kcal of this UNIMIX porridge (1.1 kcal/ml) was recommended per day.	Milk or non-milk based LNS in 3 doses (10, 20, and 40 g/d) compared to no LNS, control group.	FS (LNS) Nutriset5.3 kcal/g vs. CSB with 1.1 kcal/g, compares 25 vs 50 g FS vs. CSB. NOTE FS is made by an NGO, not commercially available	Milk-cereal supplement produced by a local dairy; produced in foil packets; quantified by twice weekly maternal report of proportion of packet(s) given. Not entirely clear if the milk cereal supplement is commercially available
Outcome (how it was measured)	Breast milk intake measured by deuterium dose to the mother	Breast milk intake measured by deuterium dose to the mother	Breast milk intake measured by deuterium dose to the mother	Main study outcome was infant weight and length. Mothers report= source of information for energy intake from non-breast milk sources, prevalence of BF, and BF frequency.
Results	Mean breast milk intake was not different between RUCF (705±236 g/d) vs. UNIMIX (678±285 g/d), p=0.69; nor was there a difference when expressed per kg infant body weight.	Mean intake of breast milk compared to the control: 10g dose =+62 (-18,143); 20 g dose +30 (-40,99); 40 g dose +2(-68, 72). Differences not significant (wide CIs). CF did not reduce breast milk intake in any group at "non-inferiority margin" of -86 g/d pre-established by study design.	No intergroup differences in mean breast milk intake. Expressed as g/kg/day, infants consumed 7-13% less breast milk after 1 month of CF, but there were no intergroup differences. Infants in the 25 g supplement group had lower weight gain.	Proportion of infants breastfed significantly lower [-12.8% (-4, -21)] in the FS group compared to visitation group at 52 weeks; [-5% (-12.3,-0.4) at 38 weeks]. Mean BF frequency was lower compared to visitation group at 26 weeks [-1.7 (-2.7,-0.70)] and 38 weeks [-1.2 (-2.34, -0.06)]

Table 1.1, con't Risk of bias assessment				
Author, Year	**Owino, 2011 (14)**	**Kumwenda, 2014 (12)**	**Galpin, 2007 (13)**	**Bhandari, 2001 (11)**
Sequence generation	LOW RISK. Random-number generator to assign infants to study groups	LOW RISK: allocation prior to study	LOW RISK: 3 envelopes with study group prepared	UNCLEAR RISK: not indicated
Allocation concealment	LOW RISK. Done by computer, data entry clerk blinded to study group. Suitable for larger study: staff presented study assignment to mothers in sealed envelopes.	UNCLEAR RISK: initial randomization to sub-study was done at enrollment, but owing to attrition and need for adequate sub-study sample, more participants were added from the main trial.	UNCLEAR RISK: not indicated: mother chooses 1 of 3 envelopes with group assignment info, not clear which study staff knew group assignment	UNCLEAR RISK: not indicated
Blinding	HIGH RISK: Statisticians and data entry clerks were blinded to the identity of study foods, field staff and mothers are not blinded. CFs are different, blinding not possible	HIGH RISK: foods delivered in different packaging depending on assigned dose	HIGH RISK: investigator blinded, participant not blinded (different foods)	HIGH RISK: NOT blinded (CF vs. no CF groups, blinding not possible)
Attrition/incomplete outcome	LOW RISK: No attrition (cross sectional)	LOW RISK: balanced by study group	LOW RISK: lost 3/44 participants	MODERATE RISK: completion rates at 52 weeks: 87% in FS, 97% in counselling, 93% in no intervention and 91% in visitation groups.
Selective outcome reporting	LOW RISK:	LOW RISK:	LOW RISK:	LOW RISK:
Other sources of bias	Intent-to-treat analysis used, non-compliance may have affected results. Since preparations are different for each treatment, mothers not blind to treatment - compliance may have varied between groups. Results may be different in infants receiving no study foods, but the study did not include a no-treatment control arm. Systematic selection from larger RCT, sample includes those coming to clinic			Authors note that mothers may have over-reported consumption of FS
OVERALL QUALITY ASSESSMENT	Low	Low	Low	Low

Table 1.2 Study Characteristics Q1 Observational Studies				
Author, Year	**Pani, 2014** [15]	**Hernandez, 2011** [18]	**Foterek, 2014** [16]	**Bell, 2013** [17]
Design	Observational, longitudinal	Observational, cross sectional study	Observational, open-cohort, longitudinal	Secondary analysis of longitudinal data from RCT of obesity prevention
Location/year/setting	2007-2008, Institute of Maternal Health in Trieste, Italy	Guatemala city infants attending a health center serving low income population, August 2008	Dortmund Germany, open cohort began in 1985	Australia, multisite (Brisbane, Adelaide) NOURISH study (3/2008-4/2009, SAIDI study 9/2008-3/2009
Recruitment strategy	Those born in the Trieste maternal hospital between July 2007 and July 2008	Mothers approached when attending clinic for well-child care, illnesses, vaccinations	Open cohort. Personal contacts, maternity wards and pediatric practices were used as avenues for recruitment	Mothers recruited for the parent studies at birth. For the current study, NOURISH controls and SAIDI dyads were selected
Sample size (n) (recruited vs. final)	400 infants enrolled at birth, 268 had complete data at 6 month follow up.	97 initially included, 64 completed. Most excluded owing to missing 3 days of intake data, unbalanced M/F	Used data from 366 infants	552 (14 months), 493 (24 months)
Age (age at recruitment and duration of study)	Birth, 6 month duration, data from 6 months used for current study	6-12 months, median=8 mo.	Recruited at age 3 months, followed until young adulthood. Current study uses data from 6-24 months.	Data from, 14 and 24 months analyzed as cross sectional data.
Inclusion/exclusion criteria	Eligible: 2000g+, gestational age 36 weeks+, no severe diseases or congenital malformation, mother resident in Trieste	Must be breastfed and receiving CF, no congenital anomalies	[From the background paper] Inclusion: no prevalent diseases affecting growth and/or diet, German, age 3-6 months, with a willing mother/father who consents to this long-term study, and a German-speaking parent	Full term, > 2500 g included
Commercial food studied/comparison group (how CF intake was measured)	3 non-consecutive feeding diaries gave type, quantity and method of feeding in the previous 24 hour period. Food labels provided nutrient intake from commercial products. Mothers gave frequency and ~duration of BF.	Intake of full range of CFs assessed, intakes include CACFs such as Incaparina®	3-day weighed dietary records. Reported brand and type of food, recipes, information from food labels.	This was an analysis of dietary patterns using PCA. One pattern was characterized by low intake of commercially-available infant foods
Outcome (how it was measured)	Analyzed in breastfed/non-breastfed strata. Estimated volumes of 60, 80 and 100ml for short, normal or long duration of breastfeeding.	Breast milk intake MODELED: Energy intake from breast milk assumed to be estimated requirement - measured intake from CFs. Note that this method precludes assessment of how CFs may influence breastfeeding.	Scale for weighing breastfed babies before and after breastfeeding.	Breast milk intake was quantified as time sucking, assuming 10 g/min, up to 10 minutes. BF duration reported by the mother. Dietary pattern is the outcome: thus not appropriate for this question
Results	NBF infants had more milk energy intake from formula than estimated breastmilk intake in the breastfed category (median 363 Kcal, IQR 274–469 vs. 301 Kcal, IQR 243–393). Mean differences not significant. NBF infants had more macronutrients from commercial baby foods than BF infants (183kcal vs. 87kcal).	Can use data for this analysis since calculated breast milk intakes cannot be related to CF intake. Results presented in paper focus on extent to which intakes meet recommendations	Infants with high (>62%) CACF consumption also had significantly lower duration of full breastfeeding (19.4 vs. 13.6 wk), lower duration of total breastfeeding (41.9 vs. 31.8 wk), and lower age at introduction of CF (5.5 vs. 5.2 mo), higher total CF intake (54.3 vs. 69.8 kcal/kg birth weight. (Values are compared with low CF consumption)	Longer BF duration associated with dietary pattern characterized by lower intake of CACFs; breast milk loads positively in the pattern characterized by higher intake of breads, other milks, dairy products

Table 1.2, con't Risk of bias assessment				
Author, Year	**Pani, 2014** [15]	**Hernandez, 2011** [18]	**Foterek, 2014** [16]	**Bell, 2013** [17]
Inclusion/exclusion	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability
Recruitment	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers
Appropriate comparison group	HIGH RISK OF BIAS: BF and nonBF groups are self-selected, and nutrient and food intakes in these strata	Comparison group not defined	HIGH RISK OF BIAS: groups with high and low CACFs are self-selected	Comparison group is not purely CACFs
Was outcome assessor blinded	NA	NA	NA	NA
Valid and reliable measures	NO: Mothers estimated duration and frequency, breast milk intake was then estimated based on estimates of intake per minute of BF from prior studies	NO: breast milk intake not appropriately measured	YES. Breast milk intake from test weighing of infants is reasonably accurate, CF 3-day weighed food records is best method for CF intake	NO: Mothers estimated duration and frequency, breast milk intake was then estimated based on estimates of intake per minute of BF from prior studies
Length of follow-up	6 months	Cross sectional	1 year	2 cross sectional analyses at different ages
Attrition	High level of attrition: from 400 at birth to 268 at 6 months	High level of attrition: 64/97 included	Open-cohort	2 cross sections analyzed so attrition is not relevant in their analysis
Was selection bias addressed?	Baseline characteristics were different for baseline and final sample, raising the potential for selection bias	No	No	No
Confounding	No adjustment for confounders (Descriptive study)	Demographic characteristics of sample presented, but results not adjusted for confounders	Adjusted for total kcal, maternal employment, ongoing breastfeeding, maternal education, maternal age at birth, household size, parental overweight and birth weight	Analysis of how dietary pattern relates to SES. Analysis of dietary pattern to BMI was adjusted, but this outcome is not relevant for the current study
Stratification, propensity scores?	No	No	No	No
OVERALL QUALITY of EVIDENCE	Very low	Very low	Very low	Very low

Table 1.2, con't Risk of bias assessment				
Author, Year	**Pani, 2014** [15]	**Hernandez, 2011** [18]	**Foterek, 2014** [16]	**Bell, 2013** [17]
Inclusion/exclusion	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability	LOW RISK OF BIAS: Eligibility criteria appropriate for study, but may limit generalizability
Recruitment	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers	HIGH RISK OF BIAS: Participants are self-selected/volunteers
Appropriate comparison group	HIGH RISK OF BIAS: BF and nonBF groups are self-selected, and nutrient and food intakes in these strata	Comparison group not defined	HIGH RISK OF BIAS: groups with high and low CACFs are self-selected	Comparison group is not purely CACFs
Was outcome assessor blinded	NA	NA	NA	NA
Valid and reliable measures	NO: Mothers estimated duration and frequency, breast milk intake was then estimated based on estimates of intake per minute of BF from prior studies	NO: breast milk intake not appropriately measured	YES. Breast milk intake from test weighing of infants is reasonably accurate, CF 3-day weighed food records is best method for CF intake	NO: Mothers estimated duration and frequency, breast milk intake was then estimated based on estimates of intake per minute of BF from prior studies
Length of follow-up	6 months	Cross sectional	1 year	2 cross sectional analyses at different ages
Attrition	High level of attrition: from 400 at birth to 268 at 6 months	High level of attrition: 64/97 included	Open-cohort	2 cross sections analyzed so attrition is not relevant in their analysis
Was selection bias addressed?	Baseline characteristics were different for baseline and final sample, raising the potential for selection bias	No	No	No
Confounding	No adjustment for confounders (Descriptive study)	Demographic characteristics of sample presented, but results not adjusted for confounders	Adjusted for total kcal, maternal employment, ongoing breastfeeding, maternal education, maternal age at birth, household size, parental overweight and birth weight	Analysis of how dietary pattern relates to SES. Analysis of dietary pattern to BMI was adjusted, but this outcome is not relevant for the current study
Stratification, propensity scores?	No	No	No	No
OVERALL QUALITY of EVIDENCE	Very low	Very low	Very low	Very low

Table 1.3 Other studies on aspects of complementary feeding that may influence breast milk intake. These studies did not use commercially-available products, and thus did not fit inclusion criteria, but are noted because of their *potential* to inform the main question.

Author, Year	**Islam, 2008** [19]	**Singh, 2005** [20]	**Bajaj, 2005** [21]	**Owino, 2007** [22]
Design	Clinical RCT in hospital, compares CFs with 3 different energy densities; sequence of densities altered across 3 study periods	Clinical crossover RCT in hospital testing feeding frequency of 3 vs. 4 times/d	Clinical crossover RCT in hospital testing CF with oil or no oil added to alter energy density	RCT of fortified CF blend (vs. similar blend with amylase added compared to control
Setting	Dhaka, Bangladesh periurban community 11/2005-9/2006	New Delhi, date not given	New Delhi, date not given	Lusaka, Zambia; middle income urban population, date not given.
Recruitment	Community survey	Normal siblings of older children hospitalized or recovering from minor illnesses	Normal siblings of older children hospitalized or recovering from minor illnesses	Invited to participate when attending immunization clinic at 5 mo.
Sample size (recruited & final)	n=18, achieved with replacement if mother-child pair did not complete the protocol	n=20, 10 in each feeding frequency group	n=20, 10 in each feeding frequency group	In breast milk sub-study, 14 to CMBA, 12 to CMB, 27 controls
Age at recruitment & duration of study	8-11 mo, 42 d study	6-10 mo. 48 hr study	6-10 mo. 48 hr study	6 months, followed until 9 months
Inclusion criteria	BF≥6 times/d, CF≥2 times/d, LAZ>-2, WLZ>=1.5, <1.5, no acute or chronic illness, mom BMI>18.5	Receiving CF for >1 mo prior to enrollment, not febrile, WAZ>-3, no conditions that interfere with feeding	Receiving CF for >1 mo prior to enrollment, not febrile, WAZ>-3, no conditions that interfere with feeding	No chronic disease, BW>2.5 kg
CF used in study	CF prepared from commercial rice powder, rice starch, maltodextrin, sucralose, thickening gum, nonfat milk powder, soybean oil and cocoa powder, 0.5, 1.0, 1.5 kcal/g,	Traditional gruel of rice and pulses, 54 kcal/100 g	Traditional gruel of rice and pulses, 54 kcal/100 g	CF was industrially processed locally, from maize, beans, bambaranuts and ground nuts, fortified with MN; half of the produced batch was treated with amylase
Outcome	Breast milk intake by test weighing of infant in 12 hr period, with extrapolation to 24 hr.	Breast milk intake by test weighing of infant, with correction for invisible water loss, CF intake by weighing container before and after feeding, accounting for spillage	Breast milk intake by test weighing of infant, with correction for invisible water loss, CF intake by weighing container before and after feeding, accounting for spillage	Breast milk intake using deuterium dose to the mother, CF intake by 24 hour recall
Results	Total time spent nursing fell by 13%, total breast milk consumption decreased by 11% as energy density increased from 0.5 to 1.5 kcal/kg (p<0.001). Total breast milk intake fell by 8% when feeding frequency was increased from 3 to 5 times/d (p=0.04). For each additional 1 kcal/d intake of CF, energy intake from breast milk diminished by 0.18 kcal/d.	Breast milk intake was lower with CF feeding frequency of 4 vs. 3 times per day (-61.2 g, p=0.05)	Infants consumed 121 g (35, 207), p=0.008 less breast milk/d when given CF with oil (35 kcal/100g) vs. no oil (20 kcal/100g). Energy density of CF was inversely associated with breast milk intake (r=-0.34, p=0.032)	No significant differences in daily breast milk intake between the groups: CMB= 614 (566, 741); CMBA=635 (512, 758); control=653 (566, 741)

Table 1.3 Other studies, con't				
Author, Year	**Islam, 2008** [19]	**Singh, 2005** [20]	**Bajaj, 2005** [21]	**Owino, 2007** [22]
Risk of bias assessment	Double blind, not possible to determine sequence generation or allocation concealment, incomplete cases replaced to maintain sample size	Randomized after weight screening, no information about blinding	Randomized after weight screening, no information about blinding	Control group had potential to be healthier because they were healthy when recruited at 9 mo (intervention group recruited at 6 mo could have illness at 9 m) random allocation, double-blinded, baseline characteristics balanced across groups but differential attrition in study groups vs. control
Comments	Highly selected group of infants screened for initial weight status and BF & CF feeding patterns	1 d of 3x/d and 1d 4x/d likely insufficient to alter infant patterns		

1.5 Conclusions

To what degree do commercially-available products replace, rather than complement, the intake of breast milk in children 6-23 months of age? From RCTs of CACFs or comparable CFs, there is low quality evidence to suggest that energy dense foods do not displace breast milk. However, the supplemental studies on other aspects of complementary feeding suggest that breast milk intake is sensitive to energy density of the CFs fed, and to feeding frequency, providing some evidence for potential displacement of breast milk by CFs depending on characteristics of the CF and how often they are fed. The inconsistency in these findings strongly suggest that more RCTs are needed, with protocols that include accurate methods of quantification of breast milk in response to feeding of CF, with consideration of amount and energy density as well as feeding frequency of CFs.

Evidence from observational studies often report reduced breastfeeding duration or frequency with introduction of CFs, but since the studies measure concurrent breastfeeding and CF intake, and likely make simultaneous choices about these feeding practices, no causal inferences can be drawn from these studies about how CF affects breast milk intake.

The included studies represented a very limited selection of CACFs. They were primarily focused on products designed to improve nutritional status of infants during the weaning period in LMIC settings with high rates of stunting and micronutrient deficiencies. There were no RCTs in high income settings, using any of a broad range of CACFs for infants. This large gap in the literature limits ability to draw conclusions about a wider range of CACFs and their effects in infants of high income countries. Additional rigorous RCTs in healthy infants are needed to assess change in objectively measured breast milk intake *in response to* feeding of specific CFs.

PART 2. RESEARCH QUESTION 2

To what degree do commercially-available products consumed by children 6-23 months of age increase the risk of childhood obesity or chronic disease risk factors?

2.1 Background

Most research on the relationship of infant feeding to child obesity or chronic disease risk factors has focused on mode of feeding, mainly breast vs. bottle feeding of infant formula, [23-25] the timing of introduction of solid foods, [26] and the type or macronutrient composition of foods. [27] Less attention has been paid to specific infant foods or food sources other than types of milks. Infant diet composition is a concern because eating habits and taste preferences are established early in life, [28] and because short term responses to foods may initiate pathophysiology that persists into later life. [29] In the context of obesity and chronic disease risk, some CACFs are of particular interest because of their high macronutrient density and added salt and sugars. For example, Cogswell et al. [30] in their review of 1074 US infant and toddler foods and drinks noted that while most infant vegetables, dinners, fruits, dry cereals and ready-to-serve mixed grains were low in sodium, a high percentage of toddler dinners, and savory infant and toddler snacks had a high sodium content, and 41/79 infant mixed-grain foods and fruits included one or more added sugars. Studies of 240 infant and toddler foods sold in US retail stores, [31] and 186 sold in Canada [32] found that 58% and 63%, respectively, had high sodium or >20% of energy from sugar. A study of all infant foods made by 6 suppliers in the UK (n=479 products) found that 65% were "sweet foods", with energy density similar to breast milk. Studies examining potential adverse effects of specific foods are quite limited.

2.2 Objective

The objective for Q2 is to review evidence on the degree to which commercially-available products consumed by children 6-23 months of age increase the risk of childhood obesity or chronic disease risk factors.

2.3 Methods

2.3.1 Criteria for considering studies

We did not restrict our search by study design. We included evidence on infants and young children, ages 6-23 months randomized or observed to be consuming CACFs compared to home-prepared or local complementary food products. For this question, CACFs included follow-on formula for infants 6 months of age and older. We included studies which reported on anthropometric indicators of adiposity or rapid weight gain (attained weight, weight-for-length or BMI Z-scores, or change in Z-scores) or other methods of assessing body composition; or chronic disease risk factors (elevated blood pressure or glucose, abnormal blood lipids, inflammation).

2.3.2 Search method strategies for identification of studies

2.3.2.1 Electronic searches

The following electronic databases were searched to identify relevant studies:

- PubMed (2000 – 7 Apr 2015)

- CINAHL plus (2000 – 8 Apr 2015)
- EMBASE (2000 – 7 Apr 2015)
- Agricola (2000 – 8 Apr 2015)
- CAS (2000 – 8 Apr 2015)
- Clinicaltrials.gov (2000 – 9 Apr 2015)
- Cochrane (2000 – 9 Apr 2015)
- Global Health (2000 – 8 Apr 2015)
- WHO Global Library (2000 – 9 Apr 2015)
- Business Source Premier (2000 – 8 Apr 2015)

2.3.2.2 Searching other sources

We also searched other economics databases (AgEcon, Mintel Oxygen), relevant conference proceedings (Association for Consumer Research, International Health Economics Association), and sources of grey literature (New York Academy of Medicine's Grey Literature Report, Open Grey, PH Partners). Additionally, we reviewed reference lists from highly relevant reviews and articles.

2.3.2.3 Search strategy

The search strategy was created using a combination of subject headings and free-text keywords to identify publications (see **Appendix 2.1**). We did not restrict by language or study design. We restricted to studies published after 2000, to ensure that the commercially-available products analyzed would provide relevant and contemporary evidence. References were extracted and imported into EndNote. Duplicate articles were identified and removed first in EndNote, and then manually in Excel. All articles were assigned a unique record number.

2.3.3 Data collection and analysis

2.3.3.1 Selection of studies

Two reviewers independently screened titles and abstracts from electronic databases to identify potentially eligible studies. Prior to starting the work, inter-rater agreement was assessed by screening a subset of titles and abstracts and calculating Cohen's Kappa. Discrepancies were resolved by discussion with a third reviewer. One reviewer screened titles and summaries from the other resources. Full-text articles were obtained, and were independently reviewed by two reviewers according to the inclusion criteria. Discrepancies were resolved with discussion. When the full-text was not available in English it was excluded.

2.3.3.2 Data extraction

Excel workbooks created for systematic review data management were utilized in the abstract screening and full-text review process. [6] Record numbers, titles, and abstracts were exported from EndNote into the Excel workbook, and all title and abstract screening and full-text review took place within Excel. Comments on reasons for full-text exclusions were noted in a separate file. Each reviewer had her own Excel workbook, to keep the review process blinded.

One reviewer extracted data into standardized tables. Information was extracted on: general study characteristics (design, location/setting, recruitment strategy), participant characteristics (sample size, age, inclusion/exclusion criteria), description of the commercially-available complementary food and comparison foods, outcome, and results. Two separate risk of bias assessment tables were created (for RCTs vs. observational studies).

2.3.3.3 Assessment of risk bias and quality in included studies

Articles included in the review were assessed for quality using Cochrane criteria for RCTs and AHRQ guidelines for non-randomized and observational studies. [7,8] Since only 4 studies were identified, and found to be highly heterogeneous in design, focus, types of CFs, study site, and analysis, they were not combined in a meta-analysis. Overall quality of evidence from the final studies was evaluated using GRADE criteria. [10]

2.4 Results

2.4.1 *Literature search*

We identified 929 abstracts for initial screening, from which 17 were referred for full-text review. Of these, 4 were included in the review (**Figure 2.1**). The main reasons for exclusion were that the study did not include commercially-available foods, obesity/adiposity/rapid weight gain or chronic disease risk factors were not an outcome of the study, the comparison group was not infants consuming home-prepared CFs, or the full-text was not available in English (see **table 2.1** for a description of full-texts that were reviewed and excluded from the final set).

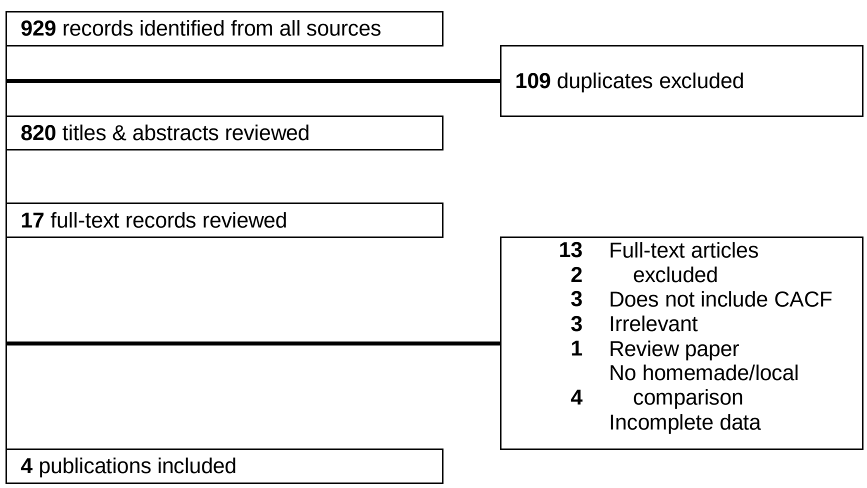


Figure 2.2 Flowchart of review process

Of the 4 papers included in the review, two were RCTs. The first was a multi-center European trial focused on comparing low vs. high protein infant formula, which included follow-on formula given to infants from 6-12 months. [33] The second was a trial aimed at improvement of nutritional quality of weaning diets in Cambodia, and compared animal source CFs to corn-soy-blend. [34] The two observational studies related milk-cereal drink to child obesity in Sweden. [35,36]

2.4.2 Substantive findings of the included studies(Table 2.1)

Koletzko et al. [33] randomized infants who were exclusively formula fed at 8 weeks to consume lower protein vs. higher protein formula. When mothers began to feed CFs after the fifth month, follow-on formula with low (8.8%) or high (17.6%) protein was provided up to 12 months of age. The formulas were prepared for the study by a company in France, and their protein content corresponded to the lower and upper limits of the range of commercially-available products marketed in the countries during the course of the study. Intake of other CFs, and infant weight and length were assessed at 6, 12, and 24 months. The groups randomized to high or low protein were compared to an observational group of breastfed infants. Weight-for-length and BMI Z-scores were significantly higher in the high protein compared to the low protein group at 6, 12 and 24 months, with the largest differences observed at 12 months. Growth in the low protein group did not differ from that of breastfed infants in the observation group.

During a 9 month intervention period (6-15 months) among Cambodian infants living in a food-insecure area, there were no significant differences in fat mass estimated by deuterium dilution between infant groups consuming two commercially prepared products (CSB+ and CSB++) available through the World Food Program, compared to locally produced alternative CFs with added animal source foods. [34]

The two observational studies focused on how consumption of milk-cereal drink (MCD), a product widely consumed by Swedish infants, relates to infant or child BMI. Sold as a powder, MCD is reconstituted by adding water and often given in a feeding bottle. Almquist-Tangen et al. [35] related MCD consumption to the likelihood of having a high BMI, defined as BMI >1 SD above their study population median. Bottle feeding with MCD at 6 months increased the odds of having a high BMI at 12 months [OR=1.58, (1.12-2.22)] and 18 months [OR=1.52 (1.07, 2.17)]. These associations were not different according to breastfeeding or consumption of other foods. Wilberger et al. [36] assessed older children (4-9 yr) according to their history of MCD consumption earlier in life. MCD consumers were more likely to be overweight [1.70 (1.06-2.71] compared to non-consumers, after adjusting for confounders as well as breastfeeding status in infancy. Consumers of MCD were also 4.78 (1.68-13.59) times more likely to become overweight between the baseline assessment and follow-up 2 years later.

2.4.3 Quality of included studies

The RCTs had moderate [33] and high [34] risk of bias. One was a double-blind, multi-site study with high external validity, but higher than expected attrition. [33] However, attrition and non-compliance (i.e. not feeding the study formula) was equal in the 2 randomized groups. The randomized formula groups differed from the observational breastfed group in parental characteristics. A limitation of this study for the current research question is that it is not possible to attribute differences only to the protein content of the follow-on formula, since significant differences were already apparent at 6 months of age (suggesting the importance of protein intake in the first 6 months).

The Cambodian study also had high attrition, which reduced statistical power. There was suspected sharing of the CF supplements, [34] and intake of non-study CFs was not measured.

The observational studies had high risk of bias. Both relied on maternal recall of infant consumption of MCD. In one study, anthropometric outcomes were measured during the period when toddlers were consuming MCD. [35] In the second study, participants were 2-9 years old, and MCD was reported retrospectively on parental questionnaires. [36] Children's diet during the subsequent 2 years of follow-up was not measured. No causal inferences can be made from these studies.

2.4.4 Quality of outcomes (GRADE)

Based on these studies, the overall quality of evidence that CACFs increase risk of obesity and chronic disease risk is low.

Risk of bias. Both RCTs had high rates of attrition, but equal attrition rates across randomized study groups. There was evidence of selective outcome reporting. However, one study labeled supplement packets (albeit in small print), and was therefore not blinded to participants. The observational studies had a high risk of bias.

Inconsistency. Heterogeneity in effects was not directly assessed across the studies, owing to substantial differences in recruitment strategies, participant populations, sample size, and CFs tested. The 2 observational studies of MCD were consistent in their findings of elevated risk of infant overweight associated with consumption of MCD, but the outcome in the two studies was measured at different ages.

Indirectness. Three of the populations studied were in high income countries, and their main research questions were framed in the context of child obesity. The fourth study was in a context of food insecurity, and aimed to improve quality of CFs fed to poorly nourished infants. The applicability of two of the studies is questionable: the follow-on formulas were produced specifically for the research, but mimicked commercially-available follow-on formulas. In the Cambodian study, local foods were compared to corn-soy-blend, and it is not clear whether this commodity food should be considered a CACF.

Imprecision. All studies had wide confidence intervals when comparing alternate CFs. Sample size was adequate based on a priori power calculations, but attrition substantially reduced sample size in all of the studies.

Publication bias. It was not possible to formally assess publication bias.

Table 2.1 Q2 Full-texts reviewed

RCTs

Author, Year	Koletzko, 2009 [33]	Skau, 2015 [34]
Design	RCT, multicenter	RCT, WINFOOD products vs. CSB
Location/setting/year	Multi-site: Belgium, Germany, Italy, Poland, Spain 2002-2004	7 communes in rural Cambodia March 2011-March 2012
Recruitment strategy	Recruited shortly after birth (in hospital/clinic)	6 mo infants attending referral hospital in PeaRieng town.
Sample size (n) (recruited vs. final)	1090 randomized, final sample at 24 mo = 636 (58%). Recruited 619 for BF observation group, final sample = 298 (48%)	419 randomized, final = 358 (85%)
Age	Enrolled at 8 weeks (baseline), followed until 24 months	6 mo at baseline, followed until 15 mo
Inclusion/exclusion criteria	Inclusion: exclusively formula fed at 8 wks (for RCT) or BF since birth (comparison group). Exclusion: multi-birth, maternal hormonal/metabolic disease, illicit drug addiction, medical conditions that might restrict growth, relocation far from study center.	Severe malnutrition [<–3 (WLZ)], pitting edema, clinical signs of vitamin A deficiency, and severe anemia.
Commercial food studied/comparison group (how was CF measured)	Low & high protein infant/Follow-on "study formula" randomized, compared to BF. Food intakes measured w/3-d weighed food records at 3, 6, 12, and 24 months	4 processed CACFs: WF, WF-L (fortified with a mineral and vitamin mix), CSB+, or CSB++. Both WF products locally produced. Daily rations before cooking: 50 g at 6–8 mo, 75 g at 9–11 mo, and 125 g at 12–15 mo
Outcome (how it was measured)	Height and weight, conversion to Z scores with WHO growth reference. Performed twice - took average	Changes in fat and fat-free mass assessed using deuterium dilution. Also assessed change in iron status.
Results	At 24 mo. High protein group had 0.20 SD higher WLZ compared to low protein. Low protein group not different from BF group. Energy intake: low protein>high protein at 6 months, not different at 6 or 24 mo	No difference in mean fat mass (kg) or increments in fat or fat free mass in the animal food supplement group compare to the CSB

Observational

Author, Year	Almquist-Tangen, 2013 [35]	Wiberger, 2014 [36]
Design	Observational cohort	Observational cohort
Location/setting/year	South-western Sweden October 2007 - December 2008	Sweden, part of multi-country study, 2007-2008
Recruitment strategy	All families at first visit to child health centers.	Recruited in preschool/primary school
Sample size (n) (recruited vs. final)	3860 births, 2666 chose to participate, 2241 remained at 18 mo. (84%)	Initial study: 2759 contacted, 1837 participated, current study included 1077 (59%) with complete feeding and anthropometric data
Age	1-2 weeks at recruitment, outcomes measured at 6, 12, 18 months	2-9 at recruitment, used retrospective data on feeding from 6-24 mo
Inclusion/exclusion criteria	Not stated	All children in school eligible
Commercial food studied/comparison group (how was CF measured)	Milk cereal drink (MCD) and/or porridge compared to breast milk and/or semi-solids	Välling: a milk-cereal drink, ever/never consumed, age first consumed, # months consumed
Outcome (how it was measured)	BMI at 12 and 18 mo. Anthropometry done by trained child health nurses using digital scales and calibrated stadiometers with the infant naked. Overweight defined by study specific >1 SD	BMI, weight & height measured with standard technique, portable statiometer, electronic scale IOTF definition of overweight
Results	Milk cereal drink at 6 mo increased risk of high BMI at 12 and 18 mo, respectively (OR 1.58, 95% CI 1.12–2.22, and 1.52, 1.07–2.17). No association between feeding patterns at 4 mo and a high BMI (>1 SD) at 12 or 18 mo	MCD associated with increased odds of being overweight 1.70 (1.06-2.71); 4.78 (1.68-13.59) for INCIDENT overweight, dose response with duration of consumption

Table 2.1 cont'd Risk of bias assessment

Author, Year	**Koletzko, 2009**	**Skau, 2015**
Sequence generation	Low risk: Randomization lists for each country, stratified by sex, prepared using random permuted blocks of 8 drawn through an Internet-based platform.	Low risk: Computer generated and stratified by sex with varying block sizes of 12 and 24
Allocation concealment	Low risk: Two colors each were used to label the lower and higher protein formulas.	Low risk: Identical packaging with product identification marked in small print on backside, allowing staff member to ensure correct distribution
Blinding	Low risk: All blinded except statisticians	Moderate risk: Single-blinded for investigators and enumerators, food packages labeled in small print
Attrition/incomplete outcome	High risk: Final: 313 (58%) in low-protein group, 323 (59%) in high-protein group, 298 (51%) in BF group	Moderate risk: Final = 358 (85.4%): 80% in WF, 89% in WF-L, 87% in CSB+, 85% in CSB++
Selective outcome reporting	Low risk: no selective reporting	Low risk: no selective reporting
Other sources of bias	Formula was provided free of charge; unclear whether this was disclosed before or after consent. No significant differences b/w 2 randomized formula groups, but. BF group higher edu and fewer smokers. Loss to follow-up more likely among: lower edu, smokers. Those excluded for lack of compliance weren't different	Heavy flooding may have introduced a higher dropout rate, weakening power. Potential lack of compliance to predefined portion sizes due to food sharing, resulting in underestimates of supplement use
OVERALL QUALITY	MODERATE	MODERATE

Author, Year	**Almquist-Tangen, 2013**	**Wiberger, 2014**
Inclusion/exclusion	Low risk: No exclusions identified, bias unlikely	Low risk: No exclusions identified, bias unlikely
Recruitment	Moderate risk: Healthy volunteers: families who visit the child health centers between 1 and 2 weeks old, high parental response rate, bias unlikely	Moderate risk: Healthy volunteers, all children in preschool, up to age 9 in primary school invited, bias unlikely; not population-based
Appropriate comparison group	High risk: Consumers of MCD compared to non-consumers: other foods consumed could differ between groups	High risk: Consumers of MCD compared to non-consumers: other foods consumed could differ between groups
Was outcome assessor blinded	NA	NA
Valid and reliable measures	Moderate risk: Anthropometry is reliable outcome, exposure identified from maternal recall but over short recall period	High Risk: Anthropometry is reliable outcome, exposure from maternal recall is from 1-8 yrs prior to study so recall bias is likely
Length of follow-up	Moderate risk: 18 mo, sufficient time to see effects	High risk: Children followed for 2 years, but NOT during the period of MCD consumption
Attrition	Moderate risk: moderate attrition: 16% at 18 mo	Moderate risk: 122 children lost to follow-up over 2 years.
Was selection bias addressed?	High risk: No	Moderate risk: Baseline results not changes when children lost to follow-up are excluded
Confounding	Moderate risk: Adjusted for limited paternal, maternal and infant characteristics	Moderate risk: Adjusted for age, sex, birthweight, maternal education, BMI, breastfeeding
Stratification, propensity scores?	No	No
OVERALL QUALITY	VERY LOW	VERY LOW

2.5 Conclusions

The evidence that met criteria for inclusion in this report is of low quality, and insufficient to provide a definitive answer to the question, "*To what degree do commercially-available products consumed by children 6-23 months of age increase the risk of childhood obesity or chronic disease risk factors*?"

Higher protein follow-on formula is associated with moderately high weight-for-length Z-scores at 24 months of age, and a history of consumption of MCD is associated with higher risk of toddler or young child overweight. The energy density of MCD and follow-on formulas is similar (65 vs. 72 kcal/100 ml), but the protein content of MCD is higher, at 2.7 g/100 ml and is more similar to the high protein follow-on formula used in the multi-country study (3.2 g/100 ml) than to the average level of 1.9 g/100 ml in follow-on formulas marketed in the same countries. Given these findings, further research into the health implications of similar high protein/high energy density CACFs is needed.

We found no studies meeting the inclusion criteria that related other types of CACFs to infant adiposity or chronic disease risk. While, as noted in the introduction, there are numerous studies relating timing of introduction of solid CFs or mode of feeding to infant and child weight or adiposity status, these studies do not identify specific CACFs. Thus, overall, the evidence base for how CACFs relate to infant health is extremely limited, and further focused studies on this topic are needed.

PART 3. RESEARCH QUESTION 3

Are commercially-available products nutritionally inferior or superior to home-prepared and/or local foods? Do they contain higher or lower amounts of trans-fat, saturated fat, free sugars, or salt? Do they contain higher or lower amounts of essential micronutrients? Do commercially-available products provide nutrients that are generally lacking in the diets of young children?

3.1 Background

In LMIC, locally available and affordable CFs are often of inadequate quality, and may be fed in inadequate quantities to meet infant and young child energy and nutrient needs. Thus, most of the literature relating home-prepared or local foods to CACFs in low resource settings is aimed at undernutrition, with a focus on identifying CFs that will prevent or ameliorate micronutrient deficiencies and growth faltering. Concerns about cost and sustainability have motivated efforts to develop better quality CFs from local ingredients with high nutrient density and bioavailability. Some studies use local foods or ingredients, which may be mixed in different combinations, altered to add micronutrients (commercially-available micronutrient supplements or animal foods such as dried fish or insects), or altered to change consistency or digestibility through processes such as fermentation. CACFs widely marketed in LMIC tend to be micronutrient-fortified, high energy density foods such as dry cereals to be prepared by mixing with water or milk. In the literature on CFs from LMICs, CACFs manufactured by multinational companies have been analyzed primarily as the foods given to a control or comparison group in studies aimed at development and testing of better quality home-made or locally available CFs. There is little information based on comparison of commercially-available foods with a directly comparable home-prepared product.

In contrast, studies of CACFs in high income countries tend to focus on concerns about the potential for CFs to influence obesity and chronic disease risk. [30,37] Thus, they include comparisons of macro and micronutrient content, amount or types of fat, or amount of sugar and salt based on nutrition facts labels or chemical analyses. For obvious ethical reasons, there are no randomized trials which compare high fat/high sugar foods to healthier versions.

3.2 Objectives

The objective for Q3 is to review evidence on the nutritional quality of CACFs, especially with respect to fat content, added sugar and salt, and essential micronutrients.

3.3 Methods

3.3.1 Criteria for considering studies

We did not restrict our search by study design. We included evidence related to CFs for infants and young children, ages 6-23 months. CACFs were compared to: home-prepared foods, CFs that could be home prepared with local ingredients, or CFs that closely mimic home prepared foods. Included studies are those that report results of laboratory-based analyses of the nutrient composition of selected CFs without involving any human trials, OR analysis of composition of specific foods assigned for consumption in RCTs or recorded in observational studies. We considered any studies that quantified macronutrients (including types of fats, added sugars), and/or micronutrients or added salt.

3.3.2 Search method strategies for identification of studies

3.3.2.1 Electronic searches

The following electronic databases were searched to identify relevant studies:

- PubMed (2000 – 10 Apr 2015)
- CINAHL plus (2000 – 10 Apr 2015)
- EMBASE (2000 – 10 Apr 2015)
- Agricola (2000 – 12 Apr 2015)
- CAS (2000 – 12 Apr 2015)
- Clinicaltrials.gov (2000 – 12 Apr 2015)
- Cochrane (2000 – 12 Apr 2015)
- Global Health (2000 – 10 Apr 2015)
- WHO Global Library (2000 – 12 Apr 2015)
- Business Source Premier (2000 – 10 Apr 2015)

3.3.2.2 Searching other resources

We searched other economics databases (AgEcon, Mintel Oxygen), relevant conference proceedings (Association for Consumer Research, International Health Economics Association), and sources of grey literature (New York Academy of Medicine's Grey Literature Report, Open Grey, PH Partners). Additionally, we reviewed reference lists from highly relevant reviews and articles.

3.3.2.3 Search strategy

The search strategy was created using a combination of subject headings and free-text keywords to identify publications (see **Appendix 3.1**). We did not restrict by language or study design. We restricted to studies published after 2000, to ensure that the commercially-available products analyzed would provide relevant and contemporary evidence. References were extracted and imported into EndNote. Duplicate articles were identified and removed first in EndNote, and then manually in Excel. All articles were assigned a unique record number.

3.3.3 Data collection and analysis

3.3.3.1 Selection of studies

Two reviewers each screened one-half the titles and abstracts from electronic databases to identify potentially eligible studies. Prior to starting the work, inter-rater agreement was assessed by screening a subset of titles and abstracts and calculating Cohen's Kappa. All studies identified as possibly being eligible for inclusion were screened by a third reviewer for a final decision. One reviewer screened titles and summaries from the other resources. Full-text articles were obtained, and were independently reviewed by two reviewers according to the inclusion criteria. Discrepancies were resolved with discussion. When the full-text was not available in English it was excluded.

3.3.3.2 Data extraction

Excel workbooks created for systematic review data management were utilized in the abstract screening and full-text review process. [6] Record numbers, titles, and abstracts were exported from EndNote into the Excel workbook, and all title and abstract screening and full-text review took place within Excel. Comments on reasons for full-text exclusions were noted in a separate file. Each reviewer had her own Excel workbook, to keep the review process blinded.

Two reviewers extracted information on: general study characteristics (design, location/setting, recruitment strategy), participant characteristics (sample size, age, inclusion/exclusion criteria), description of the commercially-available complementary food and comparison foods, outcome, and results. Risk-of-bias assessment criteria were evaluated for each study and presented in the tables which describe the studies. Tables were reviewed by another reviewer.

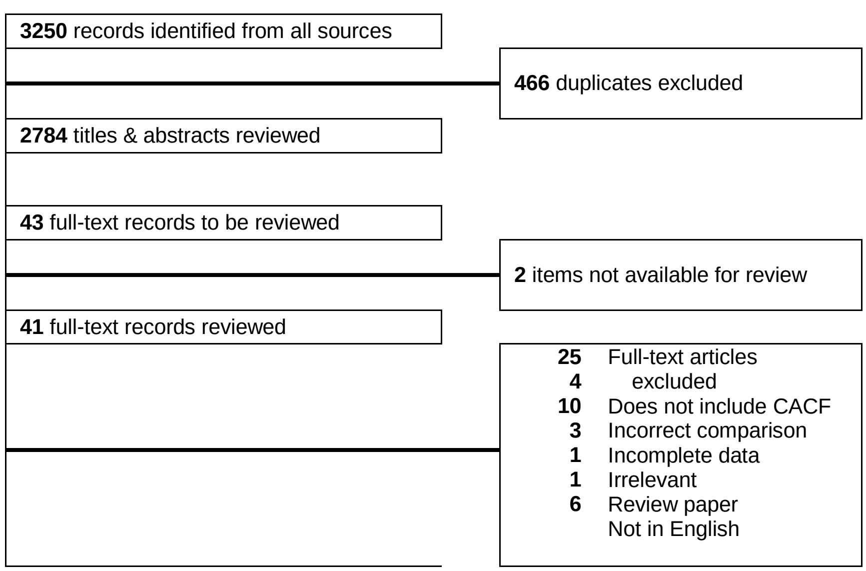
3.3.3.3 Assessment of risk bias and quality in included studies

Given the nature of this question, most of the evidence derives from laboratory analysis of different CFs. Thus, standard review criteria for RCTs and observational studies do not apply to the laboratory studies. For studies amenable to the quality assessment for human studies, we used AHRQ tools for the observational studies. [7,8] No RCTs were relevant. The studies included in the final review were highly heterogeneous in the CFs and specific nutrients analyzed, and were not amenable to a meta-analysis of results. Overall quality of the evidence from the final studies was assessed using GRADE evidence profiles. [10]

3.4 Results

3.4.1 *Literature search*

We identified and screened 3250 abstracts. Of these, 43 were referred for full-text review, and 16 were included in the final review (see **figure 3.1**). Of these, three were human studies that compared infant energy and nutrient intakes and/or nutritional quality of alternate CFs, while the remaining 13 were laboratory studies of nutrient chemical composition of alternate CFs. A list of excluded full-texts and reasons for exclusion is presented in **Appendix 3.2.**



16 publications included

Figure 3.1 Flowchart of review process

3.4.2 *Characteristics of included studies*

Owing to the differences in study design represented in the included studies, we separately reviewed studies involving humans and those based solely on laboratory assessment of the composition of CF samples. Very few studies have unaltered home-prepared foods as the comparison group. Often the investigators formulate CFs with local products so that they mimic home-prepared foods.

Of the 3 human studies, two were from LMICs (South Africa and Vietnam), and 1 from a high income country (UK). The Vietnam study was part of a RCT designed to compare two alternate CFs to home-made foods in terms of infant energy and nutrient intakes, and nutrient composition of the foods. [38] The UK study, done in the ALSPAC cohort, [39] identified dietary patterns characterized by high intake of CACFs vs. home-made foods, and related energy and nutrient intakes to those and other patterns. The South African study compared energy and nutrient intake of infants who consumed CACFs to those who did not consume CACFs. [40]

Of the 13 laboratory studies, 9 were conducted and analyzed in Africa (1 in Ghana, 7 in Nigeria and 1 in Tanzania), 3 in Europe (1 in Denmark, 1 in Italy and 1 in the United Kingdom) and 1 in Asia (India). All studies reported the mean micronutrient, macronutrient and energy contents of selected CACFs with home-made infant foods and/or laboratory-prepared formulations of infant foods made from locally available ingredients.

3.4.3 Substantive findings from the human studies (Table 3.1)

Details from the three human studies are presented in **table 3.1**. Smithers [39] et al. identified dietary patterns using factor analysis (43 food items at 6 months, 70 items at 15 months). One factor represented a home-made, traditional dietary pattern consisting of home-prepared meat, vegetables and desserts, while another represented high intake of ready-prepared baby foods. At 8 months, the ready-prepared baby food pattern score was positively associated with many micronutrients, including iron and calcium, and negatively associated with fiber and sodium, a pattern which the authors characterized as generally positive with room for improvement. Patterns were not consistent or stable over time. Faber et al. [40] compared energy and nutrient intakes among 6-12 month old rural South African infants according to whether they consumed CACFs (fortified infant cereals, ready-to-eat baby foods and infant formula) or not. Those who consumed CACFs had significantly higher intakes at 6-9 and 9-12 months of protein, calcium, iron, and zinc as well as higher intakes of vitamins A, B_6, B_{12} and C, thiamine, riboflavin, and niacin, but intakes of some of these nutrients were still less than adequate. Van Hoan et al.[38] compared the ability of 2 CF food products to increase energy and nutrient intake of Vietnamese children. They compared Favina (made from rice, soybeans, sugar, sesame, dry milk, iodized salt, $Ca_3(PO_4)^2$ and vitamin-mineral premix) and Favilase (made from soybeans, iodized salt, $Ca_3(PO_4)^2$, vitamin-mineral premix and α-amylases) to a home-made traditional gruel consumed by 6, 7, 8, and 9 month old children. Per 100g, the home-made gruel was consistently lower in energy, protein, Ca, Fe and Zn (71kcal, 2.62g, 18mg, 0.43mg, 0.39mg, respectively) compared to the Favina (99kcal, 3.61g, 116mg, 5.37mg, 1.51mg) and Favilase (105kcal, 4.30g, 175mg, 8.59mg, 1.85mg). Median infant intakes, per meal, were 11.7 g/kg body weight higher for Favina and Favilase than home-made gruels.

3.4.4 Quality of the included human studies (GRADE)

Based on these studies, the overall quality of evidence is low.

Risk of bias. Risk of bias related to recruitment was low, but other sources of bias were high: Two of the studies were observational, and one was a trial with no blinding of CFs. Each of the three studies used a different technique to quantify consumption of CACFs and home-made foods and used assessment tools that often yield biased estimates of food intake. Smithers et al. [39]used dietary questionnaires to determine patterns at 6 and 15 months of age and un-weighed 3-day diet diaries to determine nutrient intake at 8 and 18 months of age. Faber [40] used a single 24-hour dietary recall. Van Hoan et al. [38] used in-home surveying techniques to weigh and measure intake of all foods over the course of a day; their data are less subject to recall bias, but surveyors stayed in the participant's home, introducing the potential for social desirability bias.

Inconsistency Two of the studies [39,40]examined combinations or patterns of intake of CACFs and could therefore not provide insights on specific CACFs. The two studies in LMIC, found that infants who consumed CACFs had higher micronutrient intakes than those who did not, likely reflecting the micronutrient fortification of CACFs. In the third study, a higher score on the dietary pattern characterized by CACFs (ready-prepared foods), was associated with a mixed profile of what might be deemed healthy vs. problem nutrients, thus limiting any clear generalizations.

Indirectness. One of the studies used laboratory prepared porridges made with locally-available products and so these formulations did not necessarily reflect what is traditionally prepared in home settings but are plausible formulations nonetheless. The analysis of dietary patterns is unable to assess specific CACFs

Imprecision. It is not possible to directly quantify nutrient profiles of derived dietary patterns in the UK study: mean intake of nutrients by tertile of factor score, without SDs, were presented.

Publication bias. It was not possible to formally assess publication bias.

3.4.5 Substantive findings from the laboratory studies (Table 3.2)

There are 9 studies from Africa that used laboratory-formulations of meals made from locally-available foods that could be prepared in home settings. In the Ghana study, Eshun et al. [41] found that their formulation diet of soybean, groundnut and rice flour mixture provided more protein, fat, energy, iron, but less calcium compared to Cerevita™. Mosha et al. [42] reported that the two Lactogen™ and two Cerelac™ products were higher in sodium, calcium and zinc compared to the maize, cassava, millet, plantain-meat, sorghum and millet-composite home-made foods under study in Tanzania. However, their plantain-meat pap, millet-sardine-peanut gruel and millet gruel had a higher protein content compared to the CACFs. Ijarotimi et al. [43] found that their crayfish-ogi, soy-moinmoin and cooked beans had greater protein content than Cerelac™. Ijarotimi et al. [44] compared their formulation diets of green bananas and bambara groundnut seeds flour (70:30 (CBR1) or 60:40 (CBR2) ratio) to Nutrend™. The CBR2 infant diet had similar protein quality to that of Nutrend™. Total protein contents were not reported. Ijarotimi et al. [45,46] published 2 studies which compared Nutrend™ to ogi (locally available CF) and four formulations of banana and groundnut flour with different compositions to traditional fermented maize porridge, ogi, and Nutrend™. While the flour blends had a superior nutritional profile compared to ogi, some formulations were similar to or inferior in comparison to Nutrend™. Steve et al.

[47] found that fermented and blanched experimental mixes of popcorn and moringa leaves flours (FPM and BPM respectively) had higher protein content but lower energy compared to Cerelac™ and ogi. FPM sample had higher copper, calcium and magnesium than Cerelac™. BPM had higher zinc, iron, potassium, sodium and phosphorous than Cerelac™. Lalude et al. [48] found that their laboratory prepared formulation of sorghum, soyabean, groundnut and sesame-oil seeds/flours had higher protein, energy, iron, sodium and calcium contents than the Nutrend™ product. When Omueti et al. [49] compared their formulation diets of Prowena (maize flour with soyflour, groundnut meal, crayfish flour) and Propalm (maize flour with soyflour, groundnut meal, crayfish flour palm oil) to yellow maize gruel ogi and Nutrend™, they found higher protein in formulation weaning diets relative to Nutrend™ and ogi. Nutrend™ had higher fat, calcium, potassium, sodium and iron contents than the formulation diets.

The four remaining studies were set in Europe and Asia. The UK study by Garcia et al. [37] found that ready-made meat/fish/chicken had less energy and protein compared to home-made beef and chicken. Ready-made vegetarian baby food had lower energy, protein and calcium compared to home-made potato and cauliflower and cheese dishes but more than the home-made vegetable dish used in comparison. Commercial rusks/biscuits had more energy, iron and calcium compared to home-made banana and toast alternatives. Ready-made sweet foods had less protein than stewed apple with custard, or stewed apple with tinned creamed rice alternatives. The study by Roos et al. [50] was set in Denmark but focused on local foods from Asia, Africa and Europe and CACFs available in supermarkets in the UK and Denmark. Compared to their blended non-fortified foods which used traditional recipes from small- and medium-sized enterprises, the CACFs from food-aid programs contained higher quantities of iron, zinc and calcium. Thatola et al. [51] compared the nutrient profiles of a marketed weaning mix to an unfortified weaning mix of millet, soybean and skim milk powder in India. The unfortified weaning mix had higher protein, zinc and ascorbic acid but lower iron, calcium and vitamins D and B than the marketed mix. Nudda et al. [52] reported that their fresh lamb meat meal contained more omega-3 polyunsaturated fatty acids, α-linolenic acid, eicosapentaenoic acid, docosahexaenoic acid and arachidonic acids compared to the commercial lamb meat-based infant product under study in Italy.

3.4.6 Quality of included laboratory studies

The standard tools for evaluation of RCTs and trials do not apply to the laboratory studies. Key issues for these studies relate to whether they assess representative versions of CFs, and use comparable methods for determining nutrient composition of foods. The ideal study would compare nutrient profiles of home-made and commercial infant meals with similar ingredients. However, owing to the diverse commercial products available and potential home-made substitutes, such a study is not feasible. Garcia et al. [37] was distinguished in its assessment of 462 infant products. They compared means for food types (such as 'sweet fruit only', 'savoury meals with meat/fish/chicken') and those of similar home-made food types. Roos et al. [50] presented nutrient profiles of 36 CACFs that were mostly cereal-based porridges and semi-solid foods. The other studies were smaller in scale and reported on fewer than 10 infant foods.

CACFs under study included Nutrend™ (5 studies), Cerelac™ (3 studies), Lactogen™ (1 study) and Cerevita™ (1 study). The CACF was not explicitly named in the 4 remaining studies but included 1) a weaning mix fortified with micronutrients and a market weaning mix, 2) a fortified infant porridge, 3) ~318 "ready-made" spoonable baby foods and 4) homogenized and lyophilized lamb-meat based CACFs. Locally-available home-made alternatives included laboratory formulations of locally-available foods made from the flours of sorghum, soybeans, groundnuts, popcorn flour, green bananas, maize, millet, plantains, crayfish, and cassava. Other ingredients included potatoes, broccoli, parsnips, cauliflower, stewed apple with custard, stewed apple with tinned creamed rice, beans, sesame-oil seeds, palm oil, butter, moringa oleifera leaves, banana, white toast, cheese, fresh lamb meat, beef stewed, stewed chicken, and sardines. Given the variety of commercially-available infant foods and diverse home-made alternatives and laboratory formulations studied, a meta-analysis of these results is not possible.

Table 3.1 Summary of full text reviews Q3 human studies			
Author, Year	**Smithers, 2012** [39]	**Faber, 2005** [40]	**Van Hoan, 2009** [38]
Design	Observational	Observational study: baseline data from infants recruited for RCT	Cross sectional sub-study from a 3 group RCT: 1) Favina (10 villages); 2) Favilase (10 villages); 3) Traditional gruel (9 villages)
Location/setting	England; 1991-1992	Rural South Africa	Vietnam/community; April 2002 to October 2002
Recruitment strategy	Pregnant women residing in the former county of Avon, Southwest England who were expected to deliver between 1st April 1991 and 31st December 1992	Recruited through the community health worker program	Participants in village-based cluster RCT
Sample size (n)	n = 725 at 6–8 months, n = 535 at 15–18 months	475 provided diet data (from 563 recruited)	144: 36 infants from each age group (6, 7, 8 and 9 months) were randomly selected over the three food groups allowing a total of 48 infants per food groups (12 infants of 6, 7, 8 and 9 months ± 1 week were studied in each food group)
Age	6-18 months	6-12 months	6, 7, 8 and 9 months
Inclusion/exclusion criteria	Born in the last 6 months of the cohort recruitment; had nutrient intakes at 8 and/or 18 months and dietary patterns extracted at 6 and/or 15 months	Not stated	Weight-for-height Z-score >-2 and a height-for-age Z-score >-2.5 and/or suffered disease in the 7 days prior
Nature of comparison food	Home-made traditional =home-prepared meat, vegetables and desserts; Discretionary =biscuits, sweets and crisps; Home-made contemporary =herbs, legumes, nuts, cheese, raw F&V.	Comparison group was infants with no reported consumption of infant CACFs	Non-fortified traditional gruel
Commercial food studied	Ready-prepared baby foods pattern =CACF	Ready-to-eat canned baby foods, infant cereals and formula milk powder	Favina = rice, soybeans, sugar, sesame, dry milk, iodized salt, $Ca_3(PO_4)^2$, and vitamin-mineral premix. Favilase = soybeans, iodized salt, $Ca_3(PO_4)^2$, vitamin-mineral premix and alpha-amylases
Outcome	Energy and nutrient intakes at 8 and 18 months associated with dietary patterns at 6 and 15 months, respectively.	Energy and nutrient intakes of infants who consumed CACFs (n=140 6-9 mo, n=120 9-12 mo) vs. no CACFs (n=91 6-12 mo, n=123 9-12 mo).	Energy and nutrient intakes of infants between 6 and 9 months
Results	Home-made traditional pattern was positively associated with median energy, Na and K. At both times, the discretionary pattern was positively and the ready-prepared baby foods pattern was negatively associated with Na intake. At 6–8 months, Ca and Fe intakes decreased across scores on the home-made traditional and BF patterns, but increased across the ready-prepared baby food patterns.	Compared to infants who consumed infant products, those who did not consume infant products had significantly less protein at 6-9 and 9-12 mo (14, 17 vs. 16, 20g) Ca (273, 259, vs. 388, 407 mg), Fe (1, 1.5 vs. 4.6, 5.5mg) and Zn (2.2, 2.3 vs. 2.8, 3.4 mg) as well as vitamins A, B_6, B_{12}, C, thiamine, riboflavin, and niacin.	Per 100g, the home-made gruel was lower in energy, protein, Ca, Fe and Zn (71kcal, 2.62g, 18mg, 0.43mg, 0.39mg, respectively) than the Favina (99kcal, 3.61g, 116mg, 5.37mg, 1.51mg, respectively) and Favilase (105kcal, 4.30g, 175mg, 8.59mg, 1.85mg, respectively)

Table 3.1, con't Risk of bias assessment			
Author, Year	**Smithers, 2012** [39]	**Faber, 2005** [40]	**Van Hoan, 2009** [38]
Inclusion/exclusion	Low risk: Born in the last 6 months of the cohort recruitment; had nutrient intakes at 8 and/or 18 months and dietary patterns extracted at 6 and/or 15 months	Uncertain risk: Not stated	Uncertain risk: Not stated
Recruitment	Low risk: Pregnant women residing in the former county of Avon, Southwest England who were expected to deliver between 1st April 1991 and 31st December 1992	Low risk: Recruited through the community health worker program	Low risk: 144 enrolled (48 per food group and 12 per month of age). Outcomes were reported for 157: Favina (n = 48), Favilase (n = 48), Home-made (n = 61)
Appropriate comparison group	High risk: Dietary patterns derived for full sample, factor scores represent mixed consumption patterns, so CACF group is not purely CACF	Moderate risk: Consumers vs. non-consumers of CACFs, based on a single 24 hr recall. May not represent consistent patterns of consumption, but nutrient analysis reflects classification for that day.	Low risk: Comparison group was infants following usual feeding practices
Was outcome assessor blinded	Not applicable	Not applicable	Moderate risk: not blinded
Valid and reliable measures	High risk: Questionnaire not validated in this population. Diet patterns were defined prior to measurement of nutrient intake (2-3 months apart), possibly introducing measurement error	High risk: Used a single 24 hr recall to determine local foods, subject to recall bias and errors in estimating quantities	Low risk: Accurate measurement of quantities of gruels and their ingredients (experimental and home-prepared); laboratory measures of samples of gruels as prepared by participants.
Length of follow-up	Low risk: 2-3 months	Low risk: cross sectional	Low risk: cross sectional
Attrition	Moderate risk: Owing to attrition, patterns developed on different samples at 6 and 15 months	Moderate risk: 88 caregivers could not provide reliable diet info because they were not the permanent caregivers	Low risk: cross sectional
Was selection bias addressed?	Low risk: Patterns may not represent broader population, but associations not likely to be biased	NA	NA
Confounding	Adjusted patterns for total dietary energy intake	NA	NA
Other		Moderate risk: Funded by the South African Sugar Assn;	Moderate risk: Surveyors stayed in participants home, potentially influencing preparation methods and infant feeding, but bias likely to be non-differential across groups
Overall Quality Assessment	Low quality in the context of the research question owing to lack of ability to isolate the effects of specific CACFs and method of dietary intake assessment that was not validated for the study population, and is subject to recall bias	Low quality owing to use of single 24 hour recall to collect dietary data.	Moderate quality: reasonably accurate analysis of intakes and composition of CFs.

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs			
Author, Year	**Nudda, 2011** [52]	**Garcia, 2013** [37]	**Roos, 2013** [50]
Location/setting	Italy, 2008 and 2009	UK; Oct 2010 to Feb 2011	Foods from Asia, Africa and Europe - analyzed in Copenhagen. CACF were bought in supermarkets in Denmark and the UK, 2012
Recruitment strategy	NA	NA	NA
Sample size (n)	NA	NA	NA
Age	NA	NA	NA
Inclusion/exclusion criteria	Availability	Ready-made and dry foods produced by main infant food manufacturers identified by product sales; all baby drinks, smoothies and milks were excluded	Selection of products was based on covering a wide range of CACFs. Fortified blended foods were selected for being used in food aid programs.
Comparison food	Fresh meat (FM) from suckling lambs	Beef minced stewed with butter and formula milk; stewed chicken with rice and white sauce; potatoes with butter, cheese and formula milk; potatoes, broccoli, parsnip and formula milk; cauliflower, cheese and formula milk; stewed apple with custard; stewed apple with tinned creamed rice; banana; white toast with butter	Local blended food: blended non-fortified foods based on traditional recipes and local foods produced by local small- and medium-sized enterprises.
Commercial food	Homogenized (HO) from 3 different companies and lyophilized (LIO) from 2 of the same 3	Ready-made spoonable baby foods (approximately 318 foods)	Fortified instant porridge ('processed cereal-based foods') and semi-solid products ('baby foods' ready-to-eat) for European market declared as 'whole grain'
Outcome	Fatty acid profiles in fresh lamb meat compared to lamb-based CACF	Nutritional comparison of CACF to family weaning foods	Levels of anti-nutritional compounds: phytate, total polyphenol, trypsin and chymotrypsin inhibitors and lectins
Energy or other nutritive value		Ready-made meat/fish/chicken had less energy per 100 g (278kcal) compared to home-made beef (494kcal) and chicken (624kcal). Ready-made vegetarian had lower energy (267kcal) compared to home-made potato (511kcal) and cauliflower and cheese (391kcal) dishes but more than a home-made vegetable dish (253kcal). Commercial rusks/biscuits had more energy (1698kcal) compared to home-made alternatives of banana (403kcal) and toast (1270kcal).	
Macronutrients	For the FM, LIO and HO distributions were: % fat 3.4, 15.1, 4.0; % ARA 2.03, 0.29, 0.36; % EPA 0.65, 0.08, 0.11; % DHA 0.64, 0.05, 0.05. For the FM, LIO and HO distributions were: % protein - 18.7, 43.13, and 8.05.	Ready-made meat/fish/chicken had less and protein per 100 g (3.1g) compared to home-made beef (6.7g) and chicken (11.8g). Ready-made vegetarian had lower protein (2.6g) compared to home-made potato (4g) and cauliflower and cheese (4.6g) dishes but more than a home-made vegetable dish (1.8g). Ready-made sweet foods had less protein (1.5g vs. 2.2g and 2.4g).	

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't			
Author, Date	**Nudda, 2011** [52]	**Garcia, 2013** [37]	**Roos, 2013** [50]
Micronutrients		Ready-made vegetarian had lower Ca (48 mg) compared to home-made potato (97mg) and cauliflower and cheese (99mg) dishes but more than a home-made vegetable dish (35mg). Commercial rusks/biscuits had more Fe and Ca (5.8g, 273mg) compared to home-made alternatives of banana (0.3mg, 6mg) and toast (1.4mg, 98mg)	Fe: local: 5.4 ($\pm$ 3.0–10.5) vs. fortified: 12.32 ($\pm$ 9.5–19.9) mg/100 g. Zn: local: 3.4 ($\pm$ 1.8–5.2) vs. fortified: 12.7 $\pm$ 2.4–23.4) mg/100 g. Ca: local: 111.5 ($\pm$ 29–410) vs. fortified: 408 (range: 73–654) mg/100 g
Other results	Fresh lamb meat contained more Omega-3 PUFAs, α-linolenic acid, eicosapentaenoic acid, docosahexaenoic acid and arachidonic acids compared to commercial baby food.		The fortified products had higher levels of Fe, Zn, and Ca than the local blended non-fortified foods. Phytate content was high in all products. Only 4 products had rec'd phytate:Fe molar ratio (1 local), 25 for phytate:Zn (3 local) and 15 for phytate:Ca (4 local)
Risk of bias assessment		Many home-made comparison foods were made with formula milk	Some local blended foods lacked information on nutrient composition

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't				
Author, Year	**Lalude, 2006** [48]	**Steve, 2013** [47]	**Ijarotimi, 2009** [44]	**Omueti, 2009** [49]
Location/setting	Osun State, Nigeria	Akure, Ondo State, Nigeria	Akure, Ondo State, Nigeria	Nigeria
Recruitment strategy	NA	NA	NA	NA
Sample size (n)	NA	NA	NA	NA
Age	NA	NA	NA	NA
Inclusion/exclusion criteria	NA	NA	NA	NA
Comparison food	Mixture of sorghum, soybean, groundnut and sesame-oil seeds/flours	Flour from fermented popcorn and moringa oleifera leaves (FPM), and blanched popcorn and moringa oleifera leaves (BPM)	Banana fruits with bambara groundnut seeds in a flour in a 70:30 (CBR1) or 60:40 (CBR2) ratio	1) ogi or maize flour with soyflour, groundnut meal, crayfish flour = PROWENA; 2) palm oil added to Prowena = PROPALM
Commercial food	Nutrend™	Cerelac™	Nutrend™	Nutrend™
Outcome	Macronutrient contents, energy content, micronutrient composition of local food vs. Nutrend™	Macronutrient and mineral compositions	Amino acid contents, and protein quality measures	Protein, fat, carbohydrate, energy contents, micronutrient contents
Energy or other nutritive value	1846.7kJ vs. 1670kJ in Nutrend™	FPM (393.94 ± 0.39 kcal); BPM (389.69 ± 1.40 Kcal); 'Ogi' (418.08 ± 0.47 kcal) and Cerelac (431.58 ± 0.01 kcal).		Nutrend™, Prowena, Propena and yellow maize Ogi were: 4.54, 3.75, 3.883 and 2.68 kcal respectively
Macronutrients	Fat: 9.87 vs. 9.0g/100g; CHO: 71.45 vs. 68.7g/100g; Pro: 19.972 vs. 16.0g/100g	FPC, BPM, FPM, Ogi and Cerelac - Fat: 5.85±1.63, 8.67±0.14, 10.51±0.11, 5.17±0.11, and 10.53±0.02 g/100g respectively. CHO: 78.09 ±1.25, 61.91 ±0.74, 53.55 ±0.47, 86.38 ±0.21, and 68.42 ±0.01g/100g respectively. Pro: BPM (15.99 ± 0.14 g/100 g), FPM (21.27 ± 0.20 g/100 g), Ogi (6.52 ± 0.31 g/100 g) and Cerelac (15.75 ± 0.01 g/100 g)		Nutrend™, Prowena, Propena and yellow maize Ogi - Fat: 9.13, 5.86, 8.86 and 1.28 % respectively: CHO: 63.117, 62.39, 59.293 and 88.712 g respectively. Pro:16.86, 22.95, 21.997 and 4.5 % respectively

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't				
Study (author, year)	**Lalude, 2006**	**Steve, 2013**	**Ijarotimi, 2009**	**Omueti, 2009**
Micronutrients	Fe: 28.5 vs. 1.0mg/100g; Ca: 93.4 vs. 39mg/100g; Na: 40.0 vs. 22mg/100g; P 22.8 vs. 26mg/100g	FPC, BPM, FPM, Ogi and Cerelac^{TM} - Fe: 4.12 ±0.04, 1.83 ±0.01, 1.81 ±0.01, 0.26 ±0.01 and 7.50 ±0.01 mg respectively; Zn: 2.84 ±0.32, 0.16 ±0.01, 0.12 ±0.01, 0.08 ±0.00, and 5.00 ±0.00 mg; Ca: 134.80 ±0.07, 45.87 ±0.02, 85.71 ±0.02, 68.66 ±0.35 and 600.00 ±0.01 mg; Na: 140.71 ±0.45, 137.61 ±0.05, 87.62 ±0.07, 14.56 ±0.04 and 145.00 ±0.00 mg/100g respectively. P: 142.51 ±14.62, 84.12 ±0.02, 73.28 ±0.01, 85.95 ±0.02 and 400.00 ±0.01 mg; Mg: 31.44 ±0,96, 284.40 ±0.02, 285.71 ±0.01, 34.91 ±0.01 and 0.00 mg; K: 122.59 ±1.68, 270.64 ±0.25,122.86 ±0.05, 102.39 ±1.01, and 635.00 ±0.00 mg respectively.		Nutrend^{TM}, Prowena, Propena and yellow maize Ogi - Fe: 74.3, 63.45, 68.45 and 54.2 mg/kg respectively. Zn: 62.5, 57.95, 64.65 and 14.2 mg/kg respectively. Ca: 0.58, 0.47, 0.425 and 0.018 % respectively. Na: 0.305, 0.195, 0.24 and 0.022 % respectively. Mn: 26.65, 29.35, 31.35 and 4.7 mg/kg respectively; Mg: 0.21, 0.22, 0.25 and 0.14 mg/kg respectively; K: 0.4, 0.28, 0.32 and 0.05 % respectively; P: 0.425, 0.35, 0.405 and 0.32 % respectively
Other results	The experimental diet had favorable content of iron, sodium phosphorus and calcium, as well as protein, fat and carbs, and energy	Both fermented and blanched experimental mixes had higher protein content but lower energy compared to Cerelac^{TM} and Ogi. BPM had higher zinc, iron, potassium, sodium and phosphorous than Cerelac. FPM sample had higher copper, calcium and magnesium than Cerelac.	The CBR2 had similar biological value, net protein utilization, protein efficiency ratio to those of Nutrend^{TM}.	Higher protein in formulation weaning diets relative to Nutrend^{TM} and ogi. Nutrend ^{TM} had higher fat, calcium, potassium, sodium and iron contents than the formulation diets.

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't

Author, Year	Ijarotimi, 2008 [46]	Ijarotimi, 2008 [45]	Eshun, 2011 [41]
Location/setting	Akure, Ondo State, Nigeria	Akure, Ondo State, Nigeria	Winneba, Ghana
Recruitment strategy	NA	NA	NA
Sample size (n)	NA	NA	NA
Age	NA	NA	NA
Inclusion/exclusion criteria	NA	NA	NA
Nature of comparison food	Ogi (maize flour), green banana flour with fermented bambara groundnut flour in 4 different ratios: 90:10 (CBG1), 80:20 (CBG2), 70:30 (CBG3) and 60:40 (CBG4) of cooking banana and BG flour, respectively	Ogi (maize flour) , green banana flour with fermented bambara groundnut flour in 4 different ratios: 90:10 (CBG1), 80:20 (CBG2), 70:30 (CBG3) and 60:40 (CBG4) of cooking banana and BG flour, respectively	Formulation weaning diet: soya beans, groundnut and rice flour mixture
Commercial food	Nutrend™	Nutrend™	Cerevita™
Outcome	Several markers of protein quality, macronutrient and energy contents	Amino acid, micronutrient, macronutrient content	Macronutrient, energy and micronutrient compositions
Energy or other nutritive value	Ogi, Nutrend™, CBF: 1,626.97, 1,665.68, 1,569.81 - 1,658.4 kcal.	CBG energy ranged from 1569-1658 kJ, Ogi: 1626, Nutrend: 1665	
Macronutrients	Ogi, Nutrend™, CBF - Fat: 0.76 ±0.04, 8.45 ± 0.36, and 6.38 ± 0.3-6.93 ± 0.4 g/100 g respectively; CHO: 88.43, 63.84, and 67.82-73.16 g/100 g; Pro: 5.62 ±0.4, 16.0 ±0.26, and 7.02 ±0.43-15.60 ± 0.23 g/100 g.	CBG, Ogi, Nutrend: Fat: 6.38-6.93g, 0.76g, and 8.45g respectively; CHO: 67.87-73.16, 88.43 and 63.84 g/100g; Pro: 7.02-15.60, 5.62, and 16.00g/100g	Formulated diet vs. Cerevita™ - Fat: 8.99 vs. 2.49 g/100g; CHO: 67.10 vs. 86.10g/100g; Pro: 15.87 vs. 6.38g/100g.
Micronutrients	Ogi, Nutrend™, CBF - Fe: 0.3, 1.0 and 0.14-0.56 mg/100 g respectively; Zn: NA, 0.7 and 0.01-0.01 mg/100 g; Ca: 51.2, 39.0 and 22.01-34.22 mg/100 g; Na: 40.14, 22.0, and 38.95-78.33mg/100 g; Mg: 14.68, NA, and 66.03-143.71 mg/100 g; K: 52.41, 57.0, and 64.63-85.55 mg/100 g; Mn: NA, NA and 0.11-0.26 mg/100 g; P: 97.4, 22.0, and 45.85-71.72 mg/100 g.		Formulated diet vs. Cerevita™ - Fe: 19.42 vs. 10.78 mg/100g; Ca: 96.32 vs. 463.43 mg/100g; Mg: 54.44 vs. 493.59 mg/100 g; P: 269.80 vs. 524.82 mg/100g
Other results	The experimental blends ranked more favorably in terms of protein quality when compared to the local Ogi weaning food, but were significantly less favorable compared to Nutrend™. The 70% of cooking banana and 30% of BG flour mixed mixture had a nutritional profile that was almost within the range of Nutrend™.	The experimental blend was superior to Ogi but not significantly different from Nutrend™. Micronutrient content was also favorable, relative to Nutrend™, for some minerals	Formulation diet provided more protein, fat, energy, and iron, but less calcium compared to Cerevita™

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't			
Author, Year	**Ijarotimi, 2006** [43]	**Thathola, 2002** [51]	**Mosha, 2000** [42]
Location/setting	Community Health Center, Nigeria; 2005	India	Tanzania
Recruitment strategy	NA	NA	NA
Sample size (n)	NA	NA	NA
Age	NA	NA	NA
Inclusion/exclusion criteria	NA	NA	Popularity and availability in market
Nature of comparison food	1) Milk-ogi (ogi is made from fermented sorghum or corn); 2) soy-ogi, 3) crayfish-ogi, 4) soy-moinmoin (bean & soybean w/veg oil), 5) cooked beans w/veg oil	Unfortified weaning mix (UW) = Barnyard millet, local foxtail millet, black soybean and skim milk powder.	5 gruels: 1) Maize, 2) finger millet, 3) cassava, 4) sorghum and 5) millet-composite (millet, peanuts, sardines); and 1), plantains pap (plantains and beef stew)
Commercial food studied	Cerelac™	Market weaning mix (MW) (also had a fortified weaning (FW) = UW was fortified w/MVI for a CACF comparison)	Cerelac™-1, Cerelac™-2, Lactogen™-1, Lactogen™-2
Outcome	Nutritional composition of the local weaning foods used	Low cost weaning food	Nutritional composition
Energy or other nutritive value	Soy-ogi, soy-moinmoin and cooked beans provided less energy (333.0, 377.3, 330.4 kcal) than Cerelac ™ (412.6 kcal)	Milk–ogi, Crayfish–ogi, Soy–ogi, Soy–moinmoin, Cooked beans and Cerelac™ had 408.2, 438.7, 333.0, 377.3, 330.4 and 412.6kcal respectively	Local: energy ranged from 382.3 kcal/100 g - 564.3 kcal/100 g; composite porridge was higher in energy density: 483.1–685.5 kcal/100 g, Cerelac™ and Lactogen™ ranged from 419.24-509.92 kcal/100g
Macronutrients	All had greater protein than Cerelac™ (15.0g) except soy-ogi (10.8g)	Milk–ogi, Crayfish–ogi, Soy–ogi, Soy–moinmoin, Cooked beans and Cerelac ™ - Fat: 8.6, 11.6, 5.0, 9.6, 2.0 and 9.0g respectively. CHO: 65.7, 61.5, 61.5, 42.5, 52.2 and 67.9g respectively. Pro: 16.9, 22.1, 10.8, 30.4, 24.4 and 15.0g/100g respectively	Fat: 5.1–53.5% in the home-made foods and CACFs 18.7 - 44.0%. CHO: range 14.0 - 88.7% in home-made foods. In the Lactogen™ and Cerelac™ foods, CHO ranged from 42.9 -66.3%. Home-made foods had 6.2 -60.1% while CACFs ranged from 13.0–18.6% of total energy.

Table 3.2 Laboratory Studies of Nutrient Composition of CACFs, con't			
Micronutrients	Only milk-ogi provided rec'd Ca (267.4mg); soy-moinmoin and cooked beans provided rec'd Fe (17.4, 11.3mg); all were low in vitamin A and C and riboflavin, but all had rec'd levels of Thiamin.	Milk–ogi, Crayfish–ogi, Soy–ogi, Soy–moinmoin, Cooked beans and Cerelac^{TM} – Fe (mg): 4.2, 4.0, 9.8, 17.4, 11.3 and Not determined respectively; Ca (mg): 267.4, 24.6, 90.3, 227, 22.0 and Not determined respectively; P (mg): 267.8, 216.8, 107.5, 410, 124, and Not determined; Vitamin A (IU): 16.0, 0.0, 0.0, 37.5, 50.2 and Not determined respectively; Thiamine (mg) 0.41, 0.36, 0.46, 0.85, 0.9 and Not determined respectively; Niacin (mg) 2.9, 2.8, 2.98, 1.5, 1.2 and Not determined respectively Vitamin C (mg) 0.01, 0.0, 0.0, 0.0, 0.0 and Not determined respectively; Riboflavin (mg) 0.26, 0.1, 0.14, 0.15, 0.9 and Not determined respectively	Fe: home-made foods between 5.93–23.36 mg/100 g; CACF ranged between 2.50–8.40 mg/100 g. Zn: CACF was higher: 3.42 - 3.80 mg/100 g compared to home-made foods (1.02-2.81 mg/100 g). Ca: highest (429.00–770.00 mg/100 g) in the CACF and lowest (18.47–319.79 mg)/100 g) in home-made foods. Na: home-made: 8.91-3196.99 mg/100 g) CACF: 96.78–411.32 mg/100 g.
Other results		UW was superior to CACF in protein (18.37 vs. 15.50), Zn (2.72 vs. NA), and ascorbic acid (74.66 vs. 35), but was lacking in the Fe (4.9 vs. 7.5), and Ca (253.33 vs. 570), and lacked vitamins D and B.	Home-made gruels did not meet the minimum standard for Ca (435.51mg/100g). Cerelac^{TM}-1 and -2 only did not meet minimum for Fe (4.84mg/100g). The maize, plantain and millet-composite gruels did not meet the minimum for Zn (2.42mg/100g). All home-made gruels except plantain did not meet min Na (96.78mg/100g). The millet-composite and maize did not meet min Mg (29.03mg/100g). The maize, millet, millet-composite and sorghum did not meet min K (387.12mg/100g). All CACF's and the sorghum gruel met P min (290.34mg/100g). Maize and plantain and Lactogen-1 met ascorbic acid min (38.71mg/100g).

3.5 Conclusions

Our systematic review of the literature is not able to provide definitive answers to the research questions posed: "*Are commercially-available products nutritionally inferior or superior to home-prepared and/or local foods? Do they contain higher or lower amounts of essential micronutrients? Do commercially-available products provide nutrients that are generally lacking in the diets of young children?*"

CACFs <u>and</u> home-prepared foods are highly heterogeneous in quality. Some CACFs are higher in micronutrients than home-prepared foods owing to micronutrient fortification of CACFs. The CACFs to which local or home-made foods were most often compared were fortified cereals that had higher micronutrient levels, and similar energy density, but lower amounts of protein. CACFs are typically fortified with nutrients such as iron and zinc, which are often missing in the diets of young children. Some locally prepared or home-made foods were nutritionally superior to the CACFs to which they were compared. In particular, home-prepared foods that included animal source ingredients or groundnuts and legumes tended to be higher in protein.

Two recent papers excluded from our review because they lacked specific information on specific nutrients are of potential interest because they address dietary variety, which has been linked to diet quality and nutrient adequacy. A study of participants in the US Supplemental Nutrition Program for Women, Infants, and Children (WIC) found that 81% of infants age 6-12 months received commercial baby foods, and these infants consumed a significantly greater variety of fruits and vegetables compared to infants who did not consume commercial baby foods.[53] The second paper studied participants in the DONALD study in Germany, and also found that at 12 months, infants fed with commercial infant meals had a higher vegetable variety.[54]

Do they contain higher or lower amounts of trans-fat, saturated fat, free sugars, or salt? There was limited information based on direct comparison of CACFs to comparable home-prepared foods. Only one study directly compared the fat composition of a CACF to a directly comparable home-prepared food, and found that lamb processed as baby food had a less favorable fatty acid profile than freshly cooked lamb. We found no assessment of trans fat in CACFs for infants.

The parameters of the review required comparison of CACFs to similar home or locally prepared foods. While many studies assessed nutritional quality of CFs, relatively few made this direct comparison, and few identified specific CACFs. An informative alternate approach to gain insights about the nutritional quality of CACFs would be to compare their nutrient composition to a standard, such as recommended dietary allowances or estimated average requirements. Several studies have examined the nutrition quality of CACFs for infants in high income countries, and found that a high percentage of foods, particularly mixed dishes, infant snacks and dessert items to be high in added sugars or salt, as well as added fats. [30,37,55,56]

PART 4. RESEARCH QUESTION 4

Are the portion sizes of commercially-available products greater than would be appropriate based on age?

4.1 Background

There are currently no universally agreed-upon age-specific portion size definitions or recommendations for children under 2 years. Different organizations such as the American Academy of Pediatrics or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program in the US recommend amounts of foods to be fed to infants of different ages, and the WHO has guiding principles for amounts of food to be fed at different ages, but specific portion sizes are not defined. CACFs are sold in single and multi-serving packages, and the unit volume of CACFs may vary by manufacture and setting. In addition, many CACFs are instant foods such as cereals that require addition of water or milk. The portion of the product used by caregivers can therefore vary substantially according to both the dilution and the amount she chooses to feed. Infants and young children are able to self-regulate their intake if caregivers are responsive to their satiety cues, [1,57] but caregivers might feel the need to feed the entire portion (or more from multi-portion packages) of CACFs, potentially leading to overfeeding.

4.2 Objective

The objective for Q4 is to review evidence on the appropriateness of the portion sizes of commercially-available complementary food with respect to age.

4.3 Methods

4.3.1 Criteria for considering studies

We did not restrict our search by study design. Studies had to include evidence on foods for infants and young children, ages 6-23 months. The main exposure was advertised portion size of commercially-available complementary foods (CACFs) compared to the age appropriate, recommended portion size of complementary food products.

4.3.2 Search method strategies for identification of studies

4.3.2.1 Electronic searches

The following electronic databases were searched to identify relevant studies:

- PubMed (2000 – 21 April 2015)
- CINAHL plus (2000 – 21 April 2015)
- EMBASE (2000 – 21 April 2015)
- Agricola (2000 – 21 April 2015)
- CAS (2000 – 21 April 2015)
- Clinicaltrials.gov (2000 – 21 April 2015)
- Cochrane (2000 – 21 April 2015)
- Global Health (2000 – 21 April 2015)
- WHO Global Library (2000 – 21 April 2015)

- Business Source Premier (2000 – 21 April 2015)

4.3.2.2 Searching other resources

We searched other economics databases (AgEcon, Mintel Oxygen), relevant conference proceedings (Association for Consumer Research, International Health Economics Association), and sources of grey literature (New York Academy of Medicine's Grey Literature Report, Open Grey, PH Partners). Additionally, we reviewed reference lists from highly relevant reviews and articles.

4.3.2.3 Search strategy

The search strategy was created using a combination of subject headings and free-text keywords to identify publications (see **Appendix 4.1**). We did not restrict by language or study design. We restricted to studies published after 2000, to ensure that the commercially-available products analyzed would provide relevant and contemporary evidence. References were extracted and imported into EndNote. Duplicate articles were identified and removed first in EndNote, and then manually in Excel. All articles were assigned a unique record number.

4.3.3 Data collection and analysis

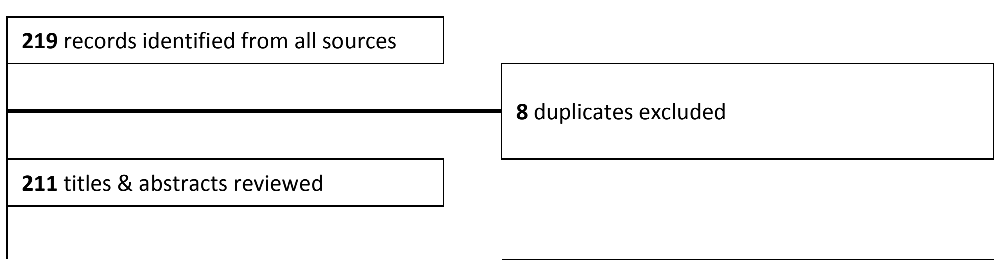
4.3.3.1 Selection of studies

Two authors independently screened titles and abstracts from electronic databases to identify potentially eligible studies. Discrepancies were resolved by discussion with a third reviewer. One reviewer screened titles and summaries from the other resources. Full-text articles were obtained, and were independently reviewed by two reviewers according to the inclusion criteria. Discrepancies were resolved with discussion. No full-text articles were eligible based on our inclusion criteria. Data extraction and quality assessment would have been comparable to the processes we followed for the other questions.

4.4 Results

4.4.1 Literature search

We identified 219 abstracts for initial screening, from which 3 were referred for full-text review. None were included in the review. **Figure 4.1** shows the flowchart of the screening and eligibility evaluation phases. Reasons for exclusion were that the study did not report on portion size, study results were incomplete, or the study was irrelevant to our research question (see **Appendix 4.2** for a full description of full-texts that were reviewed and excluded from the final set).



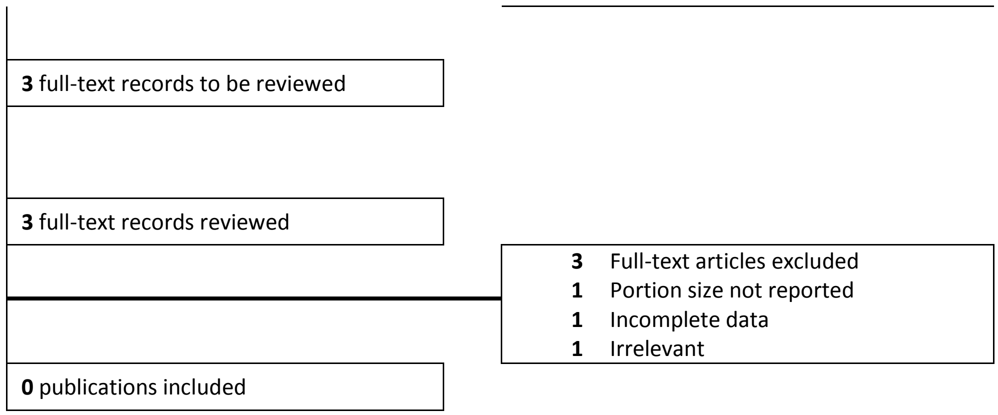


Figure 4.3. Flow chart of review process

4.5 Conclusions

Our systematic review of the literature is not able to provide an answer to the research question posed: "*Are the portion sizes of commercially-available products greater than would be appropriate based on age?*"

There is currently no evidence on the appropriateness of the portion size of commercially-available complementary foods. The dearth of studies in this area highlights a critical research gap regarding the health impacts of the consumption commercially-available complementary foods.

A key limitation is that serving sizes have not been established for children under 2 yrs, due to the dynamic and unique dietary needs of this age demographic. Therefore, any studies that do assess portion size do not have a referent against which to compare results. The USDA has also identified the need for stronger dietary guidance in this age group, and is currently working on creating dietary guidelines for infants and young children under 2. [58] Part of the evidence building process is a call for systematic reviews and data in priority research areas. One such priority is how portion size affects dietary preferences and intake. [59]

PART 5. RESEARCH QUESTION 5

Do commercially-available products reduce the risk of stunting, anemia, or micronutrient deficiencies?

5.1 Background

Stunting, anemia, and micronutrient deficiencies continue to affect millions of children worldwide. [60] Introduction of appropriate CFs should include foods that provide sufficient energy and micronutrients to promote optimal growth and development, while being affordable and sustainable. In LMIC, traditional CFs introduced at 6 months are often of poor quality with inadequate energy and micronutrient density to complement breastfeeding. [61] Additionally, while iron stores at birth may be adequate for the prevention of iron deficiency in the first few months of life, iron-rich foods are needed during the weaning period. [62]

CACFs, many of which are micronutrient fortified or energy-dense by design, have been suggested as a method to improve infant growth and nutritional status. There is little evidence that directly compares CACFs to comparable home-prepared or local CFs.

5.2 Objective

The objective for Q5 is to review evidence on the risk reduction of stunting, anemia, or micronutrient deficiencies with commercially-available food products versus home-made or local complementary food products.

5.3 Methods

5.3.1 Criteria for considering studies

We did not restrict our search by study design. We included studies of infants and young children, ages 6-23 months. The main exposure was consumption of CACFs, compared to consumption of home-prepared or local complementary foods. Outcomes were stunting, anemia, or micronutrient deficiencies (including but not limited to iron, zinc, and vitamin A). Lipid-based nutrient supplements (LNS), "fortified spreads", and micronutrient powders are considered in a separate systematic review, and therefore are not included in our review. We also did not include therapeutic foods or foods specifically formulated for research studies, but not commercially-available or typically made at home.

5.3.2 Search method strategies for identification of studies

5.3.2.1 Electronic searches

The following electronic databases were searched to identify relevant studies:

- PubMed (2000 – 17 Apr 2015)
- CINAHL plus (2000 – 18 Apr 2015)
- EMBASE (2000 – 17 Apr 2015)
- Agricola (2000 – 18 Apr 2015)
- CAS (2000 – 18 Apr 2015)
- Clinicaltrials.gov (2000 – 18 Apr 2015)

- Cochrane (2000 – 18 Apr 2015)
- Global Health (2000 – 18 Apr 2015)
- WHO Global Library (2000 – 18 Apr 2015)
- Business Source Premier (2000 – 18 Apr 2015)

5.3.2.2 Searching other resources

We searched other economics databases (AgEcon, Mintel Oxygen), relevant conference proceedings (Association for Consumer Research, International Health Economics Association), and sources of grey literature (New York Academy of Medicine's Grey Literature Report, Open Grey, PH Partners). Additionally, we reviewed reference lists from highly relevant reviews and articles.

5.3.2.3 Search strategy

The search strategy was created using a combination of subject headings and free-text keywords to identify publications (see **Appendix 5.1**). We did not restrict by language or study design. We restricted to studies published after 2000, to ensure that the commercially-available products analyzed would provide relevant and contemporary evidence. References were extracted and imported into EndNote. Duplicate articles were identified and removed first in EndNote, and then manually in Excel. All articles were assigned a unique record number.

5.3.3 Data collection and analysis

5.3.3.1 Selection of studies

Two reviewers each screened one-half the titles and abstracts from electronic databases to identify potentially eligible studies. Prior to starting the work, inter-rater agreement was assessed by screening a subset of titles and abstracts and calculating Cohen's Kappa. All studies identified as possibly being eligible for inclusion were screened by a third reviewer for a final decision. Two reviewers screened titles and summaries from the other resources. Full-text articles were obtained, and were independently reviewed by two reviewers according to the inclusion criteria. Discrepancies were resolved with discussion. When the full-text was not available in English it was excluded.

5.3.3.2 Data extraction

Excel workbooks created for systematic review data management were utilized in the abstract screening and full-text review process. [6] Record numbers, titles, and abstracts were exported from EndNote into the Excel workbook, and all title and abstract screening and full-text review took place within Excel. Comments on reasons for full-text exclusions were noted in a separate file. Each reviewer had her own Excel workbook, to keep the review process blinded.

One reviewer extracted data into standardized tables. Information was extracted on: general study characteristics (design, location/setting, recruitment strategy), participant characteristics (sample size, age, inclusion/exclusion criteria), description of the commercially-available complementary food and comparison foods, outcome, and results. Two separate risk of bias assessment tables were created (for RCTs vs. observational studies). Tables were reviewed by another reviewer.

5.3.3.3 Assessment of risk bias and quality in included studies

Articles included in the review were assessed for quality using AHRQ tools for observational studies and the Cochrane tools for interventions. [7,8] The studies included in the final review were highly heterogeneous in design, CFs, and settings, and therefore not amenable to a meta-analysis of results. Overall quality of the evidence from the final studies was assessed using GRADE evidence profiles [10].

5.4 Results

5.4.1 Literature search

We identified 773 abstracts for initial screening, from which 24 were referred for full-text review. Of these, 2 were included in the review. **Figure 5.1** shows the flowchart of the screening and eligibility evaluation phases. Main reasons for exclusion were that the study did not include CACFs, the comparison was not a home-made or local food, the population was not between 6-24 months, there was not enough information provided, or the study was irrelevant to our research question. Three texts were only available in a non-English language (see **Appendix 5.2** for a full description of full-texts that were reviewed and excluded from the final set).

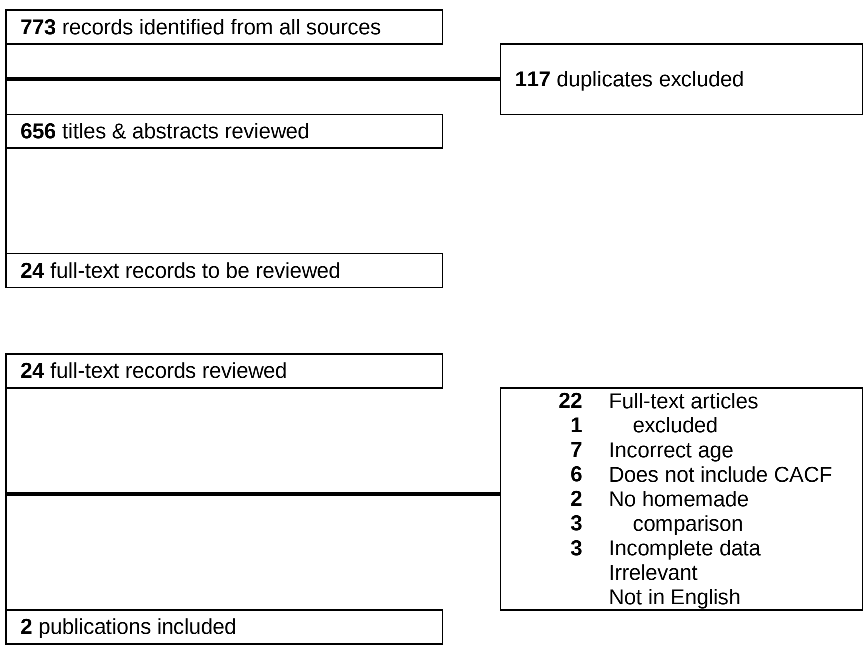


Figure 5.4. Flowchart

5.4.2 Characteristics of included studies

Both studies included in the review were RCTs. One was conducted in India and the other in Canada. One study assessed the role of CACFs on iron status and the second measured weight gain. Detailed descriptions of each included study and their results are included in **table 5.1**.

Yeung et al. conducted a RCT of Canadian infants to determine if iron rich foods provided enough iron to prevent iron depletion and/or anemia in infants who consume whole cow milk (WCM) as their primary milk source. [63] Six month old infants from low-income households were randomized to either: (1) pureed meat plus iron-fortified infant cereal plus WCM, or (2) no dietary intervention for six months.

Iron depletion (ferritin < 10µg/L) and early anemia (hemoglobin < 110g/L) were assessed every two months. There was no difference in iron status between treatment and control group (p=0.78).

Bhandari et al. examined the potential of a food supplement to improve infant weight gain [11]. Four month old Indian infants were randomized to either: (a) a milk cereal supplement, (b) nutritional counseling, (c) in-home morbidity assessments, or (d) no intervention control. Dietary recalls, weight, and length measurements were collected at 6, 9, and 12m. The proportion of stunted infants did not differ significantly across the four groups (p=0.16). Infants receiving milk cereal supplement gained significantly more weight [250 g, 95%CI= 20-480g] than the visitation group, but the 0.4 cm difference in weight and the 7% reduction in stunting were not different than the no intervention control group.

5.4.3 Quality of included studies

Both studies had moderate risk of bias. One study had differential attrition in the treatment and control arms (greater attrition in the treatment group), and excluded non-compliers from analyses. [64] The Indian study also had attrition, and it was suspected that there was non-adherence to the intervention in the milk cereal supplement arm. [11]

5.4.4 Quality of outcomes (GRADE)

Overall quality of evidence that CACFs reduce risk of stunting, anemia, or micronutrient deficiencies is low.

Risk of bias. Both studies had problems with differential attrition across treatment arms. Due to the nature of both interventions, it was not possible to blind the participants or study personnel who administered the intervention to the treatment, and thus is a potential source of bias. One study did not provide sufficient information on a number of items to assess risk of bias. [11]

Inconsistency. We are not able to comment on consistency across the two studies, as the primary outcomes were not comparable (length gain vs. iron status).

Indirectness. Yeung et al. directly linked the intervention to iron status by defining the primary end point as iron depletion (ferritin < 10µg/L) or early anemia (hemoglobin < 110 g/L). [64] The Bhandari study also directly related the treatment to stunting (percent of infants with HAZ $\leq$ -2 Z at 52 weeks). [11]

Imprecision. Both studies reported some wide confidence intervals or standard deviations. Sample size was small in the Yeung study. [64]

Publication bias. It was not possible to formally assess publication bias.

Table 5.1 Study characteristics of Q5 studies

Author, Year	Yeung, 2000 (62)	Bhandari, 2001 (11)
Design	RCT	RCT
Location/setting	Toronto, Canada	Urban slum of Nehru Place, South Delhi, India
Recruitment strategy	Mailed families with infants <6 months in low-income postal zones; solicited community health centers	Infants <4 months were selected from a household survey of the entire slum
Sample size (n)	54 controls and 49 in treatment group	418
Age	6-12 months old	4 months
Inclusion/exclusion criteria	Inclusion: Low-income Exclusion: those whose mothers wished to continue breastfeeding, refusal to feed whole cow's milk	Exclusion: major congenital malformations, those likely to emigrate
Commercial food studied/comparison group	Treatment: Iron-fortified infant cereal (10.2 mg iron) + pureed meat (0.75-1.7 mg iron) + whole cow milk; Control: no treatment	The primary exposure was a **food supplement** prepared by the National Dairy Development Board; 1) Milk-based cereal and nutritional counseling 2) monthly nutritional counseling alone 3) morbidity assessment visits 4) control (no-intervention)
Outcome	Change in hemoglobin (<110 g/L) OR ferritin (<10microgram/L)	Length, weight
Results	Among compliant treated and control infants: no statistically significant difference in the incidence of outcomes: iron-fortified group 0.83 RR 95% CI (0.35, 2.0) of low hemoglobin/ferritin p=0.66. Among non-compliant, treated infants: 7% of the 43 treatment compliers had the outcome, compared to 83.3% of the 6 treatment non-compliers. (p=0.0002).	Supplemented group was 250g 95% CI (20-480) heavier than the visitation control group. Other anthropometric contrasts not significant.

Table 5.1, cont'd Risk of bias assessment

Author, Year	Yeung, 2000 (62)	Bhandari, 2001 (11)
Sequence generation	Low risk: Random number generator	Low risk: First stratified by WHZ and then randomly assigned to one of four study groups
Allocation concealment	Moderate risk: Concealed treatment assignment from participants until after randomization	Unclear risk: Not described
Blinding	Moderate risk: Not blinded: parents and field nurses Blinded: laboratory technicians and data analysts	Unclear risk: Not described
Attrition/incomplete outcome	Moderate risk: Initial sample selected: 79 controls, 79 treated Final analytical sample: 54 controls and 49 treated	Moderate risk: Between 7-13% contributed no anthropometric data to the final survey at 52 weeks
Selective outcome reporting	High risk: Non-compliant individuals were excluded from analysis (did not do intent-to-treat analysis)	Low risk: No
Other sources of bias	1) Post-randomization, more mothers from the treatment group withdrew relative to the control group due to deciding to continue to breastfeed or were unwilling to feed whole cow milk 2) Education was related to treatment group assignment (control feeding patterns were more adherent to the guidelines of the Canadian Pediatric Society than expected, and therefore not representative of a 'true' low-income control)	Over-reporting of supplement use: so the null findings may be because those randomized to the treatment group did not actually take the treatment.
OVERALL QUALITY ASSESSMENT	Low	Low

5.5 Conclusions

Our systematic review of the literature is not able to provide definitive answers to the research questions posed: "*Do commercially-available products reduce the risk of stunting, anemia, or micronutrient deficiencies?*"

In RCTs of CACFs (excluding LNS and similar products), there is low evidence that these products reduce the risk of stunting, anemia, or micronutrient deficiencies. The combination of iron-fortified infant cereal, pureed meat, and whole cow milk did not significantly reduce the incidence of iron depletion in Canadian infants, compared to a usual diet. Consumption of a milk-based cereal did not significantly reduce the proportion of stunted Indian infants compared to a usual diet (control group).

There were no other studies that specifically address CACFs and their relation to stunting, anemia, or micronutrient deficiencies. A large number of studies assess the role of LNS on stunting, anemia, or micronutrient deficiencies, but that was outside the scope of our review. In many LMICs, local research groups are formulating novel products from locally sourced ingredients in an attempt to produce a CF that is affordable, hygienic, and highly nutritious. However, there is no clear plan on how to get these products into the commercial market, or how well they would be received by mothers. A critical limitation of existing studies is that many CFs assessed were not explicitly called out as either a CACF or a home-made/local product, resulting in ambiguity regarding the nature of the CF.

Appendix 1.1 Search terms for PubMed for question 1

1	Search infant food[MeSH Terms]
2	Search infant food*[Text Word]
3	Search baby food*[Text Word]
4	Search toddler food*[Text Word]
5	Search solid food*[Text Word]
6	Search weaning food*[Text Word]
7	Search complementary food*[Text Word]
8	Search complementary feed*[Text Word]
9	Search (((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word]
10	Search commercial[Text Word]
11	Search industrial*[Text Word]
12	Search ready prepared[Text Word]
13	Search package*
14	Search package*[Text Word]
15	Search process*[Text Word]
16	Search ultraprocess*[Text Word]
17	Search ready to eat[Text Word]
18	Search ready to use[Text Word]
19	Search ready to feed[Text Word]
20	Search food product[Text Word]
21	Search designer[Text Word]
22	Search baby food[Text Word]
23	Search market[Text Word]
24	Search jar*[Text Word]
25	Search manufactur*[Text Word]
26	Search follow on[Text Word]
27	Search growing up milk[Text Word]

Appendix 1.1, con’t

28	Search ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]
29	Search (((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND (((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word])
30	Search breast feeding[MeSH Terms]
31	Search infant nutritional physiological phenomena[MeSH Terms]
32	Search breast feed*[Text Word]
33	Search breastfeed*[Text Word]
34	Search breast milk*[Text Word]
35	Search breastmilk*[Text Word]
36	Search (((((breast feeding[MeSH Terms]) OR infant nutritional physiological phenomena[MeSH Terms]) OR breast feed*[Text Word]) OR breastfeed*[Text Word]) OR breast milk*[Text Word]) OR breastmilk*[Text Word]
37	Search (((((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND (((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]))) AND ((((((breast feeding[MeSH Terms]) OR infant nutritional physiological phenomena[MeSH Terms]) OR breast feed*[Text Word]) OR breastfeed*[Text Word]) OR breast milk*[Text Word]) OR breastmilk*[Text Word]) Sort by: PublicationDate
38	Search ("2000"[Date - Publication] : "3000"[Date - Publication])
39	Search (((((((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND (((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]))) AND ((((((breast feeding[MeSH Terms]) OR infant nutritional physiological phenomena[MeSH Terms]) OR breast feed*[Text Word]) OR breastfeed*[Text Word]) OR breast milk*[Text Word]) OR breastmilk*[Text Word]))) AND ("2000"[Date - Publication] : "3000"[Date - Publication])

Appendix 1.2 Q1 Papers excluded after full text review

Title	Exclusion Reason	Setting	Notes
Adherence with early infant feeding and complementary feeding guidelines in the Cork BASELINE Birth Cohort Study [65]	BF outcome not quantifiable	Ireland	Focuses on introduction of CF at <17 vs. >17 weeks. Good description of feeding patterns, details on what is fed, including CACFs and follow-on formula, and "hungry baby milk", but no study of how CF relates to BF; notes BF initiation and duration but not in relation to CF
Comparison of Food Intake Among Infants and Toddlers Participating in a South Central Texas WIC Program Reveals Some Improvements After WIC Package Changes [66]	Doesn't include CACF	USA	Outcome is breastfeeding duration, and exposure is differences in WIC package for 6-12 mo. infants. Might be able to infer use of CFPs, but they are not quantified.
Determinants of timely initiation of complementary feeding among children aged 6-24 months in Sagamu, Nigeria [67]	BF is not the outcome	Nigeria	Study aimed to identify socio-demographic factors which may influence initiation of CF under-five y Nigerian children, description of practices but no analysis of how CF relates to BF. Shows that early EBF is associated with later CF initiation (not our direction of interest)
Consumption of highly processed snacks, sugar-sweetened beverages and child feeding practices in a rural area of Nicaragua [68]	Doesn't include CACF	Nicaragua	Reports detailed information about a large number of specific foods, including snacks, sugar-sweetened beverages, but not specific infant foods. % contribution to recommended intakes is quantified, but there is no comparison to breastfeeding. CACFs include sweet crispy snacks and sugar-sweetened beverages.
Mixed-methods study identifies key strategies for improving infant and young child feeding practices in a highly stunted rural indigenous population in Guatemala [69]	Irrelevant	Guatemala	Mixed methods; reports prevalence of BF; doesn't related BF to CACF
A comparison of infant and toddler feeding practices of mothers with and without histories of eating disorders [70]	Irrelevant	USA	Infant feeding styles questionnaire reveals attitudes, practices of women with and without eating disorders. Not generalizable to broader population
Current infant feeding practices and impact on growth in babies during the second half of infancy [71]	Doesn't include CACF	Sri Lanka	Study focus is on growth faltering. Outcome is child growth indicators. Reports on % of children receiving CACFs, but does not relate this information to breastfeeding
Growth and HIV-free survival of HIV-exposed infants in Malawi: a randomized trial of two complementary feeding interventions in the context of maternal antiretroviral therapy [72]	Irrelevant	Malawi	Compares Ready-to-use-food to milk powder (both commercially are CFPs), does not relate their consumption to breast-feeding, outcome is infant growth.
Exclusive breastfeeding, complementary feeding, and food choices in UK infants [73]	Irrelevant		Relates BF at age 3m to complementary feeding at 8-10m (mismatch of ages for our purposes)
Complementary feeding of infants in their first year of life: focus on the main pureed baby foods [74]	Doesn't include CACF	Brazil	Evaluation in children 4-9 mo old, focuses on pureed foods, but all are home-made. Outcome is adherence to CF recommendations for Brazil
Breastfeeding infants with phenylketonuria in the United States and Canada [75]	Irrelevant	USA, Canada	Focuses on breastfeeding duration, % of infants receiving formula, in a specialized population: All have PKU.
Cross-border promotion of formula milk in Lao People's Democratic Republic [76]	Doesn't include CACF	Laos	Qualitative study of mother's attitudes about infant formula use. No specific mention of follow-on or other CACFs

Title	Exclusion Reason	Setting	Notes
Baby food giants accused of wooing mothers in India off breastfeeding [77]	Irrelevant	UK	Brief commentary/BJN news item on infant formula and cereals
Changing WIC changes what children eat [78]	Doesn't include CACF	USA	Reports on time trends in prevalence of feeding patterns (fruits and vegetables, grains, milks, etc.) Notes age at introduction of solid foods. QRE does not allow identification of CACFs
Infant feeding patterns over the first year of life: influence of family characteristics [79]	Can't isolate CACF from other feeding patterns	France	CACFs are included in dietary pattern which is found to be inversely associated with a predominant breast-feeding-focused pattern. CA -- 1st pattern is CACF ("ready prepared vegetables, fruit purees, baby main meals") plus shorter BF duration
Emerging trends in breastfeeding practices in Singaporean Chinese women: findings from a population-based study [80]	Doesn't include CACF	Singapore	Reports breastfeeding initiation rates and duration, % of women using formula or expressed milk. No information on specific use of CACFs
Dietary characteristics of complementary foods offered to Guatemalan infants vary between urban and rural settings [81]	Outcome isn't BF	Guatemala	Detailed description of all CFs fed to infants, including brand names. Commercial and non-commercial CFs are noted, with brand names. All infants are breastfed, but no quantification of breastfeeding relative to CF intake. Grouping systems for foods are infant v family foods / modern v traditional / processed v non-processed);
Preliminary data from demographic and health surveys on infant feeding in 20 developing countries [82]	Doesn't include CACF	Cross country study	Uses DHS data to describe country level prevalence of breastfeeding and age specific prevalence of feeding "solid foods". CACFs not specifically noted.
Special Supplemental Nutrition Program for Women, Infants, and Children and infant feeding practices [83]	Doesn’t include CACF	USA	This is a program evaluation of how WIC participation relates to rates of exclusive breast-feeding, timing of introduction of solid foods. No specific CACFs included but program participation was associated with decreased likelihood of adherence to AAP feeding guidelines.
Patterns of breastfeeding in a UK longitudinal cohort study [84]	Doesn't include CACF	UK	Prevalence of different feeding patterns, purely descriptive. Groups are broadly categorized: all formulas and all CFs are grouped, so not CACFs can be identified.
Weaning foods and their impact on child-feeding practices among low-income Nigerian mothers [43]	Outcome isn't BF	Nigeria	Cross sectional study that examines utilization of local foods and analyzes their composition. Commercial products are compared in terms of composition (dried milk, Cerelac) but are not studied in relation to breastfeeding duration, frequency, or to breast milk intake.
What influences the timing of the introduction of solid food to infants? [85]	Wrong age	Scotland	Infants are 4 months old. Study is focused on early introduction of solid foods. Does not study breastfeeding as outcome, nor does it identify CACF aside from formula
Breastfeeding practices in Mostar, Bosnia and Herzegovina: cross-sectional self-report study [86]	Doesn't include CACF	Eastern Europe	Purely descriptive study of prevalence of breastfeed and CF practices, along with mother's stated reasons for their feeding decisions
Infant-feeding practices of mothers of known HIV status in Lusaka, Zambia [87]	Doesn't include CACF	Zambia	Breastfeeding in HIV infected women. CFs are noted in general with no specific CACFs mentioned beyond "formula'.
Complementary feeding patterns in Pondok Labu, South Jakarta, Indonesia [88]	BF outcome not quantifiable	Indonesia	Tests hypothesis that insufficient breast milk is a common reason for introducing CF, also focuses on timing of introduction of CF. Study is in 4-6 mo old infants, and data were collected prior to 1998. Notes timing of introduction of "instant cereals".

Title	Exclusion Reason	Setting	Notes
Breastfeeding practices and attitudes relevant to the vertical transmission of HIV in rural south-west Uganda [89]	Wrong age	Uganda	Qualitative study of maternal attitudes about breastfeeding. Focus is on infants < 6 mo of age.
Average infant formula and breastmilk intake among WIC infants reflects food package changes [90]	Irrelevant	USA	Abstract only: FASEB journal, EB/ASN abstract.
The effect of nutributter supplementation on complementary feeding practices among young children in an urban slum of Haiti [91]	Irrelevant	Haiti	Abstract only: abstract for nutrition society poster presentation. CACF is Nutributter. Outcome = diet diversity.
Dietary intakes of children from birth to 24 months: What We Eat in America, NHANES 2007-2010 [92]	Irrelevant	US	Abstract only: FASEB journal, EB/ASN abstract.
Food consumption in the Diet and Nutrition Survey of Infants and Young Children 2011 (DNSIYC) [93]	Incomplete/insufficient/ partial data	UK	Meeting abstract only (Proc Nutr Society) Reports on large survey with detailed data on age specific prevalence of consuming different types of foods.
Complementary feeding of children in the second year of life [94]	Doesn't include CACF	Brazil	Compares intake of CFs in breast and formal fed infants, focusing on age at introduction. "Salty baby food" is not specifically identified as CACF
Breast feeding practices in mother's of (urban) Bangalore [95]	Doesn't include CACF	India	Purely descriptive study reporting prevalence of breastfeeding at different ages, without relating BF to CF.
Infants feeding practices among garo and non garo mothers from Netrakona district Bangladesh [96]	Doesn't include CACF	Bangladesh	Purely descriptive study reporting prevalence of breastfeeding at different ages, without relating BF to CF. Compares timing of introduction of CF, and specific foods given in 2 ethnic groups.
Infant and young children feeding practices among mothers in Warsaw and neighbouring districts [97]	Not in English		
Patterns of feeding in children under eighteen month of age in Multan; a hospital based study [98]	Not located		
Intake of energy providing liquids during the first year of life in five European countries [99]	Doesn't include CACF	Europe multi-country study	Randomized to follow-on formula, and looks at intake of other liquids, including juices.BM intake not quantified;
Early short-term infant food supplementation, maternal weight loss and duration of breast-feeding: A randomised controlled trial in rural Senegal [100]	Doesn't include CACF	Senegal	Used a food supplement which was a locally prepared, "precooked food" to study duration of breastfeeding. Women given the supplement for a short period of time had longer breastfeeding duration. No measurement of breast milk. CF is not CACF.
Infant nutrition in North Iraq [101]	Not in English	Iraq	Full text in German
Who is not breast-feeding and why [102]	Irrelevant		Letter to the Editor: not research
Impact of community based awareness campaign on breast -feeding among lactating women in Chandigarh [103]	Doesn't include CACF	India	Purely descriptive study of feeding practices. CACFs are mentioned but breast feeding is not quantified, nor are CACFs.

Title	Exclusion Reason	Setting	Notes
Weaning practices in babies between the ages of six to nine months in the inner city of Johannesburg [104]	Does not quantify breast feeding as outcome	South Africa	Purely descriptive study of feeding practices, does not quantify relationship of CFs to breastfeeding.
Infant-feeding practices and beliefs about complementary feeding among low-income Brazilian mothers: a qualitative study [105]	Irrelevant	Brazil	Qualitative study on timing of introduction of CFs, notes use of "expensive commercial foods" is a problem, but CACFs not specifically identified.
Assessment of Complementary Feeding of Canadian Infants [106]	Irrelevant	Canada	Clinical trial registry, ongoing study.
Feeding My Baby - A National WIC Study [107]	Irrelevant	US	Clinical trial registry, ongoing study. Current examination of infant and toddler feeding practices among families receiving WIC services. The study will include exploration of breastfeeding practices and support, more general feeding practices, nutritional intake of infants and toddlers, transitions in infant and toddler feeding practices, early precursors of obesity, and family factors that may influence all of these nutrition-related issues.

Appendix 2.1 Search terms for PubMed for question 2

1	Search (((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word]) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]
2	Search (Obesity[Mesh] OR obesity[tw] OR Overweight[Mesh:NoExp] OR overweight[tw] OR adipos*[tw] OR body composition[mesh] OR body composition[tw] OR Body Fat Distribution[Mesh] OR body fat[tw] OR Chronic Disease[Mesh] OR chronic disease[tw] OR Cardiovascular Diseases[Mesh] OR cardiovascular disease[tw] OR Blood Pressure[Mesh:NoExp] OR blood pressure[tw] OR Hypertension[Mesh:NoExp] OR hypertension[tw] OR Prehypertension[Mesh] OR pre-hypertension[tw] OR elevated blood pressure[tw] OR high blood pressure[tw] OR Blood Glucose[Mesh] or blood glucose[tw] OR insulin/blood[mesh] OR Lipids/blood[Mesh] OR Triglycerides[Mesh:NoExp] or triglyceride[tw] OR Cholesterol, LDL[Mesh] OR LDL[tw] OR Cholesterol, HDL[Mesh] OR HDL[tw] OR Inflammation[Mesh:NoExp] OR inflammation[tw] OR Metabolic Syndrome X[Mesh] or metabolic syndrome[tw] OR Risk Factors[Mesh])
3	Search (((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word]) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word])) AND ((Obesity[Mesh] OR obesity[tw] OR Overweight[Mesh:NoExp] OR overweight[tw] OR adipos*[tw] OR body composition[mesh] OR body composition[tw] OR Body Fat Distribution[Mesh] OR body fat[tw] OR Chronic Disease[Mesh] OR chronic disease[tw] OR Cardiovascular Diseases[Mesh] OR cardiovascular disease[tw] OR Blood Pressure[Mesh:NoExp] OR blood pressure[tw] OR Hypertension[Mesh:NoExp] OR hypertension[tw] OR Prehypertension[Mesh] OR pre-hypertension[tw] OR elevated blood pressure[tw] OR high blood pressure[tw] OR Blood Glucose[Mesh] or blood glucose[tw] OR insulin/blood[mesh] OR Lipids/blood[Mesh] OR Triglycerides[Mesh:NoExp] or triglyceride[tw] OR Cholesterol, LDL[Mesh] OR LDL[tw] OR Cholesterol, HDL[Mesh] OR HDL[tw] OR Inflammation[Mesh:NoExp] OR inflammation[tw] OR Metabolic Syndrome X[Mesh] or metabolic syndrome[tw] OR Risk Factors[Mesh]))
4	Search (((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word]) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word])) AND ((Obesity[Mesh] OR obesity[tw] OR Overweight[Mesh:NoExp] OR overweight[tw] OR adipos*[tw] OR body composition[mesh] OR body composition[tw] OR Body Fat Distribution[Mesh] OR body fat[tw] OR Chronic Disease[Mesh] OR chronic disease[tw] OR Cardiovascular Diseases[Mesh] OR cardiovascular disease[tw] OR Blood Pressure[Mesh:NoExp] OR blood pressure[tw] OR Hypertension[Mesh:NoExp] OR hypertension[tw] OR Prehypertension[Mesh] OR pre-hypertension[tw] OR elevated blood pressure[tw] OR high blood pressure[tw] OR Blood Glucose[Mesh] or blood glucose[tw] OR insulin/blood[mesh] OR Lipids/blood[Mesh] OR Triglycerides[Mesh:NoExp] or triglyceride[tw] OR Cholesterol, LDL[Mesh] OR LDL[tw] OR Cholesterol, HDL[Mesh] OR HDL[tw] OR Inflammation[Mesh:NoExp] OR inflammation[tw] OR Metabolic Syndrome X[Mesh] or metabolic syndrome[tw] OR Risk Factors[Mesh])) Filters: Publication date from 2000/01/01

Appendix 2.2 Full texts reviewed and EXCLUDED for question 2.			
Title	**Exclusion Reason**	**Setting**	**Notes**
Diet quality of U.K. infants is associated with dietary, adiposity, cardiovascular, and cognitive outcomes measured at 7-8 years of age[108]	Doesn't include CACF	UK	Focus is on how degree of adherence to complementary feeding guidelines relates to obesity, CVD risk and cognitive outcomes at age 7-8. A dietary pattern associated with "Processed foods" is identified, but it is not possible to isolate the effects of any specific foods in the derived dietary patterns. Authors do note if foods are home-prepared or ready-made. Adherence to CF guidelines was weakly associated with waist circumference (inverse) and BP, but not to BMI at age 7-8
Infant feeding and later obesity risk[29]	Review/position/policy paper	Europe	This is a qualitative review of general principles relating infant feeding to later obesity, and includes finding from the multi-center European Child Obesity Project by Koletzko.
Can infant feeding choices modulate later obesity risk?[109]	Review/position/policy paper	Europe (multi-center)	This paper summarizes results from the European Child Obesity Project, which focuses on effects of early protein intake on obesity. Part of a series of papers presented at a workshop.
Milk feeding and dietary patterns predict weight and fat gains in infancy[110]	Doesn't include CACF	UK	Examines growth of infants who follow CF guidelines to infants with other dietary patterns. Factor analysis is used to define two patterns: "infant guidelines and "adult food" (neither pattern is high on CACF). Adult foods pattern included highest frequency of breads and processed foods); outcome = conditional weight/length/skinfold thicknesses
High protein intake from meat as complementary food increases growth but not adiposity in breastfed infants: A randomized trial[111]	No home-made/local comparison group	USA	This small RCT compares commercially available foods to each other rather than to home prepared foods: meats vs 2 types of infant cereal, among BF infants, finding that higher protein intake from meat was associated with greater linear growth but no excessive gain in adiposity.
Early infant feeding and obesity risk[112]	Irrelevant		Patient educational material in JAMA
Factors associated with rapid infant weight gain[113]	Insufficient information		Abstract only, published in J. Investigatory Medicine for a conference
Baby food low in protein prevents overweight: The first months of life are crucial[114]	Insufficient information	Germany	Brief report in German Language journal
Feeding patterns in The first year of life are related to toddlers' growth[115]	Insufficient information	?	Abstract for a poster presentation at an Obesity conference
Finger millet in nutrition transition: An infant weaning food ingredient with chronic disease preventive potential[116]	Irrelevant	Africa	Commentary on potential implications for humans of an animal study.
Diabetes mellitus: Prevention is already in the baby food?[117]	Irrelevant	Germany	Commentary in German language journal
The effects of increased protein intake on kidney size and function in healthy infants: A randomized clinical trial[118]	Meeting Abstract: published paper has different title	Spain	Reports on RCT of high vs lower protein formula in the first 6 mo. Some infants switched to follow-on formula between 4 and 6 months. Outcome is measured at 6 mo so met inclusion criteria, but exposure was only prior to 6 mo.
Interventions for preventing obesity in children[119]	Review/position/policy paper		This is a review of intervention strategies for obesity prevention: no specific focus of CFs

Appendix 3.1 Search terms for PubMed for question 3

1	Search ((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word])
2	Search ((((((((((((((((((((((((((sodium, dietary[mesh]) OR salt*[tw]) OR sodium[tw]) OR fatty acids[mesh]) OR saturated fat[tw]) OR sat fat[tw]) OR trans fatty acids[mesh]) OR trans fat*[tw]) OR nutritive sweeteners[mesh]) OR dietary sucrose[mesh]) OR sugar*[tw]) OR micronutrients[mesh]) OR micronutrient*[tw]) OR dietary proteins[mesh]) OR dietary protein[tw]) OR protein) OR iron [mesh]) OR iron[tw]) OR zinc[tw]) OR iodine[mesh]) OR iodine[tw]) OR zinc[mesh]) OR zinc[tw]) OR calcium[mesh]) OR calcium[tw]) OR nutritive value[mesh:noexp]) OR nutritional quality[tw]) OR nutritive value[tw]
3	Search ((((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]))) AND ((((((((((((((((((((((((((sodium, dietary[mesh]) OR salt*[tw]) OR sodium[tw]) OR fatty acids[mesh]) OR saturated fat[tw]) OR sat fat[tw]) OR trans fatty acids[mesh]) OR trans fat*[tw]) OR nutritive sweeteners[mesh]) OR dietary sucrose[mesh]) OR sugar*[tw]) OR micronutrients[mesh]) OR micronutrient*[tw]) OR dietary proteins[mesh]) OR dietary protein[tw]) OR protein) OR iron [mesh]) OR iron[tw]) OR zinc[tw]) OR iodine[mesh]) OR iodine[tw]) OR zinc[mesh]) OR zinc[tw]) OR calcium[mesh]) OR calcium[tw]) OR nutritive value[mesh:noexp]) OR nutritional quality[tw]) OR nutritive value[tw])
4	Search ((((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word]))) AND ((((((((((((((((((((((((((sodium, dietary[mesh]) OR salt*[tw]) OR sodium[tw]) OR fatty acids[mesh]) OR saturated fat[tw]) OR sat fat[tw]) OR trans fatty acids[mesh]) OR trans fat*[tw]) OR nutritive sweeteners[mesh]) OR dietary sucrose[mesh]) OR sugar*[tw]) OR micronutrients[mesh]) OR micronutrient*[tw]) OR dietary proteins[mesh]) OR dietary protein[tw]) OR protein) OR iron [mesh]) OR iron[tw]) OR zinc[tw]) OR iodine[mesh]) OR iodine[tw]) OR zinc[mesh]) OR zinc[tw]) OR calcium[mesh]) OR calcium[tw]) OR nutritive value[mesh:noexp]) OR nutritional quality[tw]) OR nutritive value[tw]) Filters: Publication date from 2000/01/01; Humans; Infant: birth-23 months Sort by: PublicationDate

Appendix 3.2 Q3 Papers excluded after full text review			
Title	**Exclusion Reason**	**Setting**	**Notes**
Nutritional and sensory evaluation of a complementary food formulated from rice, faba beans, sweet potato flour, and peanut oil [120]	Doesn't have home-made/local comparison	Nigeria	Three weaning food formulations made and compared to a CAP (Nutrend); weaning food formulations are not mimicking a homemade food a mom would make -- are an attempt to incorporate additional nutrients into an existing weaning food used by local moms
Sweet potato-based complementary food for infants in low-income countries [121]	Irrelevant	Africa	Comparison of nutrients in Weanimix (CAP) to a sweet-potato based weaning food (created by the study team); have an industrial and a home preparation based on the method used -- extrusion cooking vs oven toasting -- but both use a processed initial product (the "cream-fleshed sweet potato flour"). Depends on if this home-based product qualifies as a "home-made or local" comparison
Nutrient adequacy and organoleptic quality of complementary food mixes made from combinations of digitaria exilis, sesamum indicum and glycine max [122]	Incomplete/insufficient/partial data		Poster abstract
Development of local processed complementary food products-'WinFoods'-in Cambodia, for food aid programmes for prevention of child malnutrition [123]	Incomplete/insufficient/partial data		Poster abstract
Adequacy of family foods for complementary feeding [124]	Review/policy/position paper		Editorial
Complementary feeding: Is the nutritional profile of a homemade baby food the same as the commercial jar baby foods? [125]	Not in English		
Comparison of carbohydrate composition in sweetpotato-and maize-based infant foods [126]	Incomplete/insufficient/partial data		Poster abstract
Nutrient composition of commonly used complementary foods in North western Nigeria [127]	Doesn't include CAP	Nigeria	Comparison of the nutrient content of common traditional/local complementary foods in different regions of Nigeria
Comparison of nutritional contents between homemade and industrial baby food [128]	Not in English		
Ca, Cd, Cu, Fe, Hg, Mn, Ni, Pb, Se, and Zn contents in baby foods from the EU market: comparison of assessed infant intakes with the present safety limits for minerals and trace elements [129]	Doesn't include CAP	Europe (Italy, Spain, Slovakia, Sweden)	Nutritional analysis of infant formula/solids/beverages
Orange-fleshed sweet potato-based infant food is a better source of dietary vitamin A than a maize-legume blend as complementary food [130]	Doesn't have home-made/local comparison	n/a (New Zealand?)	Nutrient comparison of Weanimix v. Cerelac v. sweet potato based v. maize based; sweet potato versions are meant to be something that *can* be made at home, but are not currently home-made products
Sweetpotato-based complementary food would be less inhibitory on mineral absorption than a maize-based infant food assessed by compositional analysis [131]	Doesn't include CAP	Africa	Assess bioavailability of nutrients in two formulations of sweet potato based complementary foods (one "home-made", one processed) v. Weanimix; so based foods are created by study team, are not current home-made; Because Weanimix was enriched, so not CAP anymore

Title	Exclusion Reason	Setting	Notes
Chemical and protein quality of soybean (Glycine max) and tigernut (Cyperus esculentus) based weaning food [132]	Doesn't have home-made/local comparison	Nigeria	Trying to develop a new weaning food using soy and tigernut; compare to Cerelac (CAP);
Development of yoghurt-based weaning foods for 1-3 years old toddlers by incorporation of mung bean (Vigna radiata), soybean (Glycine max) and brown rice (Oryza sativa) for the Sri Lankan market [133]	Doesn't have home-made/local comparison	Sri Lanka	Three weaning food formulations using yogurt were made and compared against Cerelac (CAP); three experimental formulations were made using locally available cereals (rice) and legumes (soybean and mung bean)
Microbial safety, nutritive value and residual pesticide levels are comparable among commercial, laboratory and homemade baby food samples - a pilot study [134]	Irrelevant	Canada	Pilot study; compare CAP to home-made and lab-made baby food; report on kcal, fat, protein, iron…; but "home-made" actually refers to moms making recipes according to Heinz instructions ("homemade versions of manufactured products") -- is that really a home-made product, or is it just someone else making a CAP?; result is that all three are similar, but they are essentially all testing the same recipe/instructions and it's just different people making it...? Study was funded by Heinz...
Nutritional and rheological properties of sweet potato based infant food and its preservation using antioxidants	Doesn't have home-made/local comparison	Uganda	Trying to develop two sweet potato based foods; compare to Cerelac and Heinz baby food
Evaluation of the nutritional value of a composite meal prepared from pearl millet (Pennisetum typhoideum) and cowpea (Vigna unguiculata)	Doesn't include CACF	Nigeria	Comparison of home-made/local (ogi) with two ratios of new formulations (Addition of legumes to cereal)
The protein quality value of two homemade cereals legume mixtures compare to a commercial baby food sample	Not in English		
Development of sweet potato-soybean blend, an alternative to maize-legume mix as complementary food for infants in Ghana [135]	Doesn't have home-made/local comp	Ghana	Comparison of sweet potato based complementary food ("home-made") with Weanimix (CAP)
Nutritional and sensory profiles of sweet potato based infant weaning food fortified with cowpea and peanut [136]	NOT available		
Comparison of quality proteins regarding evaluation in two samples of home made cereal/legume mixtures with a sample of commercial baby food [137]	Not in English		
Formulation of an infant food based on breadfruit (Artocarpus altilis) and breadnut (Artocarpus camansi) [138]	Not available		
Calcium and phosphorus content in some food products assigned for infants and small children nutrition [139]. / Zawartośc´ wapnia i fosforu w wybranych produktach przeznaczonych do zywienia niemowlat i maych dzieci	Not in English		
Chemical evaluation of multimixes formulated from some local staples for use as complementary foods in Nigeria [140]	Doesn't include CAP	Nigeria	Comparison of formulations of new multimixes (supplemented local staple weaning foods)
Calcium and magnesium in food products for infant and children nutrition [141].	Not in English		
Bioavailability of calcium from milk-based formulas and fruit juices containing milk and cereals estimated by in vitro methods (solubility, dialyzability, and uptake and transport by Caco-2 cells) [142]	Doesn't have home-made/local comparison	Europe	Comparing the bioavailability of calcium from formulas (adapted, follow-up, toddler formula) and fruit-juices containing milk and cereal
Modification in Complementary Food Composition to Improve the Status of Iron and Fatty Acids in Infants [143]	Doesn't have home-made/local comparison	Germany	Comparing quantities of meat in infant diet -- but both arms' diets are CAP

Appendix 4.1 Search terms for PubMed for question 4

Search (((((((((infant food[MeSH Terms]) OR infant food*[Text Word]) OR baby food*[Text Word]) OR toddler food*[Text Word]) OR solid food*[Text Word]) OR weaning food*[Text Word]) OR complementary food*[Text Word]) OR complementary feed*[Text Word])) AND ((((((((((((((((commercial[Text Word]) OR industrial*[Text Word]) OR ready prepared[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]) OR follow on[Text Word]) OR growing up milk[Text Word])) AND ("Portion Size"[Mesh] OR "portion size"[tw] OR "Serving Size"[Mesh] OR "serving size"[tw] OR "meal size"[tw]) Filters: Publication date from 2000/01/01; Humans

Appendix 4.2 Q4 Papers excluded after full text review

Title	Exclusion Reason	Setting	Notes
Toddler foods, children's foods: assessing sodium in packaged supermarket foods targeted at children [144]	Doesn't report on portion size	Canada	Sodium content of several CACFs were assessed, and compared against UK sodium recommendations, but not actual portion size
Quantities and types of foods reported for complementary feeding in a peri-urban area of South Africa[145]	Incomplete/insufficient/ partial data	South Africa	Poster abstract
Perceptions of infant cereals and dietary intakes of children aged 4-24 months in a rural South African community[146]	Irrelevant	South Africa	Objective is to determine perceptions of infant cereals; compare the amount of infant cereal that caregivers feed infants (4-24mo) with recommended portion size; children are only fed ~1/4 of recommended amount; PICO says to age appropriate

Appendix 5.1 Search terms for PubMed for question 5

1	Search stunt*[tw]
2	Search anemi*
3	Search (((((((("Infant Nutrition Disorders"[Mesh:NoExp]) OR "Deficiency Diseases"[Mesh:NoExp]) OR "Anemia"[Mesh]) OR "Micronutrients/deficiency"[Mesh]) OR "Trace Elements/deficiency"[Mesh]) OR "Avitaminosis"[Mesh]) OR "Iron/deficiency"[Mesh]) OR "Zinc/deficiency"[Mesh]) OR "Calcium/deficiency"[Mesh]) OR "Vitamin A Deficiency"[Mesh]
4	Search micronutrient deficien*[tw]
5	Search iron deficien*[tw]
6	Search zinc deficien*[tw]
7	Search calcium deficien*[tw]
8	Search vitamin A deficien*[tw]
9	Search "Malnutrition"[Mesh:NoExp]
10	Search ((((((((((((((((("Infant Nutrition Disorders"[Mesh:NoExp]) OR "Deficiency Diseases"[Mesh:NoExp]) OR "Anemia"[Mesh]) OR "Micronutrients/deficiency"[Mesh]) OR "Trace Elements/deficiency"[Mesh]) OR "Avitaminosis"[Mesh]) OR "Iron/deficiency"[Mesh]) OR "Zinc/deficiency"[Mesh]) OR "Calcium/deficiency"[Mesh]) OR "Vitamin A Deficiency"[Mesh])) OR "Malnutrition"[Mesh:NoExp]) OR stunt*[tw]) OR anemi*) OR micronutrient deficien*[tw]) OR iron deficien*[tw]) OR zinc deficien*[tw]) OR calcium deficien*[tw]) OR vitamin A deficien*[tw]
11	Search ((((((((infant food[MeSH Major Topic]) OR infant food*[tw]) OR baby food*[tw]) OR toddler food*[tw]) OR weaning food*[tw]) OR solid food*[tw]) OR complementary food*[tw]) OR complementary feed*[tw])) AND ((((((((((((((commercial*[Text Word]) OR industrial*[Text Word]) OR "ready prepared"[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market*[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word])
12	Search ((((((((((infant food[MeSH Major Topic]) OR infant food*[tw]) OR baby food*[tw]) OR toddler food*[tw]) OR weaning food*[tw]) OR solid food*[tw]) OR complementary food*[tw]) OR complementary feed*[tw])) AND ((((((((((((((commercial*[Text Word]) OR industrial*[Text Word]) OR "ready prepared"[Text Word]) OR package*[Text Word]) OR process*[Text Word]) OR ultraprocess*[Text Word]) OR ready to eat[Text Word]) OR ready to use[Text Word]) OR ready to feed[Text Word]) OR food product[Text Word]) OR designer[Text Word]) OR baby food[Text Word]) OR market*[Text Word]) OR jar*[Text Word]) OR manufactur*[Text Word]))) AND ((((((((((((((((("Infant Nutrition Disorders"[Mesh:NoExp]) OR "Deficiency Diseases"[Mesh:NoExp]) OR "Anemia"[Mesh]) OR "Micronutrients/deficiency"[Mesh]) OR "Trace Elements/deficiency"[Mesh]) OR "Avitaminosis"[Mesh]) OR "Iron/deficiency"[Mesh]) OR "Zinc/deficiency"[Mesh]) OR "Calcium/deficiency"[Mesh]) OR "Vitamin A Deficiency"[Mesh])) OR "Malnutrition"[Mesh:NoExp]) OR stunt*[tw]) OR anemi*) OR micronutrient deficien*[tw]) OR iron deficien*[tw]) OR zinc deficien*[tw]) OR calcium deficien*[tw]) OR vitamin A deficien*[tw]) Filters: Publication date from 2000/01/01; Humans

Appendix 5.2 Q5 Papers excluded after full-text review			
Title	**Exclusion Reason**	**Country**	**Notes**
Randomized controlled trial of the effectiveness of a soybean-maize-sorghum-based ready-to-use complementary food paste on infant growth in South Kivu, Democratic Republic of Congo [147]	No homemade/local comparison	DRC	
Infant and young child feeding in the Peruvian Amazon: the need to promote exclusive breastfeeding and nutrient-dense traditional complementary foods [148]	Irrelevant	Peru	Report on common complementary foods; table 4 talks about the relative % energy/nutrients from traditional vs. "market" food, but there is no explantion of what constitutes market food; this % energy/nutrients is not related to a stunting/anemia/mnd outcome
Complementary feeding with fortified spread and incidence of severe stunting in 6- to 18-month-old rural Malawians [149]	No homemade/local comparison	Malawi	RCT of LP (CACF) vs RUCF (CACF); 1o outcome = weight gain, 2o outcome = length gain, various anthro indices, Hb and ferritin
Effect of weaning period on nutritional status of children [150]	Population not 6-23m	Pakistan	Cross-sectional study looking at CACF v. homemade foods; outcome = anthro indicators (st/wa/uw); looking at 4-6m period; CACF is just cereal biscuits and rusk (=/= CACF); age at outcome measurement not given
[Prevalence of iron deficiency in healthy 12-month-old infants] [151]	Not in English		
Formulation and substantiation of homemade complementary baby food by selective feeding trial [152]	Doesn't include CACF	Bangladesh	Feeding trial of a study formulation (made from locally available food stuffs). Control is no intervention (=homemade), but there is no CACF
Breastfeeding, complementary feeding and nutritional status of 6 - 12-month-old infants in rural KwaZulu-Natal [153]	Doesn't include CACF	South Africa	Descriptive study of BF and complementary feeding and nutritional status; don't relate complementary foods to stunting/anemia outcomes; don't really assess CACF (mention savory snacks, have unquantified FFQ that asks about sugar, biscuits, sweets, infant cereal)
Supplemental feeding with ready-to-use therapeutic food in Malawian children at risk of malnutrition [154]	No homemade/local comparison	Malawi	RCT of RUTF vs. micronutrient fortified CSB
Effects of weaning cereals with different phytate content on growth, development and morbidity: A randomized intervention trial in infants from 6 to 12 months of age [155]	No homemade/local comparison	Sweden	RCT of regular-phytate and low-phytate MCD/formula (both CACF, so no homemade comparison)

Appendix 5.2 Q5 Papers excluded after full-text review

Title	Exclusion Reason	Country	Notes
Processed Complementary Food Does Not Improve Growth or Hemoglobin Status of Rural Tanzanian Infants from 6-12 Months of Age in Kilosa District, Tanzania [156]	Doesn't include CACF	Tanzania	RCT of unprocessed placebo vs processed complementary food, but neither are a CACF or home-made food
Complementary foods fortified with micronutrients prevent iron deficiency and anemia in Vietnamese infants [157]	Doesn't include CACF	Vietnam	RCT of micronutrient fortified flour and complementary food vs. usual gruel; intervention is specially made for the study so not a CACF
Randomized controlled trial of meat compared with multimicronutrient-fortified cereal in infants and toddlers with high stunting rates in diverse settings [158]	Doesn't have home-made/local comparison	DRC, Zambia, Guatemala, Pakistan	RCT of meat (lyophilized beef -- made by a camping company, so not CACF) vs. MNF cereal (looks like a CACF http://www.nutrica.com.gt/Productos_Products.html)
Effect assessment of nutrition intervention in 6-24 months old infants and young children [159]	Not in English		
Efficacy of amaranth grain (Amaranthus cruentus) on anaemia and iron deficiency in Kenyan pre-school children [160]	Doesn't include CACF	Kenya	Thesis of a nutritional assessment, then analysis of amaranth
Nutritional rehabilitation using energy dense local food as ready to use therapeutic food in hospitalized malnourished children: case for primary prevention at grass root levels [161]	Irrelevant	India	population has PEM; RCT of family diet only vs. family diet/RUTF vs. family diet/RUTF/multivitamin. RUTF =/= CACF here
A six-month intervention with two different types of micronutrient-fortified complementary foods had distinct short- and long-term effects on linear and ponderal growth of Vietnamese infants [162]	Doesn't include CACF	Vietnam	RCT of micronutrient fortified flour and complementary food vs. usual gruel; intervention is specially made for the study so not a CACF
Neither a zinc supplement nor phytate-reduced maize nor their combination enhance growth of 6- to 12-month-old Guatemalan infants [163]	Doesn't include CACF	Guatemala	RCT of low-phytate (imported) v. control maize (local) and zinc supplementation (tablet)v. placebo (tablet)
Infant feeding practices and nutritional status of children in North Western Nigeria [164]	Incomplete/insufficient/partial data	Nigeria	Only reports prevalences

Appendix 5.2 Q5 Papers excluded after full-text review

Title	Exclusion Reason	Country	Notes
Supplementary feeding with fortified spread among moderately underweight 6-18-month-old rural Malawian children [165]	Doesn't have home-made/local comparison	Malawi	RCT of fortified spread (not CACF or homemade/local) vs. likuni phala (CACF)
Deterioration in the nutritional status of young children and their mothers in Brazzaville, Congo, following the 1994 devaluation of the CFA franc [166]	Irrelevant	Brazzaville, Congo	Data collection took place in the 1990s
A comparative study of the weaning practices and growth pattern in 3-24 month old infants fed formula and food in Nitel Health Centers and PHC's of Mushin Local Government area of Lagos, Nigeria [167]	Incomplete/insufficient/partial data	Nigeria	
Prevalence of iron-deficiency anemia according to infant nutrition regime [168]	Not in English	Brazil or Portugal	

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