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Feeding Interventions for Improving the Physical and Psychosocial Health of Disadvantaged Children Aged Three Months to Five Years: Protocol for a Systematic Review

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PROTOCOL

THE CAMPBELL COLLABORATION

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1 Background

1.1 BACKGROUND

Feeding programs for preschool-aged children are intended to help address the single biggest cause of the global burden of disease: undernutrition (Lopez 2006, p 297). The most recent figures indicate that 830 million people globally were undernourished between 2005 and 2007 (United Nations 2010); most of them in low- and middle-income countries. The Food and Agriculture Organization estimates that the number of undernourished people in 2010 was 925 million (FAO 2010). Although this represents a decrease from an estimated one billion in 2009, these extremely high levels of undernourishment make the Millennium Development goal of halving the number of hungry people by 2015 seem out of reach.

Many of those who are undernourished are children. Globally in 2010, 27% of children under five years of age (171 million) were stunted and 16% (104 million) were underweight (Lutter 2011). Child and maternal undernutrition and suboptimal breastfeeding are responsible for about 35% of child deaths and 11% of the global burden of disease (Black 2008). The crisis of child hunger and undernutrition is not limited to low- and middle-income countries (LMIC); in 2003, 18% of American children lived in food-insecure households (Nord 2004). UNICEF estimates show that between 1996 and 2005 in the United States, 2% of children were underweight, 1% were stunted, and 8% had low birthweight (UNICEF 2006).

Poverty and undernutrition are closely linked (Haddad 2000); poverty is "the leading cause of hunger" (World Hunger Education Service 2012). As noted above, most undernutrition occurs in LMIC. Among low-income countries in the 1990's, the percentage of underweight preschoolers declined sharply as gross domestic production rose (Haddad 2000). Furthermore, a recent analysis found significant socioeconomic inequalities in child malnutrition within 47 LMICs; these inequalities were sharper for stunting than for wasting (Van de Poel 2008). They described three distinct patterns of inequality in stunting: mass deprivation (most children in the country are stunted), queuing (average stunting is lower than in 'mass deprivation' but poorer communities are worse off than the richer groups) and exclusion (the

majority of children in the country are not stunted but a poor minority are). In higher income countries, such as Canada (Office 2007) and the United States (Nord 2010), food insecurity is strongly associated with low income.

1.2 DESCRIPTION OF CONDITION

Malnutrition is more accurately referred to as undernutrition using the following definition**:** "undernutrition is defined as the outcome of insufficient food intake and repeated infectious diseases. It includes being underweight for one's age, too short for one's age (stunted), dangerously thin for one's height (wasted) and deficient in vitamins and minerals (micronutrient malnutrition)" (UNICEF 2006). Throughout the lifecycle, undernutrition contributes to increased risk of infection, lowered cognitive performance, chronic disease in adulthood, and mortality (United Nations 2000). Many of those who suffer from undernutrition are children. The consequences of undernutrition in early childhood are particularly severe; both physical and intellectual development may be affected (Ivanoc 2004; Petrou 2010). More than 35% of deaths and another 35% of the disease burden in children less than five years old are attributable to undernutrition (Black 2008). The main causes of child deaths are diarrhoea, pneumonia, malaria, measles, AIDS, and perinatal conditions; undernutrition is an underlying cause for most of these (Black 2003; Black 2003a; Caulfield 2004). Zinc deficiency, for example, contributes to child morbidity and mortality by increasing the prevalence and severity of diarrhoea and pneumonia (Jones 2003). Undernutrition also increases the risk of mortality from disease by increasing the likelihood that the illness will be prolonged or severe (Shankar 2000). In turn, severe illness may lead to appetite loss, metabolic changes, and behavioural changes (Tomkins 1989), thus worsening nutritional status; this may place children at risk of future more prolonged or severe illness episodes (Fishman 2003). Early and persistent undernutrition may cause permanent changes in physiology, metabolism, and endocrine function (Barker 2001; Prentice 2005) and has been increasingly linked to adult onset chronic disease such as obesity, hypertension, diabetes, stroke, and coronary heart disease (Barker 1992; Gaskin 2000; Hoffman 2000; Barker 2001; Caballero 2001; Prentice 2005; L¢pez-Jaramillo 2008).

Although the brain continues to grow throughout childhood, the period between birth and three years of age is a time of particularly rapid growth. During these years, the brain is very sensitive to factors that can inhibit brain growth and cognitive development, such as protein-energy malnutrition or micronutrient deficiency (Tanner 2002). Although it is sometimes difficult to disentangle the effects of undernutrition from other deprivations to which children living in poverty are exposed, early undernutrition (assessed through anthropometric indicators and tests for micronutrient deficiency) is

linked to lowered cognitive functioning and poorer school performance (Schrimshaw 1998; Worobey 1999; Tanner 2002; Alderman 2004; Grantham-McGregor 2007). In the short term, skipping breakfast can result in lower performance on memory and verbal fluency tasks (Pollitt 1998). It is possible that many of the effects of undernutrition on cognition are produced through decreased motivation and interaction. Animal studies show that malnutrition leads to changes in motivation, emotionality, and anxiety (Strupp 1995; Walker 2007). These effects may limit a child's capacity to interact with his/her environment and to learn from these interactions (Beaton 1993; Pollitt 1994; Walker 2007). Maternal, fetal, and early childhood undernutrition is also linked to lower educational attainment and lower economic productivity in later life (Grantham-McGregor 2007; Victora 2008).

1.3 DESCRIPTION OF THE INTERVENTION

The intervention of interest concerns provision of energy (with nutrients/ micronutrients) in the form of food or beverage to children aged three months to five years of age. This may include wet or dry feeding in the form of meals or snacks (for example, biscuits) as well as fortified and unfortified beverages (for example, milk) that provide energy. The intervention may be administered in preschool, daycare, or community settings. Take-home rations considered as packages of wet or dry ingredients for meals, fortified foods (for example, Plumpy Doz), or snacks given to children/family to be consumed at home (see Figure 1). The intervention is usually given programmatically. The goals of these programmes generally include one or more of: improved survival, prevention or amelioration of growth failure, lowered morbidity, and promotion of normal cognitive and behavioural development (Beaton 1993). Interventions may be targeted, for example, to socioeconomically disadvantaged children or areas; they may also be universal (covering all young children in a village, province, or country).

1.4 HOW THE INTERVENTION MIGHT WORK

It is important to intervene in early childhood to maximise developmental potential and lifelong health (Power 1997; McCain 2007). Feeding programmes for disadvantaged young children are designed to provide energy, nutrients, and micronutrients to accomplish this. According to Beaton and Ghassemi (Beaton 1982), these programmes are usually designed to meet 40% to 70% of the estimated energy gap and therefore should exist alongside usual meals consumed at home. Substitution can be a problem. In take-home feeding programmes, approximately 40% to 60% of the food distributed appeared to reach targeted children, with the remainder either

consumed by other family members or sold. The food or beverage given may improve growth and micronutrient status through providing additional energy, macronutrients, and micronutrients; it may also boost immune status and reduce the risk of infection (Schrimshaw 1998; Barker 2001; Prentice 2005). The energy, nutrients, and micronutrients given may also improve motivation and psychosocial health, including cognitive functions such as intelligence, attention, psychomotor skills, language, visuospatial skills, and memory. Feeding-related cognitive benefits may be achieved through both neurological and behavioural mechanisms. Nutrition can influence the development and function of a young child's brain through several mechanisms: development of brain structure, including increased brain volume (Ivanoc 2004), myelination, and neurotransmitter operation (Wachs 2000; Tanner 2002). Feeding may also improve social behaviour, through increased interaction with the world, improved emotional state, and lowered anxiety (Barrett 1985). Increased social interaction may, in turn, enhance cognitive functioning and learning. Better nutrition in the first two years of life is associated with achieving a higher level of schooling (Victora 2008; Martorell 2010).

The amount of energy given and the macronutrient and micronutrient composition of the food are critical for achieving adequate growth and meeting physiological needs (Beaton 1982; Rivera 1991; Allen 1994; Rush 1998).There is evidence that the effects on growth, particularly linear growth, may be most pronounced for children two years of age and under (Schroeder 1995; Dewey 2008).

While there is a lack of evidence about effectiveness by socioeconomic status, some research has shown that feeding may be more effective for the most undernourished (typically very poor) young (Beaton 1982) and school-aged children (Kristjansson 2009). Related to this, based on their finding of different patterns of socioeconomic inequalities in stunting, Van de Poel 2008 suggested that in countries with mass deprivation, a universal approach be used, while in situations of exclusion, targeted approaches should be used to improve the health of the poorest children.

However, despite the obvious benefits (namely significant reductions in underweight and wasting that have occurred in most countries), supplementary feeding programmes in some LMIC, particularly in Latin America, may be contributing to a slight rise in the prevalence of obesity (Kain 1998). It was estimated that change in percentage prevalence of obesity in Chilean preschoolers ranged from 2% among the under three year olds to as much as 4% in four to five year olds during a school year (Uauy 2001). The explanation for this phenomenon or adverse effect is that some nutrition programmes have evolved beyond solely providing food supplements and

have become a component of multifaceted approaches that also include social economic benefit schemes (for example, conditional cash transfer programmes). This process may be driven by the continued plight of populations living in poverty.
Our conceptual model is found in Figure 2.

1.5 WHY IT IS IMPORTANT TO DO THIS REVIEW

In order to intervene, we need good evidence on what works, and why. A great deal of money is invested in feeding programmes for young children, making it important to learn whether or not they are effective and cost-effective interventions. Thus it is vital to review evidence on the effectiveness of feeding interventions for young children. It is equally important to understand the drivers of change or how context and implementation impact on effectiveness. Systematic reviews on feeding programmes for preschool-aged children are especially timely in an era when governments and leading international organisations are placing increasing emphasis on evidence-based strategies to improve the health of the poor. It is important for governments, funders, and nongovernmental organisations to have evidence about these programmes in order to make important decisions about the distribution of scarce resources (Irwin 2007).
Yet, thus far, this evidence is limited. Two non-systematic reviews (Beaton 1982; Beaton 1993) of supplementary feeding programmes for young children have been performed; one of the reviews (Beaton 1993) focused on nutrition and cognition. A Cochrane systematic review (Sguassero 2012) of rigorous randomised controlled trials (RCTs) examined the effectiveness of community-based feeding interventions for growth in young children living in LMIC. Another recent systematic review (Dewey 2008) studied the efficacy and effectiveness of complementary feeding interventions for children aged six months to two years in LMIC. Bhutta 2008 reviewed interventions that affect maternal and child undernutrition, using a cohort model to assess the potential effect of these interventions on children in the 36 countries that have 90% of children with stunted linear growth. One ongoing Cochrane review (Sguassero 2007) is evaluating nutritional education in addition to supplementary food as an intervention. This review is focusing on assessing the effects of a combined approach (nutrition education and supplementary food) on growth and development for children from birth to five years of age. Several other ongoing reviews are examining the use of micronutrients or the fortification of foods with micronutrients only as nutritional interventions. For this reason we will not consider such interventions.

There may be partial overlap with another ongoing Cochrane review that examines the effectiveness of different types of food for children with moderate acute malnutrition (MAM) in LMIC (Lazzerini 2012). The main

question to be addressed in this review is therapeutic and as such includes children with MAM to the extent of weight for height of -3 standard deviation from the mean as well as those treated in hospital. Though overlap in our population, the primary outcome of our review includes both growth and development/cognition and also includes children without MAM. Our review, along with these ongoing reviews, provides much needed information to fill the gap on the effectiveness of feeding interventions aimed at children in various contexts and using various approaches.

Limitations of existing research

Although the above reviews provide valuable information, they fail to give us a comprehensive, reliable picture of the effectiveness of feeding programmes for preschool-aged children globally. All were limited in scope to a few outcomes and/or to a few countries. Three of the five reviews were not systematic reviews in which details on search strategies, inclusion and exclusion criteria, number of studies found and considered were provided, and the quality of studies was not formally assessed. The review by Dewey 2008 focused on infants and toddlers only; it did not cover adverse outcomes. The review by Sguassero 2012 focused particularly on growth outcomes assessed by randomised controlled trials (RCTs).
Our review will build on existing reviews in the following ways. Firstly, it will be broader by including controlled before and after (CBA) studies, controlled clinical trials (CCTs), and interrupted time series (ITS). This will be done because it is increasingly recognised that reviews containing study designs other than RCTs are advantageous in capturing important population level (or population health) interventions (Ogilvie 2005; Tugwell 2010). Secondly, we will have a rigorous process evaluation to elucidate pertinent information on factors that impact on effectiveness. Thirdly, we will assess the effect of the intervention on many outcomes, including psychosocial development, physical activity, and infectious disease, in addition to physical development. Thus our review may help to address one of the evidence gaps identified by Bhutta 2008: the lack of evidence about whether adverse effects of undernutrition on cognition and infectious disease may be ameliorated.

2 Objectives of the review

PRIMARY OBJECTIVE

1. To assess the effectiveness of programmes that provide energy, nutrients, or micronutrients, or both through food or drink to improve the physical and psychosocial health of disadvantaged children aged three months to five years.

SECONDARY OBJECTIVES

1. To assess the potential of such programmes to reduce socioeconomic inequalities in undernutrition and its consequences.
2. To evaluate process of implementation and to understand how this may impact on outcomes.

3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

Randomised controlled trials randomised either at the cluster or individual level, CCTs (controlled clinical trials), CBA studies (controlled before and after studies) and ITS (interrupted time series designs) with three time points before and after the intervention, with or without a control group) will be eligible for this review. All other types of studies will be excluded.

3.1.2 Types if participants

Children aged three months to five years will be included. We are interested in studies from all countries of the world; results will be analysed separately for low- and lower-middle income countries and higher-income countries (includes upper-middle and high-income countries). Country income will be classified according to the 2009 World Bank List of Country Economies (World 2011).
To meet our study objectives (studying the effectiveness of giving energy to children who need it) studies must include children from:

1. socioeconomically disadvantaged groups; OR
2. both high and low socioeconomic groups if results are or can be stratified by some indicator of socioeconomic status (for example, high/low income, high/low education, rural/urban).

Definition of socioeconomic disadvantage:
LMIC: from rural areas, villages, or provinces, or deprived urban areas OR parents have low average education (primary school or below) OR parents are manual workers (including small farmers) or unemployed OR families are materially disadvantaged/low socioeconomic status (SES) OR children are described as low income, malnourished, undernourished, underweight or

stunted, OR they are at least two standard deviations (SDs) below mean for weight and height for age.
Higher-income counties: families or children described as low SES, low income, low education (high school or below), or from low-income areas (ghettos, inner city).

We will exclude studies of high income children only or studies that mix high and low income children where results are not stratified by SES and data is not available to the review authors to perform such analyses. In this way, we can both study effectiveness for disadvantaged children and compare effectiveness for disadvantaged and advantaged children.

Because we are not including therapeutic feeding, we will exclude severely acutely malnourished children (those with a weight for height z score of > 3 SD). For this reason, we will also exclude studies that focus exclusively on children with diagnosed illnesses (for example, diabetes, HIV). We will also exclude interventions that feed children in emergency and refugee settings.

3.1.3 **Types of interventions**

Provision of energy, nutrients or micronutrients, or both through:

1. hot or cold meals (breakfast or lunch);
2. snacks (including both food and beverages such as milk or milk substitutes);
3. meals or snacks in combination with take-home rations;
4. take-home rations.

These interventions must be delivered in a preschool, in daycare, or in the community. Foods and beverages may be centrally fortified or not. There may also be co-interventions (for example, nutrition education). Studies must compare children who receive feeding to a non-intervention control. We will accept either no treatment controls (no feeding) or placebo controls (for example, low energy foods (less than 5% of the energy provided by the intervention) or drinks (without fortification). For example, a low energy, unfortified (30 kcal) drink would be acceptable as a control.
We will exclude food stamps, food banks, and modifications to meals to lower the energy, fat or sodium content. We will exclude therapeutic feeding designed for children with severe acute malnutrition and illnesses that are outside the scope of this review. Feeding cannot take place in a hospital setting.
Figure 1 shows the types of feeding programmes that will be included in the review.

3.1.4 **Types of outcomes**

The outcomes of this review represent two major domains in child health, namely, physical health and psychosocial health (including behaviour).

Primary outcomes

Physical health
1.Growth (weight, height, weight for age, height for age, weight for height).

Psychosocial health
2. Intelligence (the ability to learn or understand or deal with new or trying situations).
3. Attention (the ability to apply one's mind to something or the condition of readiness for attention including a selective narrowing of consciousness).
4. Language (the ability to comprehend receptive language and apply expressive language to communicate).
5. Memory (the ability to recover information about past events or knowledge).
6. Psychomotor development (the progressive attainment of skills that involve both mental and muscular activity. For example, the ability to turn over, crawl, and walk).

Adverse effects
7. Substitution (where the family cuts rations for the child who has been fed in order to spread food to the other family members).
All primary outcomes will be used to populate the 'Summary of findings' table.

Secondary outcomes

Physical health
1. Biochemical markers of nutrition (vitamin A, haemoglobin, haematocrit).
2. Physical activity (body movements that work muscles and require more energy than resting, for example, running, jumping, playing ball, walking around school yard).
3. Morbidity (physician diagnosis of acute illness such as pneumonia, diarrhoea, malaria).
4. Mortality (death).
5. Overweight/obesity (adverse outcome).

Psychosocial outcomes
6. Stigmitisation (adverse effect, involves being shamed or disgraced).
7. Behaviour problems (aggression, disruptive behaviour).

We will analyse outcomes at short term (two months or less), medium term (less than a year) and long term (more than one year.

Where possible, we will extract data on cost and resource use.

The outcome of reduction of dental caries will be excluded, as will increased nutritional knowledge (although the latter will be included in the data extraction form to help elucidate findings). Intermediate physical health outcomes such as reduction of hunger and nutrient intake will also be excluded.

For cognitive and behavioural outcomes, we will accept reliable and valid psychometric measures (for example, Weschler Intelligence Scale for Children, Raven Progressive Matrices). For physical outcomes, we will accept clinical measures of growth (for example, length/height boards, digital or balance beam weighing scales, skinfold thickness, mid upper arm circumference), biochemical nutritional status (for example, blood tests), and morbidity (diagnosis by physician).

3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

3.2.1 **Electronic searches**

We have worked with an information specialist from the Cochrane Developmental, Psychosocial and Learning Problems Group as well as Tamara Rader to develop a search strategy.

The search will be performed in the following electronic databases: Cochrane Controlled Trials Register (CENTRAL), MEDLINE and PreMedline, EMBASE, CINAHL, PsycINFO, ERIC, Sociofiles, HMIS (Health Management Information Consortium), OVID Healthstar, LILACS, Open Grey, WHOLIS, the WHO nutrition databases (http://www.who.int/nutrition/databases/en/), Social Science Index, and Dissertation Abstracts International. We will also search the websites of selected development agencies or research firms (for example, JOLIS, IDEAS, IFPRI, NBER, USAID, World Bank). The trials registry Clinicaltrials.gov will be searched for ongoing trials.

3.2.2 **Searching other resources**

A robust search strategy is important for eliminating publication bias, therefore, every effort will be made to contact relevant organisations and experts in the field to identify unpublished or ongoing studies. References of included articles, relevant reviews, and annotated bibliographies will be scanned for eligible studies. We will also use SCOPUS to track the cited

references of included studies. Our advisory panel of six experts in the field will be contacted by email to determine whether we have missed relevant studies. We will also identify key researchers in the field and write to them to ask about any unpublished or forthcoming works.

3.2.3 **Search terms**

Ovid MEDLINE(R) search terms

1 Dietary Supplements/
2 Diet Therapy/
3 Food, Fortified/
4 Functional Food/
5 Nutrition Therapy/
6 ((extra or take-home or take home) adj3 (food$ or feed$ or ration$)).tw.
7 Nutrition Policy/
8 ((feed$ or food$) adj3 program$).tw.
9 ((fortif$ or enrich$) adj3 (food$ or diet$ or spread$ or flour$ or cereal$)).tw.
10 (lunch$ or dinner$ or break-fast$ or breakfast$ or breakfast$ or supper$ or snack$ or meal$ or milk).tw.
11 (plumpy$ or nutri spread$).tw.
12 ((supplement$ or complement$) adj3 (food$ or feed$ or diet$ or nutrition$ or nutrient$ or micronutrient$ or micro-nutrient$)).tw.
13 (blended adj3 food$).tw.
14 (energy adj3 supplement$).tw.
15 (lipid based adj3 supplement$).tw.
16 or/1-15
17 Infant/
18 Child, Preschool/
19 toddler$.tw.
20 (baby or babies or infant$ or preschool$ or pre-school$ or child$).tw.
21 or/17-20
22 16 and 21
23 "Growth and Development"/
24 *Growth/
25 Child Development/
26 milestone$.tw.
27 exp Motor Skills/
28 Psychomotor Performance/
29 Psychomotor Disorders/
30 (psychomotor adj3 development).tw.
31 psychosocial.tw.
32 Stress, Psychological/
33 Adaptation, Psychological/
34 Social Support/

35 Cognition/
36 Cognition Disorders/
37 Learning Disorders/
38 (cognit$ adj4 ability).tw.
39 cognit$.tw.
40 Attention/
41 Attention Deficit Disorder with Hyperactivity/
42 Child Behavior Disorders/
43 (on task adj4 behavio$r).tw.
44 exp Vocabulary/
45 exp Language Development/
46 exp Intelligence/
47 exp Intelligence Tests/
48 exp Bone Density/
49 (bone adj3 mineral adj3 test$).tw.
50 exp Motor Activity/
51 (physical adj3 activit$).tw.
52 *Exercise/
53 exp Morbidity/
54 exp Stereotyping/
55 stigma$.tw.
56 Aggression/
57 (bully or bullying).tw.
58 victimization.tw.
59 disruptive behavio$r.tw.
60 Obesity/
61 Weight Loss/
62 (excess$ adj3 weight adj3 loss).tw.
63 Memory/
64 Logic/
65 Problem Solving/
66 reasoning.tw.
67 Psychometrics/
68 height.tw.
69 weight.tw.
70 length.tw.
71 Anthropometry/
72 Body Weight/
73 Body Height/
74 Body Size/
75 Weight Gain/
76 Body Composition/
77 Physical Fitness/
78 fitness.tw.

79 or/23-78
80 22 and 79

3.2.4 Searching other resources

A robust search strategy is important for eliminating publication bias, therefore, every effort will be made to contact relevant organisations and experts in the field to identify unpublished or ongoing studies. References of included articles, relevant reviews, and annotated bibliographies will be scanned for eligible studies. We will also use SCOPUS to track the cited reference of included studies. Our advisory panel of six experts in the field will be contacted by email to determine whether we have missed relevant studies. We will also identify key researchers in the field and write to them to ask about any unpublished or forthcoming works.

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Due to the large number of expected hits, half of the titles and abstracts of articles retrieved by the electronic database searches and the handsearches will be scanned independently by two review authors (DF and EK), while two different review authors (SL and MBJ) will independently scan the second half. These will be scanned for eligibility according to the inclusion criteria above. Full copies of all those deemed eligible by one of the review authors will be retrieved for closer examination. All studies that initially appear to meet inclusion criteria from this first screening but on closer inspection do not meet the inclusion criteria will be detailed in the table of excluded studies. This full text review will be done independently by two review authors (EK and SL). Disagreements will be settled by a third author (DF).

The team comprises review authors who are fluent in Portuguese, Spanish, French, and English. Therefore, we will be able to interpret articles written in these languages. Studies in all other languages will be retrieved, and held for later assessment.

3.3.2 Data extraction and management

Data will be extracted by one of four review authors (MBJ, SL, DF, and KM) who will thoroughly review each other's work. EK will also verify extraction.

Our data abstraction forms are based on the data collection forms from the Cochrane Effective Practice and Organisation of Care (EPOC) review group (see Kristjansson 2009), and they will be modified for the purposes of this review. We will extract data on study design, description of the intervention

(including process), details about participants (including number in each group, age, and socioeconomic status), length of intervention and follow-up, definition of disadvantage, all primary and secondary outcomes, costs and resource use, critical appraisal (see below), and statistical analysis. Data on all outcomes listed above will be extracted. Where possible, effects will be recorded by socioeconomic status, geographic location, gender, race/ethnicity, and age.

We will pilot test the forms on a sample of two studies. In this pilot, four review authors will extract data. As our data extraction forms were created in Excel, they can be compared.

As energy content is critical for interpreting results, intensity of approach (portion size, energy content, and percentage of requirements) and appropriateness for the age group will be determined by the nutritionists (DF, SL, and MB). Where possible, we will record protein and micronutrient content. A nutritionally adequate intervention should provide at least 30% of daily energy. We will also use guidelines set out by Golden 2009 for recommended nutrient intakes for children with acute malnutrition. The nutritionists will also assess and describe the characteristics of the placebo or attention given to children in the control group. Energy content will be used as the exposure and type/mealtime as the intermediate variables (Hauspie 2004).

Process of implementation

The following process elements will be abstracted (list modified from Arblaster 1996 and Kristjansson 2009).

1. Type of meal.
2. Multifaceted approaches (are other supports (nutrition education, etc.) used in addition to providing food?
3. Coverage of the program.
4. Implementation fidelity.
5. Settings (for example, where is food given: preschool, daycare, community).
6. Prior needs assessment to inform intervention design (possibly to identify when, where, and how to give food).
7. Ensuring interventions are culturally appropriate (for example, are provisions made for dietary restrictions?)
8. Agent administering the intervention (for example, community, government).
9. Agent delivering intervention (is it peer supervised, teacher supervised, supervised by lunchroom staff, volunteers?).

10. Provision of material support (was food provided free of charge or for a reduced price according to income?).
11. Provision of prompts/reminders to attend.
12. Monitoring intake.
13. Quality of food given (in terms of palatability and variety).
14. Cost and time to run program.
15. Policy exigencies. Is it mandatory to run feeding programs?

We will use results from this checklist in interpreting the data and in understanding the mechanisms of action.

3.3.3 Assessment of risk of bias in included studies

Two review authors (BK and BS) will independently assess the risk of bias for each study using the criteria below.

Randomised controlled trials (RCTs), cluster-randomised controlled trials (cRCTs), controlled before and after studies (CBAs)

For RCTs including cluster RCTS, we will use the Cochrane Collaboration 'Risk of bias' tool (Higgins 2011). For CBAs, we will use the 'Risk of bias' tool from the Cochrane Effective Practice and Organisation of Care Group (EPOC 2009). It covers allocation sequence, similarity of baseline outcome measurement, similarity of baseline characteristics, incomplete outcome data, blinding of allocation, protection against contamination, selective outcome reporting, and other risks of bias. Furthermore, we will assess questions on reliability and validity of measurement tools; withdrawals and dropouts; intervention integrity, and analyses, using the Quality Assessment Tool for Quantitative Studies (http://www.ephpp.ca/tools.html) developed by the Effective Public Health Practice Project (Thomas 2004; EPHPP 2009). These issues are not all covered in the other tools and are important for judging the integrity of the intervention. Each component is covered by one or more items, and a dictionary gives thorough definitions for each item. Most items are scored as 'yes', 'no', or 'can't tell'. Once each item is scored, each component is rated as strong, moderate, or weak. We will give component ratings, but will not give an overall rating.

Interrupted time series (ITS)

Our appraisal criteria for ITS studies will be adapted from the 'Risk of bias' checklist developed by the Cochrane Effective Practice and Organisation of Care Group (EPOC: http://epoc.cochrane.org/epoc-author-resources). In assessing risk of bias in the ITS designs, we will consider protection against secular changes, predefined shape of effect, effect on data collection, knowledge of allocated interventions, incomplete outcome data, selective outcome reporting, and other biases.

3.3.4 Measures of treatment effect

Statistical analysis will be performed using RevMan5 (RevMan 2011). Appropriate measures of treatment effect will be determined in consultation with our statistician, GW, depending on the type of data collected in the included studies.

Dichotomous data

We will analyse categorical data using odds ratio (OR), and risk ratio (RR).

Continuous data

Continuous data will be analysed from means and standard deviations wherever possible. there is no clear evidence of significant skewness (skewness > 1) in the distribution. When means and standard deviations are not reported, we will use other available data (for example, confidence intervals, t values, P values) and appropriate methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 7.7.3, Higgins 2008) to calculate the means and standard deviations, in consultation with our statistician. Where other available data are not sufficient to calculate standard deviations, we will contact the trial authors. Standard deviations will not be imputed.

3.3.5 Unit of analysis issues

Multiple outcomes

We have a number of different outcomes and outcome subcategories. Conceptually, these subcategories cannot be combined (for example, within cognitive development, language cannot be combined with intelligence). Therefore, a meta-analysis will be conducted separately for each outcome. Furthermore, for each outcome, we will separately meta-analyse: 1) LMIC versus higher-income countries; 2) different study designs (ITS, RCT, and CBA). We have chosen to analyse by LMIC versus higher-income country as the two settings are very different in terms of needs, delivery, and other contextual factors. Furthermore, we are planning subgroup analysis of SES within LMIC and then separately within higher-income countries as we believe that there may be different magnitude of effectiveness within higher- and lower-income countries. We believe that a subgroup analysis of SES across both low- and high-income countries may hide such relevant effects.

Cluster-randomised trials

Where trials have used clustered randomisation, we anticipate that study investigators would have presented their results after appropriately controlling for clustering effects (for example, variance inflated standard errors, hierarchical linear models). If it is unclear whether a cluster-

randomised controlled trial has appropriately accounted for clustering, the study investigators will be contacted for further information. Where appropriate controls for clustering were not used, we will request individual participant data and an estimate of the intra-class correlation coefficient will be calculated. The data will be re-analysed using multi-level models which control for clustering. If individual patient data cannot be obtained, we will calculate an interclass correlation coefficient based on the other studies in the review and used in the variance inflation factor to adjust the standard errors appropriately. Following this, effect sizes and standard errors will be meta-analysed in RevMan using the generic inverse method (Higgins 2008). They will be combined with estimates from individual level trials.
We will use sensitivity analyses to assess the potential biasing effects of using the interclass correlation coefficients that have been derived in different ways (for example, based on individual patient data, estimated from other studies).

3.3.6 **Dealing with missing data and incomplete data**

We will contact trial authors to supply any missing or unreported data such as group means, standard deviations, details of attrition or details of interventions received by the control groups. If outcome data are only reported for participants completing the trial or who followed protocol then we will contact the authors for additional information to enable an analysis to be conducted according to intention-to-treat principles. Missing data and attrition will be described for each included study in the 'Risk of bias' table. If missing data are unobtainable, the extent to which the results or conclusions of the review might be affected by this will be assessed and discussed.

3.3.7 **Assessment of heterogeneity**

Heterogeneity between trial results will be tested using a standard Chi^2 test, to assess whether observed differences in results are compatible with chance alone. The I^2 test will be used to assess the impact of heterogeneity on the meta-analysis. It shows the percentage of variability in effect estimates that are due to heterogeneity rather than to chance. Values over 75% indicate a high level of heterogeneity (Higgins 2003). If high heterogeneity is detected, we will combine studies by narrative summary only and explore heterogeneity by conducting predefined subgroup analyses.

If heterogeneity exists, we will examine potential sources using the following steps: subgroup analysis and meta-regression.

4 We shall also obtain an estimate of the between studies variance component (I^2) through a random-effects meta-analysis.
5 If sufficient studies are found, funnel plots will be drawn to assess the presence of possible publication bias. Ten studies are usually considered sufficient to draw a funnel plot.

6 Whilst funnel plot asymmetry may indicate publication bias, this is not inevitably the case (Egger 1997), and possible explanations for any asymmetry found will be considered and discussed in the text of the review.

6.1.1 **Assessment of reporting biases**

If sufficient studies are found, funnel plots will be drawn to investigate any relationship between effect size and study precision. Asymmetry could be due to publication bias, but can also be due to a *real* relationship between trial size and effect size, such as when larger trials have lower compliance, and compliance is positively related to effect size. In the event that we find such a relationship, we will examine clinical diversity of the studies (Higgins 2008, section 10.4). As a direct test for publication bias, we will compare results extracted from published journal reports with results obtained from other sources (including correspondence).

3.4 DATA SYNTHESIS

3.4.1 Data synthesis

Randomised controlled trials (RCTs), cluster-randomised controlled trials (cRCTs), controlled before and after studies (CBAs)

To perform meta-analyses of continuous data, we will input data on means, standard deviations, and the number of participants for each outcome in the two groups. It is important to note that, in all cases, these means and standard deviations will be unadjusted for confounders; however, they will be adjusted for clustering when needed.

We will use the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 16.1.3.2) (Higgins 2008) to calculate standard deviation of change scores with available information. For these calculations, we will seek a correlation coefficient for baseline and end of study measurements from the authors or from similar studies that measured the same outcome, and we will conduct sensitivity analyses around these estimates. If end of study results cannot be converted to change scores, these results will be analysed and reported separately from change score data.

In performing our meta-analysis, we will use the inverse-variance random-effects model. If continuous outcomes are measured identically across studies, an overall mean difference (MD) and 95% confidence interval (CI) will be calculated. If the same continuous outcome is measured differently across studies, an overall standardised mean difference (SMD) and 95% CI

will be calculated (Higgins 2008). SMDs will be calculated using Hedges *g*. It is important to note that we will take the direction of effect into account. Following the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 9.2.3.2), if scales measure in different directions (high on some represents greater disease severity while high on others represents less severity), we will multiply the mean values from one set of studies by –1 to ensure that all the scales measure in the same direction. Results will be interpreted using clinical significance as well as statistical significance. Categorical and continuous data will be analysed separately.

Interrupted time series (ITS)

We will calculate relative and absolute mean difference in before and after values. When possible, we will use time series regression to calculate mean change in level and mean change in slope.

For discrete outcomes (for example, underweight versus adequate weight), we will present the relative risk of the outcome compared to the control group. We will also calculate the risk difference, which is the absolute difference in the proportions in each treatment group. Finally, we will calculate the number needed to treat to achieve one person with the desired outcome.

Reporting by socioeconomic group

When possible, comparisons will be reported by socioeconomic group as well as by other relevant sociodemographic variables including baseline nutritional status, gender, race/ethnicity, and place of residence. Where results by socioeconomic variables are not available in the primary articles and reports, we will request these data from the authors and recalculate effect sizes and P values.

'Summary of findings' tables

We will construct 'Summary of findings' tables for all of the primary outcomes. We will develop separate tables for LMIC and high-income country settings and for significant subgroups using the GRADE protocol (Guyatt 2011).

Data will be synthesised for all studies. Process data will be summarised and used to interpret results. We will also assess clinical meaningfulness of the outcomes. A clinically meaningful outcome is an improvement of at least 0.5 standard deviation in any outcome in at least one child.

3.4.2 Subgroup analysis, moderator analysis and investigation of heterogeneity

We will conduct subgroup analyses across six categories.

1. Age: three months to two years versus greater than two years to five years. In cases where combined estimates are given by authors, attempts will be made to retrieve data appropriate for analysis according to defined age groups.
2. Sex: male versus female.
3. Socioeconomically disadvantaged: more versus less.
4. Underweight (our definition is 1 SD below mean) versus normal weight. We are using this definition as participants in the sample are limited in the range of underweight they will exhibit (none below -3). This will give us a reasonable proportion in each group.
5. Amount of daily requirements for energy provided (less than 15%, 15% to 30%, 30% to 50%, above 50%).
6. Micronutrients added versus not added.

We hypothesise that feeding will be more effective for:

1. younger children;
2. most disadvantaged, poorest, lowest socioeconomic status;
3. those with the poorest nutritional status (underweight, stunted);
4. children who receive more of the daily energy requirements.

Assessing impact on socioeconomic inequities in the health and psychosocial outcomes

We will assess this potential for each outcome separately.
Our assessment of the potential for reductions in socioeconomic inequities in health will be classified as: effective for reducing inequities in health, potentially effective for reducing inequities in health, ineffective for reducing inequities in health, or uncertain.

a. Effective: we will consider an intervention effective for reducing socioeconomic inequities in health if the intervention works and if improvements in health are greater for children in lower socioeconomic groups than in higher groups.

b. Potentially effective: an intervention will be classified as potentially effective if delivered only to children of lower socioeconomic groups, and if it shows statistically significant and meaningful effects.

c. Ineffective: an intervention will be classified as ineffective for reducing socioeconomic inequities in health if it results in greater improvements for children in higher socioeconomic groups than for children in lower socioeconomic groups or if it is not effective for children in lower socioeconomic groups.

Meta-regression

If heterogeneity is an issue, we will conduct meta-regression to assess the relation of size of effect to characteristics of the trials. The characteristics we will include in the meta-regression are sex, age, and energy content of meals (as above)

3.4.3 Sensitivity analysis

Sensitivity analyses will be performed to consider the impact of the following.

1. Reliable primary outcome (direct versus indirect).
2. Placebo versus no treatment control.
3. Allocation concealment (adequate versus inadequate and/or unclear).
4. Attrition (< 10% versus >= 10%).
5. Imputed correlation coefficient in estimating standard deviations for change (calculated with the assumption of a correlation (P) of 0.5 versus independence (correlation = 0)).

4 Acknowledgments

We gratefully acknowledge funding from 3ie. This funding enabled us to develop the protocol, and will allow us to complete the review in a timely manner.

We are also grateful for the advice and enormous amount of assistance received from three members of the Cochrane Developmental, Psychosocial and Learning Problems Group review: Margaret Anderson, Laura MacDonald, and Geraldine Macdonald.

We acknowledge Jane Dennis, of the Campbell Social Welfare Group, who kindly converted this protocol into Campbell format.

5 Contribution of authors

Betsy Kristjansson - will lead the review. She led the funding application and led development of the protocol, writing much of it. She will be involved in screening studies, deciding on inclusion/exclusion, overseeing data extraction and analyses, leading the writing, and leading the knowledge translation.

Damian Francis - is a co-author who was involved in proposal development as well as writing the protocol. As a nutritionist, he will be integral is assessing the nutritional composition and quality of the meals (intervention) administered to the participants. He will also be involved in data management including data analysis, writing, and the knowledge translation plan for this review.

Selma Liberato - contributed to the proposal and protocol writing. She will help with the screening process of retrieved studies based on inclusion/exclusion criteria, data extraction, quality assessment, data analysis, and writing. She will collaborate in the assessing the nutritional composition and quality of the meals (intervention) administered to the participants.

Maria Benkhalti Jandu - was involved in writing the protocol as well as in funding proposal development, policy influence plan, and logic model development. She has also developed the data extraction sheet and will be contributing to the screening, data extraction, and writing of the review.

Malek Batal - was involved in the proposal and protocol writing and the drafting of the logic model. He will decide on inclusion/exclusion of retrieved studies, extract data on nutritional quality of food/drink given, rate quality of anthropometric measures, participate in write-up, edit, and revision of review prior to submission.

Vivian Welch - Vivian contributed to the policy influence plan, proposal development, development of the search strategy, and will contribute to analysis of the non-randomised studies and analysis of process and implementation issues using realist methods.

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

Eamonn Noonan - will, with others, write a policy brief based on the review and participate in the dissemination of the review and in activities under the policy influence plan. He will also contribute to writing the final review.

Laura Janzen - contributed to the proposal and protocol writing, will rate the quality of the cognitive and behavioural measures and contribute to the discussion of the cognitive and behavioural results.

George A Wells - has and will continue to provide statistical advice on analyses. He will also carry out the meta-regressions.

Beverley Shea - reviewed the protocol, will assess the methodological and reporting quality, and assist with the sensitivity analysis.

Tamara Rader - will develop and run search strategies in over 10 databases according to the *Cochrane Handbook for Systematic Reviews of Interventions* and in collaboration with subject experts. She will assist in document delivery of full text papers, contribute to the development of the data extraction form, and help draft the protocol. Specifically, she will report the plan for the search methods and draft the search sections for the final review including providing the exact search strategy.

Mark Petticrew - reviewed the proposal and will contribute to the synthesis of the data, including summarising the findings and writing the final review.

6 Declarations of interest

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8 Figures

Figure 1: Types of feeding programs included and excluded in the review

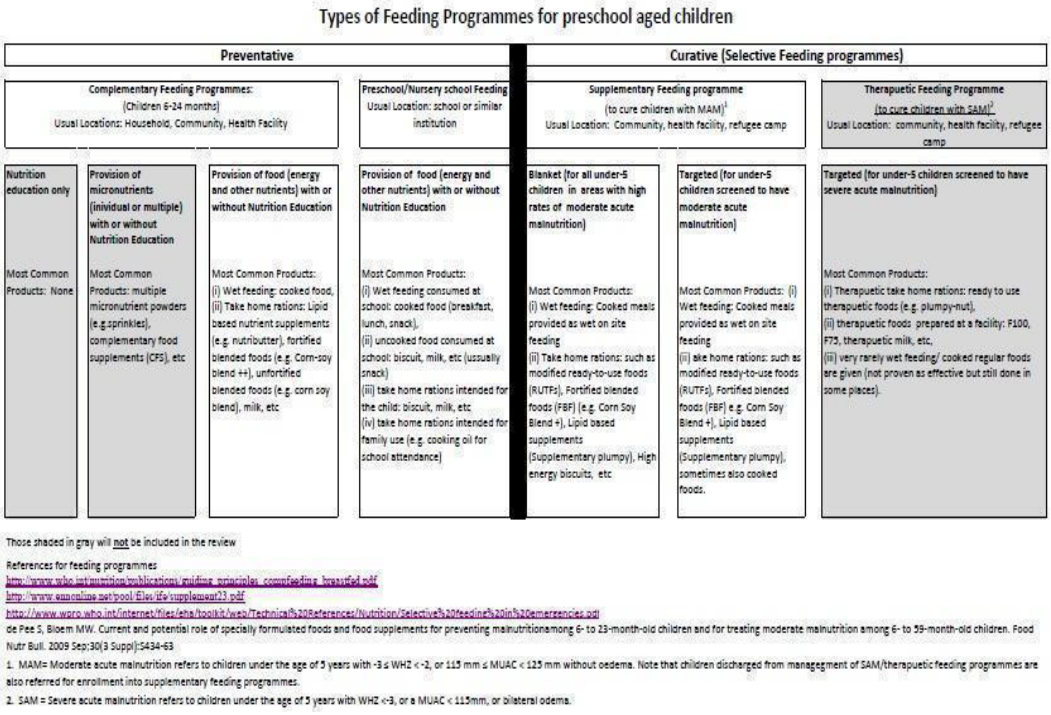
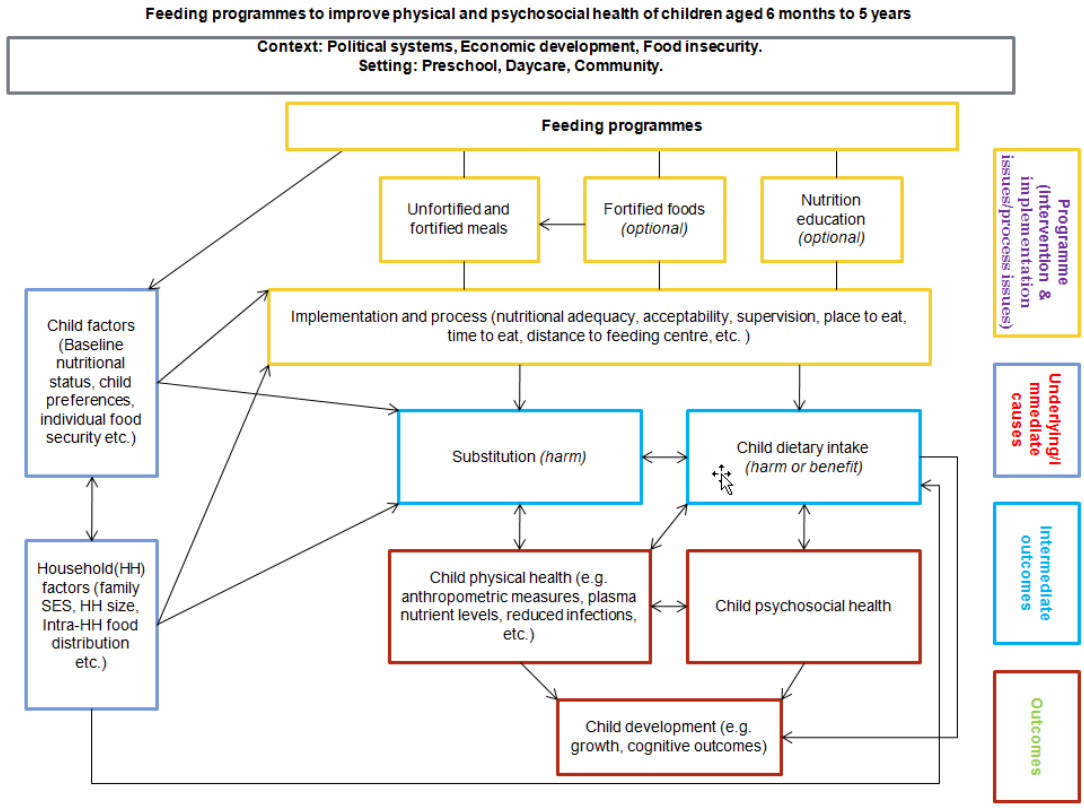


Figure 2: Our conceptual model



9 Sources of support

9.1 INTERNAL SOURCES

No sources of support provided.

9.2 EXTERNAL SOURCES

- 3ie, UK

  We have received an $86,000 grant to enable us to perform this review.

- Canadian Institutes of Health Research, Canada

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