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Cochrane Database of Systematic Reviews 2015, Issue 2. Art. No.: CD011504.

DOI: 10.1002/14651858.CD011504.

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[Intervention Protocol]

Community-level interventions for improving access to food in low- and middle-income countries

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Editorial group: Cochrane Public Health Group.

Publication status and date: New, published in Issue 2, 2015.

Citation: Durao S, Schoonees A, Ramokolo V, Oliveira JMD, Kristjansson E. Community-level interventions for improving access to food in low- and middle-income countries. *Cochrane Database of Systematic Reviews* 2015, Issue 2. Art. No.: CD011504. DOI: 10.1002/14651858.CD011504.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

Primary objective

To determine the effects of community-level interventions that aim to improve access to nutritious food in LMICs, for both the whole community and for disadvantaged or at-risk individuals or groups within a community, such as infants and children, women, the elderly, the poor, the unemployed, or minority groups.

Secondary objectives

To determine the features of community-level interventions that enable or impede the effective implementation of these interventions to improve access to food.

To identify unintended consequences of interventions to improve access to food.

BACKGROUND

Description of the condition

Food security exists when “all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active

and healthy life” (FAO 2003). When this is not the case, the population is said to be food insecure.

Food insecurity and associated undernutrition affect health and socioeconomic development on different levels (Black 2013; Ecker 2012; Victora 2008). For adults it has been associated with increased risk of disability, morbidity and mortality, and with income generating potential (Black 2008, Black 2013, Victora 2008).

Food insecurity is also associated with mental health problems such as depression and anxiety, both in high-income as well as low- and middle-income settings (Carter 2011; Cole 2011; Hadley 2006; Hadley 2008). Children who are affected may suffer impaired physical and cognitive development and decreased school performance (Black 2008; Black 2013; Liu 2012; Victora 2008). At the macro-level undernutrition is associated with direct and indirect costs. Direct costs are due to increased healthcare costs for preventing and treating affected individuals (Black 2013; Victora 2008). Indirect costs are due to poor productivity and losses of human resources due to mental and physical underperformance and death (Victora 2008). Given these consequences, and that food security is considered a human right by the United Nations (FAO 2003), it is important to address food insecurity.

The first Millennium Development Goal (MDG) is to eradicate extreme poverty and hunger; its target is to halve the number of people who are hungry by 2015 (Fanzo 2011). Despite improvements in the global levels of undernutrition since the MDGs were developed, the world is nowhere near reaching this target, especially among countries in sub-Saharan Africa and South Asia, which are home to 80% of the world's children with stunted growth (DFID 2012). Globally, one in eight people around the world did not have a sufficient dietary intake of energy between 2011 and 2013; 97% of these people live in low- and middle-income countries (LMICs) as defined by the World Bank (FAO 2013). In LMICs, 18% and 29% of children under five years old are underweight and stunted, respectively (UN 2012). Factors that have delayed improvements in rates of chronic hunger include the food price crisis of 2008, brought about by trade restrictions of major food exporters, biofuels policies, and increased commodity speculation, among others (Ecker 2012). The higher demand for food due to changing dietary patterns and growing population, and food price increases and volatility due to climate change are other factors that will contribute to food insecurity in the long term (Ecker 2012). Food security is a complex concept that encompasses several different dimensions (Ecker 2012; FAO 2013; Gross 2000), where i) food availability refers to the quantity of food that is physically available in the relevant vicinity of a population during a given period (ACF 2009); ii) food access is a measure of the capacity of a household to acquire sufficient and appropriate foods to ensure a diet that is diverse, nutrient-rich and safe, and that satisfies the nutrient needs of its members during a given period, which is often influenced by the proximity and price of food (ACF 2009; WHO 2013); iii) food utilization refers to the intake of food by the people within a household and how the body assimilates the nutrients physiologically; and iv) food stability introduces the condition of time to the food security concept, that is it refers to chronic or transient food insecurity (FAO 2003). Chronic food insecurity refers to long-term, persistent lack of food and results from continued problems with structural poverty, which relates to the inability of the labour market to produce enough jobs to keep people out of poverty, low incomes, and with lack of sufficient

social safety nets to assist the poor (Ecker 2012; FAO 2003; Rank 2003). On the other hand, transient food insecurity refers to food and nutrient shortages during certain periods of food crises due to natural disasters, economic collapse or conflict (Ecker 2012; FAO 2003). In addition, the nutrition dimension was added to the food security concept at the 2009 World Food Summit (Ecker 2012) as food insecurity is associated with nutrient deficiencies and poor nutritional outcomes. Furthermore, food and nutrient intake interact in a bidirectional manner with health status (Ecker 2012). This means that nutritional status is the primary measure of food security.

The four dimensions of food security operate at different levels of influence, although these are often inter-related (Ecker 2012; Gross 2000). At the macro- (national, regional, global) and meso-levels (community), food security issues are mainly related to food availability and stability, whereas at the micro-level they are mainly related to food access and utilization by households and individuals (Ecker 2012; Gross 2000; Pinstrup-Andersen 2009). Food security in one level does not assure food security at another level (Gross 2000). For example, food might be available at the national level but not accessible for certain disadvantaged communities or districts, or among lower income or otherwise marginalized population groups. In Ghana, despite improvements in reducing poverty and increasing food production, there has been less progress in reducing undernutrition and disparities remain (FAO 2013; Hjelm 2013). There, poorer households and women-headed households tend to be more food insecure due to intake of diets with poor diversity compared with the wealthier or male-headed households (FAO 2013; Hjelm 2013). In Nepal, there is still widespread undernutrition despite the country producing sufficient food, and those living in rural areas are at higher risk of food insecurity and have a higher prevalence of undernutrition and of stunting in children as poor infrastructures and poverty limit their physical and economic access to food (FAO 2013; MOHP 2012). Furthermore, households might have access to food but this does not guarantee that all individuals in the household are able to access and utilize sufficient amounts of good quality, safe food. This is because the distribution of food within the household may be influenced by cultural beliefs, practices, attitudes, gender and age-specific roles and responsibilities, and decision-making hierarchies (Gittelsohn 2003; Pinstrup-Andersen 2009; Renzaho 2010).

In addition to the burden from undernutrition, LMICs also experience a high burden from overweight and obesity, with rates having increased considerably over the last couple of decades (Hossain 2007; Popkin 2012; Subramanian 2011). In an analysis of data from 54 low- and middle-income countries, 27% of women were overweight (Subramanian 2011). The prevalence of overweight in 2008 ranged from approximately 18% in low-income countries to 59% in upper middle-income countries, with a mean prevalence of 28% in the African region (WHO 2010). Among children younger than five years, the prevalence of overweight and obesity is also increasing (Black 2013), with 10% to 25% of children

being overweight in developing countries (Hossain 2007). These increased rates of overweight and obesity are associated with the nutrition transition, which is characterized by changing dietary patterns of diets increasingly consisting of more affordable processed foods, high intake of refined sugars and fats, and increased intake of food away from home; and decreased levels of physical activity (Popkin 2012). In LMICs the consumption of processed or junk foods and sugar-sweetened beverages has increased, with 54% of the global consumption of soft drinks occurring within the LMICs between 1997 and 2010 (Basu 2013). These dietary patterns are partly the result of high food prices, which cause consumers, particularly those in poorer households, to buy less expensive foods. These are often energy dense (higher in calories) and less nutritious (containing fewer nutrients per serving size). Consumption of these foods is therefore associated with increased risk of overweight, obesity, and micronutrient deficiencies. In this context, it is important to consider not only the quantity but also the quality of the food intake in any intervention.

Description of the intervention

The complexity of food security allows for a wide range of interventions addressing the different dimensions and at different levels of influence. In order to better conceptualise the framework for our review, in terms of defining the type(s) of intervention(s) to assess, the eligibility criteria for study selection, and the outcomes to be assessed, we conducted a scoping review of existing systematic reviews of interventions addressing food security in LMICs (more information about the methods is available on request).

We included 29 systematic reviews in the scoping review (references available on request). Most reviews addressed food availability (n = 14), mainly assessing food production interventions and food utilization (n = 13, including five which also addressed availability), specifically around issues of nutrition education for people to improve their dietary intake. Fewer reviews addressed food access (n = 7). The scoping review also revealed that the included reviews were unclear regarding the description of participants and settings, types of interventions and comparisons, or the outcomes they would assess (Table 1). The quality of reviews varied considerably, some with very low quality scores using the AMSTAR tool (Shea 2009).

Based on the findings of the scoping review, we decided to focus this Cochrane Review on community-level interventions that aim to improve access to nutritious food in LMICs; as we found that there are fewer reviews addressing food access compared to food availability or utilization. Furthermore, we know that in many areas of LMICs nutritious food is available at national level but physical distance and financial constraints prevent thousands of people from accessing the food (FAO 2013). As explained above, increased intake of ultra-processed food products and sugar-sweetened beverages has contributed to the rise in overweight and obe-

sity in LMICs and poor diet quality is also responsible for micronutrient deficiencies. Thus, interventions should aim to improve access to nutritious food. Nutritious foods can be defined as those that are nutrient dense, that is providing substantial amounts of vitamins and minerals (Pennington 2007). This includes fresh or minimally processed foods from the different food groups, such as whole grains, lean meats, dairy products, legumes, vegetables and fruits and excludes ultra-processed products and sugar-sweetened beverages that provide empty calories (Ministry of Health of Brazil 2014; Drewnowski 2005).

The interventions addressing food access include those aimed at infrastructure and transport, food prices, the social environment, coping strategies, and buying power. In our scoping review we did not find any systematic reviews addressing infrastructure and transport or coping strategies. We did find reviews addressing food prices, social environment, and buying power but these did not assess all relevant outcomes and not all were good quality reviews. Therefore, we will include all of these interventions addressing food access in this review.

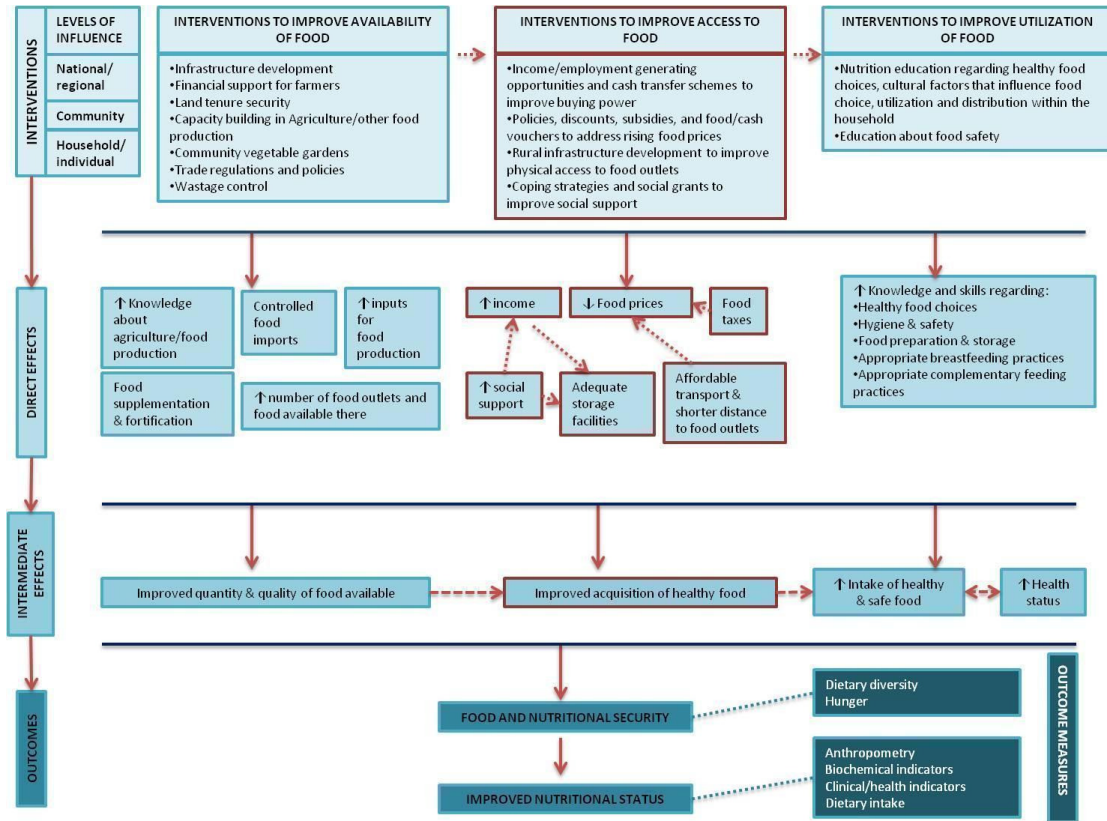
We chose to assess community-level interventions because for these types of interventions the community is the setting where the intervention is implemented and thus every community member can potentially benefit from it (McLeroy 2003). These types of interventions have been shown to be effective (Bhandari 2003; Mohammadifard 2009). This includes interventions that are city-wide or interventions that take place within community institutions, such as schools, neighbourhoods, churches, or work sites. The intervention may involve individuals, families, organizations, or public policy.

We will focus particularly on LMICs as they suffer the greatest burden from food insecurity and malnutrition and because another Cochrane review (Burns 2010) is addressing food security in developed countries.

How the intervention might work

Based on the literature cited in the above sections, and on guidance on how to use logic models in systematic reviews (Rohwer, unpublished), we developed a logic model that illustrates how interventions addressing food insecurity might work in improving the nutritional status of individuals (Figure 1). In this model we represent interventions that address food availability, access, and utilization. The interventions may operate at different level of influence, the macro-level (national, regional, global), meso-level (community), and micro-level (household and individual). As mentioned above, food security at one level does not assure food security at another level (Gross 2000). As our review will focus on chronic food insecurity, the logic model depicts interventions that address this and thus doesn't include interventions that address transient food insecurity.

Figure 1. Food security logic model - how interventions influence food and nutritional security.



Although this logic model encompasses three dimensions of food security, availability, access, and utilization, we will explain the section relevant to this review, that is how interventions addressing access to food may lead to food and nutrition security. As mentioned above, access to food concerns the ability of households (and communities) to acquire sufficient and appropriate foods to ensure a diet that is diverse, nutrient dense, and safe, and that satisfies the nutrient needs of its members (ACF 2009; WHO 2013). This logic model provides examples of interventions that address the determinants of food access. These include the creation of income or employment generating opportunities, coping strategies (for example borrowing money from a community fund, childcare), social grants, food price policies and regulations, rural infrastructure development, and food or cash vouchers. The direct effects of these interventions include increased financial resources in the household, reduced food prices, increased social support and assistance (for example from family, neighbours, or the government), having adequate facilities to store food, ensuring that there is affordable transport to food outlets as well as existence of food outlets closer to where people live (Ecker 2012; FAO 2012; Cotta 2013). Many of these factors influence each other. For example, having more

money may enable the household to buy a fridge to store fresh food; being able to borrow money increases the money available to buy food; or the existence of adequate road infrastructure may lead to decreased food prices. These direct effects all lead to a common intermediate effect, which is better ability of households to acquire healthy and nutritious food. The acquisition of healthy food is dependent on there being food available. Being able to acquire healthy food makes it easier for households to make healthy food choices, which in turn influences their intake of healthy and safe food. This represents the interaction across the different dimensions of food security. When the intermediate effects across all dimensions of food security are in place - that is when nutritious food is commonly available in sufficient quantities at fair prices - households are able to acquire healthy food, all individuals within the household can eat healthy food that meets their nutritional requirements as well as their preferences, and long-term outcomes of food and nutrition security, and thus of improved nutritional status of everyone in the household and in the community, are achievable.

One potentially harmful unintended consequence of interventions

that improve access to food is the increased risk of overweight or obesity (Ruel 2013; Cotta 2013). This may be due to increased intake of energy dense ultra-processed products and sugar-sweetened beverages (Lignani 2011). People may choose to acquire these foods because of lower cost, lack of knowledge about healthy diets, or other social, cultural, or individual preferences (Ruel 2013). Although we are assessing interventions addressing access to food, it is important to note that in order to have long-term food and nutrition security all three dimensions need to be in place: food needs to be available, people need to be able to access it, and they also need to know how to choose the correct foods, prepare them, and store them appropriately (Pinstrup-Andersen 2009; WHO 2013).

Why it is important to do this review

Many interventions are being implemented to address food insecurity globally, but given the lack of sufficient improvements in levels of undernutrition over time, particularly in LMICs as mentioned above, there is a need to assess the effectiveness of these interventions. Furthermore, our scoping review highlighted that existing reviews addressing access to food in LMICs were not of high methodological quality. We therefore aim to apply rigorous Cochrane review procedures to produce a high quality review to identify effective interventions addressing a dimension of food security. This will inform relevant stakeholders' decisions about which interventions to implement in order to achieve desirable results and to ensure that scarce resources are utilized efficiently. Furthermore, improving access to food will help to improve overall food security and the health and nutritional status of populations, which are requisites for the socioeconomic development of individuals and societies (FAO 2003).

OBJECTIVES

Primary objective

To determine the effects of community-level interventions that aim to improve access to nutritious food in LMICs, for both the whole community and for disadvantaged or at-risk individuals or groups within a community, such as infants and children, women, the elderly, the poor, the unemployed, or minority groups.

Secondary objectives

To determine the features of community-level interventions that enable or impede the effective implementation of these interventions to improve access to food.

To identify unintended consequences of interventions to improve access to food.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and cluster randomised controlled trials (cRCTs). We will also include non-randomised studies because: 1) we do not expect to find many RCTs that will answer our question, and 2) to increase the external validity of the review findings. We will include controlled before and after studies (CBAs), interrupted time series (ITS), and prospective analytical cohort studies. CBAs refer to studies in which observations are made before and after an intervention has been implemented in the intervention and control groups. ITS studies observe the effects of an intervention at multiple time points before and after an intervention. ITS studies need to have at least three time points both before and after the intervention in order to be included. Prospective cohort studies recruit participants into the intervention and control groups before an intervention is implemented and then follow them over a period of time after which outcomes are measured.

Types of participants

We will include all population groups living in communities in LMICs exposed to community-level interventions aiming to improve food access. For the purpose of this review, a community is defined as a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings (MacQueen 2001). We will include both adults and children living in those communities, as well as disadvantaged groups within those communities. LMICs are defined according to the World Bank (www.worldbank.org).

It is likely that most interventions addressing food insecurity will be implemented in areas and among populations at high risk for food insecurity, such as low-income areas, the unemployed, women and children. However, we will not restrict studies on the basis of social and demographic characteristics, and these characteristics will be reported in the review.

We will exclude studies which only included participants with specific diseases or conditions (for example severely malnourished children) as these types of participants require specialized approaches to address the malnutrition caused by these diseases or conditions.

Types of interventions

We will include community-level interventions that aim to improve access to food, as detailed in our logic model (Figure 1). Community-level interventions are those in which the community is the setting where the intervention is implemented, with

every member of that community potentially benefiting from it (McLeroy 2003). This includes interventions that are city-wide or interventions that take place within community institutions such as schools, neighbourhoods, churches, or work sites. The intervention may involve individuals, families, organizations, or public policy. Based on the literature in this field, and on the findings of our scoping review, we have decided to include the following interventions that address access to food:

- interventions that improve buying power (e.g. create income generating opportunities, cash transfer schemes);
- interventions addressing food prices (e.g. policies, discounts, vouchers, and subsidies);
- interventions addressing infrastructure and transport that affect physical access to food outlets;
- interventions addressing the social environment and social support (e.g. social support from family, neighbours, or government).

We will include studies in which these interventions, individually or in combination, were compared to no intervention or to other eligible interventions.

We have chosen this broad approach because we do not expect to find many eligible studies to include for each of the aforementioned intervention types.

As we anticipate variability in the duration of included interventions, we will include interventions of any duration.

Although we are interested in interventions that have measured access to *nutritious* food, we will not include this as an inclusion criterion. Instead, we will capture this information when extracting the details of included interventions.

We will exclude interventions that address transient food insecurity (for example food aid during natural disasters and wars) and that provide short-term relief from food insecurity (for example once-off food voucher, food banks, or soup kitchens).

Types of outcome measures

Given the complex nature of food security, outcomes will be assessed at different levels, namely at the community, household, and individual levels.

The findings of our scoping review showed that the types of outcomes measured across food security interventions vary considerably. For this reason, we will take a broad approach regarding the outcomes to include.

Given that our main interest is in determining whether these interventions improve access to food and, consequently, food security and nutritional status, only interventions that have measured outcomes related to food access or nutritional status, or that used a food security measurement tool, will be included in the review. We will include any study that has at least one of the outcomes listed below.

Primary outcomes

Since our main objective is to assess how effective these interventions are in improving access to food, our primary outcomes will be those that measure access to food at the household and community level. Following from our logic model, these will include the following (FAO 2013; Smith 2006).

At the household and community level:

- prevalence of undernourishment (i.e. proportion of people with insufficient food intake to meet dietary requirements);
- proportion of household expenditure on food (as proportion of household income or of total household expenditure);
- proportion of households who are food secure (e.g. according to dietary diversity and hunger measures), as measured in the included study.

Secondary outcomes

Secondary outcomes will be those that reflect not only access to food but also food availability and utilization. Thus they reflect nutritional status, which is the ultimate goal of food security interventions at the individual level. Following from our logic model, these will include the following.

At the individual level:

- change in adequacy of dietary intake (e.g. food or energy intake and whether it meets energy and nutrient requirements);
- change in anthropometric indicators (e.g. stunting, wasting, and underweight in children, according to height, weight, height-for-age, weight-for-height, and weight-for-age Z-scores, respectively; underweight and overweight in adults according to body mass index (BMI) classifications);
- change in biochemical indicators (e.g. micronutrient levels in the blood);
- cognitive function and development during the intervention period (e.g. Denver Developmental Screening Test, Bayley Scales of Infant Development);
- change in proportion of anxiety or depression (as described by the included study's authors);
- morbidity (as described by the review authors);
- adverse outcomes (e.g. proportion overweight or obese as a potentially harmful consequence of these type of interventions).

We will only include outcomes that were measured at least three months after the intervention was implemented as we feel that outcomes measured earlier do not reflect sustainable changes.

Search methods for identification of studies

Electronic searches

We will search electronic databases from 1980 onwards for relevant studies. We chose the year 1980 as the starting point because it was around this time that the term 'food security', encompassing access to food, started being used (Masset 2011). When nearing completion of our review, we will update the search and include any further eligible studies to ensure the findings reflect studies published at least six months prior to the review's publication date. There will be no language or publication status limits. The following electronic databases will be searched:

- Cochrane Public Health Group Specialized Register;
- Cochrane Central Register of Controlled Trials (CENTRAL);
- MEDLINE (via PubMed);
- EMBASE;
- CINAHL (via EBSCOhost);
- Trials Register of Promoting Health Interventions (TRoPHI);
- PsycINFO;
- Sociological Abstracts;
- Web of Science databases: Conference Proceedings Citation Index, Science Citation Index Expanded, and Social Science Citation Index;
- IBSS;
- Food Science and Technology Abstracts;
- Greenfile;
- Agricola;
- WHO GINA;
- British Library for Development Studies (BLDS);
- WHO's Global Health Library, which includes LILACS, PAHO and African Index Medicus (AIM);
- Indian Citation Index (ICI);
- AfricaBib databases, specifically the *Africana Periodical Literature* and *African Women* databases;
- African Journals Online (AJOL);
- Bangladesh Journals Online (BanglaJOL);
- CAB Abstracts and Global Health via CAB Direct;
- Bioline International;
- Jolis Library catalogue.

A combination of text words and controlled vocabulary terms related to the interventions and possible outcome measures will be used to develop a sensitive search strategy. An example of the MEDLINE search strategy for PubMed is in [Appendix 1](#), which is an adaptation of the search strategy for the Cochrane review assessing interventions to improve food security in developed countries (Burns 2010). We will apply a study design filter to the search that has been developed by Joy Oliver, the information specialist on our team. The final search strategy will be modified for the other databases and reported as appendices in our full review. We will recruit an information specialist to advise on and implement the search strategy.

We will also search the top five journals in which the included studies are most frequently published in.

Some of the electronic databases specified above index a combination of published and unpublished studies, such as doctoral dissertations and conference abstracts. Therefore the electronic searches will capture some of the unpublished studies. For further searching for unpublished studies see '[Searching other resources](#)' below. We will contact the authors of included studies and undertake citation tracking of these studies.

Searching other resources

We will search the reference lists of the included studies for other relevant studies. We will also handsearch key journals not indexed in the electronic databases, as determined by experts in the field. If any systematic reviews are identified, we will handsearch their reference lists for relevant studies to include.

We will search for unpublished studies in the grey literature database OpenSIGLE and on websites of relevant organizations, such as AGRIS (Food and Agriculture Organization), World Health Organization (WHO), Eldis, International Food Policy Research Institute (IFPRI), World Bank, Global Alliance for Improved Nutrition (GAIN), and Science Development Net.

We will also search for ongoing and unpublished studies in databases such as [clinicaltrials.gov](#) and WHO's International Clinical Trials Registry Platform (ICTRP).

We will contact experts working in various areas related to food security for studies that are relevant to include.

Data collection and analysis

Selection of studies

Given the many interventions that address access to food and the various sources we will be searching, we expect to retrieve a large number of results. Therefore, one author (SD) will conduct an initial screening to exclude titles that are obviously irrelevant. Two authors (SD and AS, VR, or JO) will independently screen the remaining titles and abstracts to determine eligibility against the inclusion criteria. Full-text copies of eligible titles and of those for which eligibility is unclear will be retrieved for closer examination. Any disagreements regarding eligibility will be resolved through discussion or through an arbitrator (EK), if necessary. We will keep a record of the reasons for excluding studies, after we have preliminarily selected full-text articles. Sufficient information about inclusion decisions will be documented in order to complete a PRISMA flow chart and a table 'Characteristics of excluded studies'. In this table, we will report studies that apparently met inclusion criteria but in the end were not eligible.

If we find any relevant studies in a language other than English, Portuguese, or Spanish, we will contact the Cochrane Public Health Review Group for options for translations.

We will use EndNote software to manage the retrieved records and for removing duplicate reports of the same study. The study will be the unit and all references related to the same study will be grouped together.

Data extraction and management

Two authors (SD and AS, VR, or JO) will extract data independently on a standardized data collection form using [Microsoft Excel 2007](#). A third author (EK) will arbitrate any disagreements. Our data extraction form will be based on the forms from the Cochrane Public Health Review Group, modified to suit our review. We will pilot the data extraction form on five included studies of different types of interventions to ensure information is captured in a standard manner. We will extract the following data.

- Study design and methods (recruitment of participants, representativeness of sample, number of intervention groups, randomisation procedure, statistical methods).
- Details about the participants, including PROGRESS-Plus characteristics and number in each group at baseline and at the endpoint. PROGRESS-Plus characteristics refer to characteristics of participants that can be used to identify disadvantaged groups and that allow us to differentiate the effects of the intervention across social categories ([Tugwell 2010](#)). These characteristics include: place of residence, race or ethnicity, occupation, gender, religion, education, socioeconomic status, and social capital; and Plus characteristics include age, sexual orientation, and disability. We will extract details about withdrawals and dropouts, if these are available.
- Details about the intervention, including process measures (e.g. aims; social and cultural context; comparison interventions; length of the intervention; duration of follow-up; implementation factors such as amount of conditional cash transfers, number of times transport is given, or total amount of food vouchers given to each individual), and whether the intervention is universal or targeted. Extracting these will provide insight on the factors that impede or facilitate implementation of the intervention, which addresses the second objective of this review. We will also extract information on whether the intervention aimed to improve access to nutritious food, how nutrition food was defined, and if specific nutritious foods were targeted for increased access in these interventions, and what types of food were accessed by participants.
- Description of outcomes used to measure effectiveness and how they were measured.
 - Primary outcomes at the household and community level.
 - Secondary outcomes at the individual level.
 - Other process measures including intervention cost and sustainability.
 - Source of study funding and sponsorship of the interventions.

We will incorporate the Cochrane-Campbell Methods Group Eq-

uity Checklist (<http://equity.cochrane.org/sites/equity.cochrane.org/files/uploads/equitychecklist2011.pdf>) into our data extraction form.

Information on potential confounders or moderators of the study outcomes will be extracted. These include sociodemographic variables such as gender, ethnicity or race, and place of residence, and other PROGRESS-Plus characteristics based on the details available in the studies.

We expect that outcomes will be measured in the included studies using a variety of tools (for example many tools exist to measure hunger). In these cases we will report the results separately according to the outcome measure used. If outcomes are measured at multiple time points, we will extract all these measures.

If necessary, we will contact the authors of primary studies to clarify issues or find out about any missing information.

We will use [RevMan 2012](#) for data management and analysis.

Assessment of risk of bias in included studies

Two authors will conduct the risk of bias assessment and a third author (EK) will arbitrate any disagreements.

For RCTs we will use the Cochrane risk of bias tool ([Higgins 2011](#)). For non-randomised controlled trials and CBAs we will use the Effective Practice and Organization of Care (EPOC) risk of bias tool for studies with a separate control group. This tool assesses the risk of bias from inappropriate methods in the following domains: allocation sequence generation, allocation sequence concealment, similarity of baseline outcome measurements, similarity of baseline characteristics, incomplete outcome data, blinding of participants and personnel, blinding of outcome assessors, selective outcome reporting, and whether the study was protected against contamination. We will assess the risk of bias from lack of blinding of participants and personnel, and of outcome assessors, separately. We will assess the risk of bias from lack of blinding separately for objective and subjective outcomes. Risk of bias from incomplete outcome data will also be assessed separately for different outcomes.

For ITS studies we will use the EPOC risk of bias tool for ITS study designs. This tool considers protection against secular changes, protection against detection bias, reliability of outcome measures, co-intervention, and completeness of the data set.

For each item, a judgement of 'High risk', 'Unclear risk', or 'Low risk' will be made, with supportive information to justify these judgements provided in the risk of bias tables.

We will incorporate the risk of bias assessment in the interpretation of our findings, and we will not restrict analysis by degree of risk of bias.

We will present the risk of bias assessment through the risk of bias table included in the 'Characteristics of included studies' table. A risk of bias graph and a summary figure will also be presented. For blinding and incomplete outcome assessment, the risk of bias will be presented separately for each primary outcome in these figures.

Measures of treatment effect

Where data allow, we will conduct meta-analysis using Review Manager 5 (RevMan 2012).

For binary outcomes we will report the relative risk (RR) of outcomes in the intervention group compared to the control group. For continuous outcomes, and where baseline data are available, we will report the mean difference (MD) between the change in the intervention and control groups if the outcomes have been measured in the same way by all studies. If the same continuous outcomes have been measured in different ways by different studies, we will use the standardized mean difference (SMD) between the intervention and control groups. Where the change per group is not available, we will use end-values where randomisation was successful. If there is a reasonable risk of selection bias, and the change per group is not available, the study will not be included in a meta-analysis.

For ITS studies, specifically, we will calculate the relative and absolute differences in means in the before and after values.

We will report 95% confidence intervals (CIs) alongside all effect estimates.

Unit of analysis issues

Cluster RCTs (cRCTs) that randomise groups rather than individuals to intervention groups and that report analysis at the individual level need to also report the method used to account for clustering. If this is unclear we will contact the study investigator for further information. If they have not taken the clustering effect into account in their analyses, we will request individual participant data, calculate an intraclass correlation coefficient (ICC), and re-analyse the data appropriately. If we are not able to obtain primary data, we will attempt to find an appropriate ICC from the literature and adjust the sample size accordingly. We will meta-analyse the correct effect estimates and standard errors from cRCTs using generic inverse-variance methods in RevMan 2012. We will consult a statistician to help confirm that the investigators have correctly accounted for the clustering effect, and to help with the re-analysis of individual participant data in the case where that was not done. If we re-analyse the data, we will clearly mark the results as re-analysed. We will also state where re-analysis was not possible.

In cases where the outcomes were measured on the participants at multiple time points, we will group outcomes measured at similar time points. Taking into account that the minimum duration after implementation at which we will extract outcomes is three months, the short-term time point will be three to six months.

For interventions with multiple comparison groups, all groups that meet the inclusion criteria for the review will be included in the review and meta-analyses. If there are more than two relevant comparison groups we will attempt to combine the relevant experimental and control groups to make a single pair wise comparison. If this is not possible, we will make multiple pair wise compar-

isons between the relevant groups and divide the sample size of the shared intervention group evenly across the comparisons to avoid double counting of participants.

Dealing with missing data

If there are unclear or missing data related to study methodology, participants lost to follow-up, outcome data, or statistics, we will contact the study's primary author via email.

We will record all missing outcome data in the data extraction form and in the risk of bias table. If it is not possible to obtain missing outcome information after attempting to do so, we will exclude these studies from the meta-analysis.

Assessment of heterogeneity

We will assess heterogeneity, or the variability among the studies included in a meta-analysis, by visual inspection of overlap of confidence intervals, and by assessing statistical heterogeneity with the Chi² statistic ($P < 0.1$) (Deeks 2011). We will also calculate the I² statistic to quantify heterogeneity; an I² of 75% and above indicates substantial heterogeneity.

Assessment of reporting biases

For each outcome with 10 or more included studies in a meta-analysis, we will assess the likelihood of reporting bias through funnel plots (Sterne 2011). We will assess the funnel plots visually for sources of asymmetry, such as because of small-study effects, publication bias, or other. If it is likely that asymmetry is caused by small-study effects, we will conduct sensitivity analysis to explore how this affects the results and conclusions of the meta-analysis.

Data synthesis

We will conduct meta-analyses in RevMan 2012 if the included studies are sufficiently homogeneous (I² statistic < 75%) and if there is a minimum of two studies for any type of intervention being compared. If there is considerable heterogeneity (I² > 75%) we will only synthesize the results narratively. If we are unable to use RevMan we will use STATA software for data analysis, and we will consult a statistician for help with this process.

Meta-analyses will be carried out separately for each outcome and type of study design. We will use the random-effects model for all analyses, to incorporate any existing heterogeneity. We will generate a forest plot for each comparison.

We will carry out a narrative synthesis of the results, grouping our findings by the type of intervention, study population (for example adults, children, pregnant women), context (for example poor communities, schools), and outcome measured. We will also assess and discuss the implementation factors common to effective interventions, for which type of participants and in which context,

if this information is reported in included studies or in published process evaluations that are mentioned in the study report. We will include a summary of findings table for the primary outcomes of this review. It will include the number of participants and studies for each outcome, a summary of the intervention effect, and a measure of the quality of evidence for each outcome according to GRADE considerations. GRADE is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of rating quality of evidence and grading the strength of recommendations in systematic reviews, health technology assessments (HTAs), and clinical practice guidelines addressing alternative management options (Guyatt 2010). Using GRADE, the quality of the evidence is based on five items: study limitations, consistency of effect, imprecision, indirectness, and publication bias.

Subgroup analysis and investigation of heterogeneity

If data allow, we will conduct subgroup analysis to assess effectiveness for people at different levels of disadvantage. We will include the following subgroups.

- Geographic location (e.g. urban versus rural, country or region).
- Sex (male versus female).
- Age (e.g. elderly, adults, children, infants).
- Baseline nutritional status (e.g. underweight, overweight, micronutrient deficiencies).

We will also assess important implementation factors, including the following.

- Intensity of intervention (high intensity versus low intensity, e.g. in relation to amount of food vouchers or of conditional cash transfers).
- Length of study and of follow-up (e.g. 3 to 6 months, > 6 to < 2 years, and 2 years and beyond).

- Whether the intervention specifically aimed to improve access to nutritious food.

These analyses will also allow us to explore heterogeneity. In order to compare the different subgroups with each other, we will conduct a standard heterogeneity test in RevMan 2012 across the subgroup results, that is by calculating the I^2 statistic. We will make sure that the subgroup data being compared are independent.

Sensitivity analysis

If possible, we will perform sensitivity analyses in order to assess the influence of study size and study design on the findings. We will also explore the impact of components of the quality assessment of included studies (for example blinding, randomisation, etc) and the impact of studies at high risk of bias on the results of the meta-analyses.

ACKNOWLEDGEMENTS

We would like to acknowledge Dr Tamara Kredo and Professor Jimmy Volmink of the South African Cochrane Centre for their contributions to the development of this protocol. We would also like to thank Professor Paul Garner of the Liverpool School of Tropical Medicine, who is supported by the Effective Health Care Research Consortium, which is funded by UKaid from the UK Government Department for International Development, for his comments and suggestions on this protocol.

We would like to acknowledge Ms Anke Rohwer and Dr Eva Rehfues for sharing their draft guidance document on the use of logic models in systematic reviews and health technology assessments of complex interventions (Rohwer, unpublished).

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* Indicates the major publication for the study

ADDITIONAL TABLES

Table 1. Summary of PICOS and of AMSTAR scores of included systematic reviews, and how existing reviews informed the PICOS of a new Cochrane Review

Domain	Finding	How it informed our review question or methods
<i>Setting</i>	<ul style="list-style-type: none"> · 12 reviews did not specify the setting · 11 reviews stated the community as the setting · 3 reviews said the setting was LMICs · 3 reviews specified a school as the setting 	We chose the community as the setting, defined as a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings (MacQueen 2001).
<i>Participants</i>	<ul style="list-style-type: none"> · 5 reviews did not specify the types of participants for inclusion · 11 reviews included infants and children (up to school-going aged children) · 1 review included adults and adolescents · 6 reviews included pregnant women or mothers in the immediate post-partum period. One of these also targeted other adults that could be linked to women who may breastfeed. Many of these were assessing interventions on breastfeeding or complementary feeding · 1 review included only parents of children aged 2 to 5 years, as it assessed influence of parenting practices on children's dietary habits · 2 reviews included all people living in a community · 3 reviews included only poor people that were recipients of some service, such as for example recipients of a government conditional cash-transfer program 	As existing reviews specifically addressed specific high risk groups, we will not focus on these. Instead we will include all individuals across all ages that belong to the community where relevant interventions have been implemented
<i>Intervention</i> (including its duration)	<ul style="list-style-type: none"> · 14 reviews addressed interventions related to the availability of food, 5 of which also assessed interventions influencing utilization of food, such as nutrition education · 13 reviews assessed interventions addressing food utilization · 7 reviews assessed interventions addressing access to food (2 of which had a low AMSTAR score of 4) <p>28 reviews did not specify the duration of the intervention, and only one included interventions with a minimum duration of three months. As a result, the duration and the follow-up times of the interventions varied considerably within and across reviews</p>	Of the 14 reviews that addressed food availability, 5 also assessed food utilization (e.g. combination of community gardens and nutrition education). As fewer reviews addressed food access, we will include interventions that have addressed this dimension of food security. We will include interventions with any duration but will extract outcomes which were measured at least 3 months after implementation

Table 1. Summary of PICOS and of AMSTAR scores of included systematic reviews, and how existing reviews informed the PICOS of a new Cochrane Review (Continued)

<i>Control</i>	<ul style="list-style-type: none"> · 18 reviews did not specify a control group · 6 reviews compared the intervention with either no intervention, an alternative intervention, or placebo · 3 reviews did not have any control group · 2 reviews stated that included studies needed to have a control group, but did not specify further 	We will include studies in which these interventions, individually or in combination, were compared to no intervention or to other eligible intervention
<i>Outcomes assessed</i>	<p>The specific outcomes assessed across the included reviews varied considerably and often they were not clearly specified at the outset</p> <p>The most common and important outcomes reported in these reviews were related to dietary intake, anthropometric measurements, and biochemical and clinical indicators, to describe the impact of the intervention on nutritional status. Other outcomes measured include food purchase or expenditure, food production, morbidity and mortality, and breastfeeding initiation rates or duration</p> <p>Often, reviews measured the same outcome in different ways. For example, anthropometric indicators assessed differed, as did their classifications, across the included reviews. This makes it difficult to compare results across reviews and to reach a conclusion about the effectiveness of a specific intervention</p>	The most commonly specified outcomes measured food and nutrition security, and nutritional status. We will also focus on these outcomes. Examples include: diet diversity scores and hunger measures; and anthropometric, biochemical and dietary intake indicators. We will clearly define, a priori, the specific outcome measures and metrics which we will include in our review
<i>Study designs</i>	<ul style="list-style-type: none"> · 11 reviews did not specify which study designs they would include · 3 reviews included only RCTs* · 1 review included only CCTs** · 1 review included only impact evaluations · 13 reviews included a variety of study designs, which included two or more of the following: RCTs, BAS[‡], quasi-RCTs, Analytical cohort studies, ITS^α, CCTs, randomised field trials, and CSS^β <p>However, the definitions of the study design labels used were not always clear and varied across the included reviews</p>	<p>The study design labels used varied across included reviews and were not always clearly defined</p> <p>We will include both randomised and non-randomised studies, as we expect that existing RCTs in the area of food security are scarce. We want to include the best <i>available</i> evidence for our review question. We will clearly define the type of study designs to be included in our review</p>
<i>Search strategies</i>	<p>Most reviews ran comprehensive searches. They used a comprehensive set of keywords and searched a variety of relevant databases. Only 5 reviews did not indicate search terms either in the text or in an appendix</p> <ul style="list-style-type: none"> · 2 reviews conducted searches until 2012 	Our review will include updated searches across a variety of relevant databases and web sites. We will draw on common keywords used across these included reviews

Table 1. Summary of PICOS and of AMSTAR scores of included systematic reviews, and how existing reviews informed the PICOS of a new Cochrane Review (Continued)

	<ul style="list-style-type: none"> · 11 reviews searched until 2010 to 2011 · 9 reviews searched before 2010 · 7 reviews did not specify the date of the last search 	
<i>Reporting</i>	The methods sections of most reviews were often not reported clearly. The reporting of results in these reviews, in terms of characteristics of included studies, was also poor	Poor reporting of the characteristics of included studies makes it difficult to assess the context in which these results were obtained. Thus, it is difficult to generalize the results We will clearly report on the characteristics of included studies, so that the context in which the interventions have been implemented is clearly understood
<i>AMSTAR scores</i>	<ul style="list-style-type: none"> - 9 reviews were of low quality (AMSTAR score: 0 to 4) - 11 reviews were of moderate quality (AMSTAR score: 5 to 8) - 8 reviews were of high quality (AMSTAR score: 9 to 11) - 1 review did not have a score as it didn't include any studies 	Of the 8 high quality reviews, 5 assessed interventions that aimed to improve food availability and/or utilization, and 3 assessed interventions addressing food access. The other two included reviews that addressed food access were of low quality (AMSTAR = 4) We will contribute to the evidence base on interventions addressing food access by producing a high quality systematic review that assesses the effectiveness of the interventions on relevant outcomes, such as nutritional status

*RCT: randomised clinical trial; **CCT: controlled clinical trial; [‡]BAS: before-and-after study; ^αITS: interrupted time series; ^βCSS : cross – sectional study

APPENDICES

Appendix I. MEDLINE search strategy (PubMed)

Search	Query (08 July 2014)	Items found
Food security outcome and intervention terms		
#1	food secur*[tiab] OR food insecur*[tiab] OR food poverty[tiab] OR food sufficien*[tiab] OR food insufficien*[tiab] OR food desert*[tiab]	2982

(Continued)

#2	(foodstuff[tiab] or foodstuffs[tiab] or fruit[tiab] OR fruits[tiab] OR vegetable[tiab] OR vegetables[tiab] OR groceries[tiab]) AND (environment[tiab] or environmental[tiab])	4930
#3	(food[tiab] or foods[tiab]) AND (budget*[tiab] OR shopping[tiab] OR purchase[tiab] OR purchasing[tiab] OR buy[tiab] OR buying[tiab] OR acquisition[tiab] OR acquire[tiab])	6089
#4	(foodstuff*[tiab] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or groceries[tiab] or supermarket[tiab] or supermarkets[tiab] or grocery store[tiab] or grocery stores[tiab] or food store[tiab] or food stores[tiab] or food shop[tiab] or food shops[tiab] or corner store[tiab] or corner stores[tiab] or cafeteria[tiab] or cafeterias[tiab] or canteen*[tiab] or food outlet*[tiab]) AND (access[tiab] or accessibility[tiab])	1307
#5	(foodstuff*[tiab] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or groceries[tiab] or supermarket[tiab] or supermarkets[tiab] or grocery store[tiab] or grocery stores[tiab] or food store[tiab] or food stores[tiab] or food shop[tiab] or food shops[tiab] or corner store[tiab] or corner stores[tiab] or cafeteria[tiab] or cafeterias[tiab] or canteen*[tiab] or food outlet*[tiab]) AND (cost[tiab] or costs[tiab] or price[tiab] or prices[tiab])	2283
#6	(food[ti] foodstuff*[tiab] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or groceries[tiab]) AND (purchase[tiab] or purchases[tiab] or purchasing[tiab] or expenditure[tiab] or expenditures[tiab] or spend[tiab] or spent[tiab] or spending[tiab])	1027
#7	(foodstuff*[tiab] or food[ti] or foods[ti]) AND (environment[tiab] or environmental[tiab] or access[tiab] or accessibility[tiab] or cost[tiab] or costs[tiab] or price[tiab] or prices[tiab] or pricing[tiab] or purchase[tiab] or purchases[tiab] or purchasing[tiab] or expenditure[tiab] or expenditures[tiab] or spend[tiab] or spent[tiab] or spending[tiab]) AND (fresh[tiab] or health[tiab] or healthy[tiab] or nutritional[tiab] or nutritive[tiab] or nutrient dense[tiab] or nutrient-dense[tiab] or nutrient rich[tiab] or nutrient-rich[tiab] or adequate[tiab] or quality[tiab])	3919
#8	(food system*[tiab] AND (fresh[tiab] or health[tiab] or healthy[tiab] or nutrition[tiab] or nutritional[tiab] or nutritive[tiab] or nutrient rich[tiab] or nutrient dense[tiab] or	452

(Continued)

	adequate[tiab] or quality[tiab] or sufficient[tiab] or insufficient[tiab] or secure[tiab] or insecure[tiab] or safe[tiab])	
#9	(policy[tiab] or policies[tiab]) AND (food[ti] or foods[ti] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or nutrition[tiab] or groceries[tiab] or meal[tiab] or meals[tiab])	5265
#10	(council[tiab] or councils[tiab] or coalition[tiab] or coalitions[tiab] or co-op[tiab] or co-ops[tiab] or co-operative*[tiab]) AND (food[ti] or foods[ti] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or nutrition[tiab] or groceries[tiab])	827
#11	(deliver[tiab] or delivery[tiab] or deliveries[tiab] or transport[tiab] or transportation[tiab] or distribute[tiab] or distributes[tiab] or distribution[tiab]) AND (groceries[tiab] or meal[tiab] or meals[tiab] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or food[ti] or foods[ti]) AND (outreach[tiab] or service[tiab] or services[tiab] or scheme[tiab] or schemes[tiab] or program[tiab] or programs[tiab] or programme[tiab] or programmes[tiab] or policy[tiab] or policies[tiab] or project[tiab] or projects[tiab] or nutrition[tiab] or nutritional[tiab] or home*[tiab] or community[tiab] or communities[tiab] or neighbor[tiab] or neighborhood[tiab] or neighbour[tiab] or neighbourhood[tiab] or rural[tiab] or urban[tiab] or provide[tiab] or provision[tiab] or choice[tiab] or control[tiab])	3879
#12	(public transport[tiab] or transport service*[tiab] or transportation service*[tiab] or transport scheme[tiab] or transportation scheme[tiab] or travel[tiab] or travelling[tiab] or infrastructure[tiab] or access[tiab]) AND (food store*[tiab] or food shop*[tiab] or food retail*[tiab] or food outlet[tiab] or supermarket[tiab] or grocer*[tiab])	360
#13	(payment[tiab] or payments[tiab] or benefit[tiab] or benefits[tiab] or money[tiab] or purchase[tiab] or purchasing[tiab] or purchases[tiab] or buy[tiab] or buying[tiab] or welfare[tiab] or financing[tiab] or cash[tiab] or income[tiab]) AND (food[ti] or foods[ti] or foodstuff*[tiab] or groceries[tiab] or fruit[tiab] or fruits[tiab] or vegetable[tiab] or vegetables[tiab] or nutrition[tiab] or nutritional[tiab] or meal[tiab] or meals[tiab]) AND (supplement[tiab] or supplementation[tiab] or assist[tiab] or assistance[tiab] or extra[tiab] or aid[tiab] or support[tiab] or help[tiab])	5891

(Continued)

#14	(tax[tiab] OR taxes[tiab] OR taxation[tiab] OR subsid*[tiab] OR voucher*[tiab] OR coupon*[tiab] or discounts[tiab]) AND (food[ti] OR foods[ti] OR foodstuffs[tiab] OR groceries[tiab] OR fruit*[tiab] OR vegetable*[tiab] OR nutrition[tiab] OR nutritional[tiab] OR meal*[tiab])	812
#15	Cash transfer*[tiab] OR social protection[tiab]	594
#16	(community nutrition[tiab] or public health nutrition[tiab]) AND (project*[tiab] or program*[tiab])	193
#17	(diet[mh] or food[mh] or cookery[mh]) AND (health promotion[mh] or health policy[mh] or public health[mh]) AND (poverty[mh] or social class[mh] or socioeconomic factors[mh] or social welfare[mh])	10433
#18	Search (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17)	41594
Low-and-middle-income countries filter		
#19	Afghan*[Ti] or Bangladesh*[Ti] or Benin*[Ti] or Burkina Faso[Ti] or Burkinabé[Ti] or Burundi*[Ti] or Cambodia*[Ti] or Central African Republic[Ti] or Central African*[Ti] or Chad*[Ti] or Comoros[Ti] or Comorian*[Ti] or Congo*[Ti] or Eritrea*[Ti] or Ethiopia*[Ti] or Gambia*[Ti] or Ghana*[Ti] or Guinea-Bissau*[Ti] or Haiti*[Ti] or Kenya*[Ti] or Kyrgyz Republic[Ti] or Kyrgyzstani[Ti] or Lao*[Ti] or Liberia*[Ti] or Madagascar[Ti] or Malagasy[Ti] or Malawi*[Ti] or Mali*[Ti] or Mauritania*[Ti] or Mozambique[Ti] or Mozambican[Ti] or Myanmar*[Ti] or Burma[Ti] or Burmese[Ti] or Nepal*[Ti] or Niger*[Ti] or Rwanda*[Ti] or Sierra Leone*[Ti] or Solomon Islands[Ti] or Solomon Islanders[Ti] or Somali*[Ti] or Tajikistan*[Ti] or Tanzania*[Ti] or Togo*[Ti] or Uganda*[Ti] or Zambia*[Ti] or Zimbabwe*[Ti]	221787
#20	Angola*[Ti] or Armenia*[Ti] or Belize*[Ti] or Bhutan*[Ti] or Bolivia*[Ti] or Cameroon*[Ti] or Cape Verd*[Ti] or China[Ti] or Chinese[Ti] or Cote d'Ivoire[Ti] or Ivorian[Ti] or Djibouti[Ti] or Ecuador*[Ti] or Egypt*[Ti] or El Salvador[Ti] or Salvadoran[Ti] or Guatemala*[Ti] or Guyana[Ti] or Guyanese[Ti] or Hondura*[Ti] or India*[Ti] or Indonesia*[Ti] or Iraq*[Ti] or Jordan*[Ti] or Kiribati[Ti] or I-Kiribati[Ti] or Kosov*[Ti] or Lesotho[Ti] or Mosotho[Ti] or Basotho[Ti] or Maldiv*[Ti] or Marshall Islands[Ti] or Marshallese[Ti] or Micronesia*[Ti] or Moldova*[Ti] or Mongolia*[Ti] or Morocc*[Ti] or Nicaragua*[Ti] or Nigeria*[Ti] or Pakistan*[Ti] or Papua	249004

(Continued)

	New Guinea*[Ti] or Paraguay*[Ti] or Philippines[Ti] or Filipino[Ti] or Samoa*[Ti] or Senegal*[Ti] or Sri Lanka*[Ti] or Sudan*[Ti] or Swaziland[Ti] or Swazi[Ti] or Syrian Arab Republic[Ti] or Syria*[Ti] or Thailand[Ti] or Thai[Ti] or Timor-Leste[Ti] or East Timorese[Ti] or Tonga*[Ti] or Tunisia*[Ti] or Turkmen*[Ti] or Tuvalu*[Ti] or Ukrain*[Ti] or Uzbekistan*[Ti] or Uzbek[Ti] or Vanuatu[Ti] or Ni-Vanuatu[Ti] or Vietnam*[Ti] or West Bank[Ti] or Gaza[Ti] or Palestinian*[Ti] or Yemen*[Ti]	
#21	Albania*[Ti] or Algeria*[Ti] or American Samoa[Ti] or Antigua*[Ti] or Barbuda*[Ti] or Argentin*[Ti] or Azerbaijan*[Ti] or Belarus*[Ti] or Bosnia*[Ti] or Herzegovin*[Ti] or Botswana[Ti] or Motswana[Ti] or Batswana[Ti] or Brazil*[Ti] or Bulgaria*[Ti] or Chile*[Ti] or Colombia*[Ti] or Costa Rica*[Ti] or Cuba*[Ti] or Dominica*[Ti] or Dominican Republic[Ti] or Fiji*[Ti] or Gabon*[Ti] or Grenad*[Ti] or Iran*[Ti] or Jamaica*[Ti] or Kazakhstan*[Ti] or Leban*[Ti] or Libya*[Ti] or Lithuania*[Ti] or Macedonia*[Ti] or Malaysia*[Ti] or Mauriti*[Ti] or Mayotte[Ti] or Mahoran[Ti] or Mexic*[Ti] or Montenegr*[Ti] or Namibia*[Ti] or Palau*[Ti] or Panama*[Ti] or Peru*[Ti] or Romania*[Ti] or Russia*[Ti] or Serbia*[Ti] or Seychell*[Ti] or South Africa*[Ti] or St Lucia*[Ti] or Suriname*[Ti] or Turk*[Ti] or Uruguay*[Ti] or Venezuela*[Ti]	176019
#22	Developing Countries[mh]	61531
#23	America*[Ti] or Andorra[Ti] or Aruba[Ti] or Australia[Ti] or Austria[Ti] or Bahamas[Ti] or Bahrain[Ti] or Barbados[Ti] or Belgium[Ti] or Bermuda[Ti] or Brunei[Ti] Darusalam[Ti] or Canada[Ti] or Cayman Islands[Ti] or Channel Islands[Ti] or Croatia[Ti] or Cyprus[Ti] or Czech Republic[Ti] or Denmark[Ti] or Estonia[Ti] or Equatorial Guinea[Ti] or Faeroe Islands[Ti] or Finland[Ti] or France[Ti] or French Polynesia[Ti] or Germany[Ti] or Gibraltar[Ti] or Greece[Ti] or Greenland[Ti] or Guam[Ti] or Hong Kong[Ti] or Hungary[Ti] or Iceland[Ti] or Ireland[Ti] or Isle of Man[Ti] or Israel[Ti] or Italy[Ti] or Japan[Ti] or Kuwait[Ti] or Latvia[Ti] or Liechtenstein[Ti] or Luxembourg[Ti] or Macao[Ti] or Malta[Ti] or Monaco[Ti] or Netherlands[Ti] or New Caledonia[Ti] or New Zealand[Ti] or Northern Mariana Islands[Ti] or Norway[Ti] or Oman[Ti] or Poland[Ti] or Portugal[Ti] or Puerto Rico[Ti] or Qatar[Ti] or San Marino[Ti] or Saudi Arabia[Ti] or Singapore[Ti] or Slovak*[Ti] or Slovenia[Ti] or Spain[Ti] or Sweden[Ti] or Switzerland[Ti] or Trinidad[Ti] or Tobago[Ti] or United Arab Emirates[Ti] or United Kingdom[Ti] or United States[Ti] or Virgin Islands[Ti]	275525

(Continued)

#24	Developed Countries[mh]	30346
#25	Search (#19 or #20 or #21 or #22) [ALL DEVELOPING Countries]	669583
#26	Search (#23 or #24) [ALL DEVELOPED Countries]	302715
#27	Search (#26 NOT #25) [DEVELOPED NOT DEVELOPING]	287102
#28	Search (#18 NOT #27) [INTERV NOT PREVIOUS]	39737
Human filter		
#29	animals[mh] not humans[mh]	3903434
#30	#28 NOT #29	34977
Study design filter		
#31	randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR comparative study[pt] OR control groups[mh] OR control group*[tiab] OR follow-up studies[mh] OR follow-up stud*[tiab] OR follow-up assessment[tiab] OR prospective studies[mh] OR prospective*[tiab] OR non-random*[tiab] OR nonrandom*[tiab] OR before after stud*[tiab] OR (time[tiab] AND series[tiab]) OR retrospective*[tiab] OR longitud*[tiab] OR (controlled[tiab] AND cohort*[tiab] AND stud*[tiab]) OR "before and after"[tiab] OR controlled before[tiab] OR pre test[tiab] OR pretest[tiab] OR posttest[tiab] OR post test[tiab] OR pre intervention[tiab] OR post intervention[tiab]	5634523
#32	#30 AND #31	12185

CONTRIBUTIONS OF AUTHORS

SD drafted the protocol and all other authors contributed to finalizing it.

SD, AS, VR and JO will perform study selection and data extraction.

SD will enter data into RevMan and carry out the initial analysis. All other authors will contribute to the interpretation of the analysis.

SD will draft the final review and all other authors will contribute.

EK will resolve any disagreements that might occur during study selection and data extraction.

SD will be responsible for updating the review.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- South African Cochrane Centre, South African Medical Research Council, South Africa.

External sources

- No sources of support supplied