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The impact of growth monitoring and promotion on health indicators in children under five years of age in low- and middle-income countries (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

The impact of growth monitoring and promotion on health indicators in children under five years of age in low- and middle-income countries

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the role of child growth monitoring and promotion (GMP) in identifying and addressing faltering growth, improving infant and child feeding practices, and promoting contact and use of health services in children under five years of age living in the community in low- and middle-income countries.

BACKGROUND

Description of the condition

Undernutrition in the critical first 1000 days of life is the most common form of childhood malnutrition, and a significant problem in low- and middle-income countries (LMICs). Globally, 144 million (or one in five) children under five years old are stunted, which is defined as height-for-age two standard deviations below the median World Health Organization (WHO) Child Growth standards (UNICEF 2020; WHO 2020b). Meanwhile, 47 million (7%) are wasted, which is defined as weight-for-height two standard deviations below the median WHO Child Growth standards (UNICEF 2020; WHO 2020b). The vast majority of these children reside in South Asia and sub-Saharan Africa (UNICEF 2020). Childhood undernutrition occurs as a result of preconceptual, prenatal and postnatal deficiencies in protein, energy and micronutrients; recurrent infections; poor infant feeding practices; food insecurity; inadequate access to water; and sanitation and hygiene in the context of poverty, amongst other factors (UNICEF 2020). The effects of undernutrition in children under five are wide-ranging, from increased susceptibility to, and severity of, infections; impairment of physical and cognitive development, which diminishes school and work performance later in life; and death. Those who survive to adulthood have an increased risk of cardiovascular and metabolic diseases. Undernutrition causes nearly half of all deaths in children under five, which translates to three million avoidable deaths per year (WHO 2020a). Optimising child growth and nutrition is therefore a key strategy to addressing the under-five mortality rate (Sustainable Development Goal 3) and reducing undernutrition in children under five (Sustainable Development Goal 2) (SDG 2020).

There is an urgent need for appropriate programmes and policies that support the prevention of, and timely intervention for, undernutrition in children who are not achieving their growth milestones. The WHO considers growth monitoring and promotion (GMP) — the regular charting of a child's growth — in combination with follow-up activities, as 'best practice' and recommends it as a key component of child health and nutrition strategies (WHO 2017). Currently, 39 countries have a designated GMP programme, typically delivered alongside routine immunisations (WHO 2017). In addition, there is a growing school of thought that GMP may be an appropriate intervention to reduce childhood overnutrition and obesity. This is important as an estimated two-thirds of LMICs currently suffer from a double burden of both conditions (Popkin 2020). However, traditionally this has not been the intended target of either the programme, or of studies designed to assess its effectiveness. Moreover, overnutrition is typically not associated with mortality in under-fives, and instead many of the important health consequences occur later in adulthood. On the basis of these concerns, this review will focus on childhood undernutrition, which currently represents a much greater burden in LMICs.

Description of the intervention

Throughout this review, the term GMP refers to the following four steps.

1. Measurement (the regular recording of a child's weight and sometimes their height and head or mid-upper-arm circumference, during visits to healthcare providers over three months).
2. Assessment (conversion of these measures to weight for age, height for age or weight for height; and plotting weight against age or weight against height on a growth chart).
3. Analysis (interpreting the growth pattern of the child against the reference population).
4. Action related to the analysis (for example, counselling, providing nutritional supplements or examining the child for illness) (Mangasaryan 2011).

In the 1960s, Dr David Morley introduced the concept of growth monitoring (GM), the use of anthropometric indicators to monitor the growth of children in LMICs (Morley 1973). Over the years, different types of growth charts emerged. In 1978, the WHO developed a standard growth chart based on reference data from healthy children in the USA and in a format that reflected the majority preference of 55 countries (De Onis 1996; WHO 1978). Multi-country data inform the current WHO Child Growth Standards and provide more representative standardised growth references for children under five years (WHO/UNICEF 2009). Policymakers regarded the development of standardised charts to be a milestone of growth monitoring development (Mangasaryan 2011). In the early 1980s, the United Nations Children's Emergency Fund (UNICEF) developed a number of primary healthcare strategies known collectively as the 'child survival and development revolution'. One such strategy targeted growth monitoring, oral rehydration therapy, breastfeeding promotion, immunisation, food supplementation, family planning and female education and was labelled GOBI-FFF(Claeson 2000).

Policymakers introduced the concept of GMP in the mid-1980s. It emphasised linking the results of monitoring with follow-up actions — i.e. 'promotion' (including nutrition counselling, provision of supplements, early disease detection and disease treatment) — in order to improve individual child nutritional and health outcomes, and reduce child deaths (Caulfield 2006; Mason 2006; Pearson 1995). It has been a key component of UNICEF's overall nutrition strategy (UNICEF 2007), and served as a core activity in most community-based health and nutrition programmes (Mason 2006).

In 1996, the WHO and UNICEF promoted a broad child-saving strategy, 'Integrated Management of Childhood Illness' (IMCI). Policymakers integrated GMP into practice guidelines for frontline healthcare workers, which have been used in over 100 countries (WHO/UNICEF 2009). The strategy recommends that child nutrition status should be assessed by weight for age, and that counselling and follow-up services should also be provided; however, recommendations for the promotional component were less clearly defined. In 2009, the WHO Regional Office for the Eastern Mediterranean advocated the evolution of the IMCI, which was re-named 'Integrated Management of Child Health' and specified GM as one of its key aspects.

However, in the 1990s, researchers began to call GMP into question. The coverage was relatively low, and the implementation was considered weak, with poor linkage between GMP activities due to poor organisational structure of child health programmes, including staff shortages and inadequate training and monitoring of staff (Ashworth 2008; Gerein 1991). Studies such as Tarwa 2007 reported that the 'Road to Health Card', which was a tool used to monitor growth and vaccination status over several decades, was not being used effectively. GMP has been used incorrectly to identify childhood acute malnutrition rather than as a strategy to

prevent growth faltering (Mangasaryan 2011). One study identified that sharp growth faltering occurred in the first year of life, and concluded that early interventions would be the most effective (Shrimpton 2001), yet the authors enrolled many children after infancy (Mangasaryan 2011).

How the intervention might work

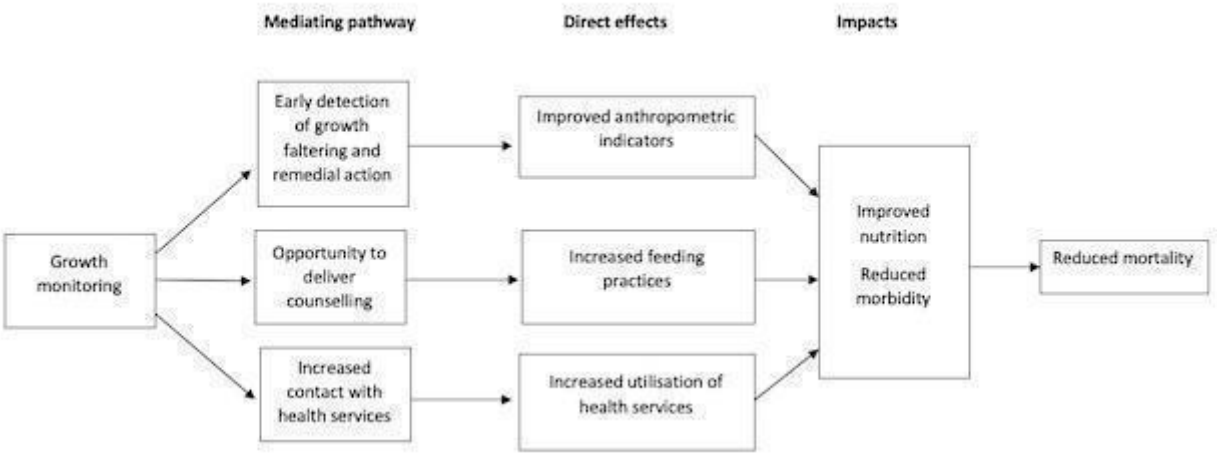
Growth monitoring in itself is not an intervention as such. Simply weighing a child will not lead to improvements in health unless the practice of weighing leads to various activities to correct for signs of faltering before malnutrition occurs. Historically, this has not always been clear, and was the reason why GMP was created to make the concept of this 'package' more explicit. However, whilst the WHO recommends GMP in its guidelines (WHO 2017), there are no specific guidelines for what to do after a child is weighed and potential faltering is identified (i.e. the promotional activities).

Growth monitoring and promotion is a complex intervention, which comprises a range of possible activities and outcomes. As a result, policymakers, particularly in international aid agencies, have differing and changeable interpretations and perceptions of the purpose of GMP. Is it to reduce mortality, to increase immunisation uptake or a vehicle for nutrition education? Compounding this are inconsistent definitions of GMP, as well as different understandings of the range of follow-up actions or interventions that constitute 'promotion' (Mangasaryan 2011). Usually the GMP programmes contain GM, but the promotion components vary and many of the programmes provide promotion activities and services not targeted or linked to the results of GM, including immunisations and curative healthcare services (Mangasaryan 2011), meaning that many children continue to have their growth tracked with no obvious benefit. This lack of understanding of the need for a combined approach is perhaps the reason for the discourse surrounding the benefits of GMP. Therefore, we intend to investigate whether the complete GMP package is effective in improving health and nutrition indicators in children under five years of age, so that clearer recommendations can be made. Due to the complexity of the intervention, the components of 'monitoring' and 'promotion' are dependant. Whilst we acknowledge that promotional activities have a direct effect on outcomes, we argue that monitoring is crucial as part of the intervention, because it provides the platform on which to provide the activities.

From the literature, the beneficial effects of GMP can be split into three areas. First, it is an opportunity to identify faltering growth and provide medical remedial action. Second, GMP provides an opportunity to discuss nutrition and promote optimal infant/child feeding and care practices. Third, although not strictly related to nutrition, contact with health services via GMP can promote an increased uptake in additional childhood interventions such as vaccinations and de-worming. Studies have described these benefits since 1988 (Lofti 1988). Although the proposed mechanisms for how GMP might improve health outcomes could include a mixture of these mechanisms in reality, we find it helpful to conceptualise them as different components to help clarify thinking about mechanisms; to help clarify exactly what GM consists of; and to help clarify which outcomes we should seek.

Over time, the understanding of GMP has developed to also include strategies such as community mobilisation, which recognise and try to address the underlying socio-economic factors associated with undernutrition at the population level (Ashworth 2008). Improved self-esteem of mothers who are able to seek guidance and receive positive feedback on their child's health has been described also (Ashworth 2008). However, they are less easily assessed quantitatively and have less clear controls, so will not be the focus of this review, and thus we have not included them in the logic model (Figure 1).

Figure 1. Potential pathways of impact from GMP



Early detection of growth faltering and remedial action

Growth monitoring and promotion allows health workers to track a child's growth so that they are able to identify those faltering, or at risk of faltering, and intervene at an earlier stage. This may lead to the supplementary activities such as home visits, referrals to specialist health facilities, provision of nutritional supplements, and detecting and treating common diseases (such as anaemia, diarrhoea, respiratory infection). We may detect such benefits in trials using both individually-randomised and cluster-randomised designs.

Delivery of nutrition counselling

Nutrition counselling may take the form of offering tailored nutrition advice upon the recognition of growth faltering or risk of faltering growth. With growth information, health workers can tailor nutrition promotion and guidance to the individual's needs and underlying problems at the individual level. However, the process of measuring is also thought to provide a focus for discussing the importance of nutrition and the relationship between nutrition and health. The interaction between healthcare workers and mothers is expected to raise maternal awareness and knowledge of childcare practice leading to changes in health behaviour (Mangasaryan 2011). For this reason, GMP as a mediator of nutrition counselling has been separated from merely a remedial action. However, in practice, the quality of nutrition counselling is variable. A study in Ghana suggested that healthcare workers often do not provide feedback on the child's growth and have limited time to go into any detail with their clients (Nsiah-Asamoah 2019). In addition, uptake of knowledge is dependent on the relationship between healthcare workers and mothers as well as socio-economic factors.

Increased contact with health workers

Regular GMP increases the frequency of contact between mothers and health services or community health teams, and is expected to build a good relationship between mothers and health workers. As a result, this may encourage the use of preventive and curative health services such as vaccinations, screening, de-worming and vitamin A supplementation at the health facility level. However, health workers can also deliver GMP as part of a community outreach programme. In this context, the programme targets populations because they have limited access to primary health centres due to socio-economic or physical barriers. They are therefore less likely to seek out preventative or curative health services.

Why it is important to do this review

Over the past few decades, opinion about GMP has ranged from untempered enthusiasm to doubts about whether has any benefit at all (Bentley 1993; Chopra 1997; Hossain 2005; Morley 1973; Nabarro 1988; Shekar 1992). The effectiveness of GMP as an approach to preventing malnutrition and, more specifically, the added value of GM to growth promotion, has been the subject of debate. Some field studies, for example, report that introducing GMP in areas where malnutrition is common dramatically reduced mortality (Alderman 1978); whilst others report national programmes that did not improve child growth (Hossain 2005). This review is important as so much time dedicated to GMP in child health clinics globally. The services, even if delivered as part of a package of care, have resource implications in terms of healthcare worker and parent time (Fiedler 2003; Reid 1984); the costs of the equipment (for example, scale, charts and manuals); training and supervision; ensuring follow-up; and actions arising as a result of faltering growth (Mason 2006). Thus, there are considerable direct costs, opportunity costs and knock-on costs, especially for facility-based programmes (Fiedler 2003).

A narrative review by Ashworth 2008 analysed the impact of GMP programmes on child nutrition and other intermediate outcomes. Whilst their overall message is supportive of the activity, it is not clear whether this is through careful critical appraisal of the science or prior beliefs about the intervention. There is no systematic appraisal of the risk of bias in the studies or the quality of the evidence. In particular, most of the evidence presented is from programmes carried out in uncontrolled, natural conditions (including cross-sectional comparisons and pre-post comparisons with or without control groups), which make the impact evaluation particularly difficult. Moreover, half of the evaluations looked at the effectiveness of GMP in comprehensive, community-based programmes, and did not distinguish the impact of different programme components from the impact of GMP (Mangasaryan 2011). It has been argued that there are confounding effects due to the other activities. For example, regular contact with health workers and socialising between mothers at clinics, rather than GMP itself, could benefit both the mother and children in terms of health improvement.

Previous versions of this review include one published in 1999 (Panpanich 1999) and one updated but not completed in 2017 due to discussion at the peer review stage; areas of concern included the suitability of some included studies, the conceptualisation of GMPs role and concerns over the clarity in reporting of the narrative synthesis due to the large heterogeneity in study design observed. The protocol was subsequently withdrawn (Liu 2017). The present review is intended to update and replace both past versions, and has addressed the concerns presented by the peer reviewers previously (Liu 2017; Panpanich 1999). Overall, these reviews found insufficient reliable information to be confident about whether GMP is effective in preventing childhood undernutrition. These reviews took a narrow, medicalised view that assumed the purpose of GMP was to detect malnutrition, to allow for targeted treatment. In reality, it is a complex intervention with several possible outcomes and intermediate activities. A review by Ashworth 2008 builds on this, and the authors developed a logic model that illustrates the potential benefits of GMP programmes that is more holistic. We utilised this line of thinking when developing our logic model above (Figure 1). Due to the lack of clear recommendations for how GMP should be delivered, especially for the promotional components, studies assessing the impact of GMP are highly heterogenous in their definition of the intervention. This, combined with heterogeneity in other aspects of study design and context, prevented the previous review authors from conducting meta-analysis (Liu 2017). We therefore intend to synthesise the evidence using a narrative approach.

OBJECTIVES

To evaluate the role of child growth monitoring and promotion (GMP) in identifying and addressing faltering growth, improving infant and child feeding practices, and promoting contact and use of health services in children under five years of age living in the community in low- and middle-income countries.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) or quasi-RCTs that use a non-random method of randomisation, such as alternation or date of birth. Randomisation may be by individual or by cluster (for example, clinics or geographical area). We will

also include non-randomised study designs (controlled before-and-after and cohort studies).

Types of participants

We will include children under five years old residing in low- and middle-income countries (according to the World Bank 2020 classification) and their caregivers in the community; and those presenting to routine maternal and child health services at health facilities. Severely malnourished children presenting to routine child and maternal health services would likely be referred to nutrition rehabilitation inpatient or outpatient programmes so would not be included in this population and are not the focus of the review. GMP is designed to identify children with faltering growth to enable early intervention to prevent the progression to malnutrition and associated conditions such as stunting and wasting. Therefore, studies conducted in hospital settings and recruiting only malnourished children are not eligible for inclusion, as they will likely be receiving targeted clinical interventions alongside promotional activities.

Types of interventions

Experimental intervention

The intervention under investigation is growth monitoring and promotion (GMP), defined as:

1. measurement (the regular recording of a child's weight and sometimes their height and head measurements, or mid-upper-arm circumference);
2. assessment (conversion of these measures to weight for age, height for age or weight for height; and plotting weight against age or weight against height on a growth chart);
3. analysis (interpreting the growth pattern of the child against the reference population); and
4. action related to the analysis (i.e. the promotional activities. For example, counselling, providing nutritional supplements or examining the child for illness) (Mangasaryan 2011). This may be either given to all mothers at the time of health promotion activities; or targeted at only those with faltering growth.

Growth monitoring, i.e. the regular charting of a child's growth, requires at least three readings over the course of at least three months to establish a growth curve. Studies that assess growth based on one or two readings in a short period of time do not meet the WHO guidance and are thus excluded from this review. Studies should record follow-up outcome measures until at least six months post-intervention.

Growth monitoring and promotion may be delivered though routine child and maternal health services or community-based programmes. Both forms of delivery will be included in this review.

Comparator interventions

1. Growth monitoring with no health promotion
2. General health promotion with no growth monitoring
3. No growth monitoring and no health promotion activity

Types of outcome measures

Primary outcomes

The primary outcomes for each of the three possible roles of GMP are as follows. We will treat these as important outcomes for inclusion in the summary of findings table and risk of bias assessment.

1. Identifying and addressing faltering growth: anthropometric indicators of nutrition (such as weight, height, z-score, weight for age, height for age or weight for height).
2. Infant and child feeding practices: improvements in children's diets and the way mothers provide milk and food, documented by external observations.
3. Promoting contact and use of health services: health service usage (such as visit rate, vaccination rate or delayed presentation rate).

Secondary outcomes

The secondary outcomes are as follows.

1. Frequency and severity of childhood illnesses.
2. Mortality.

We demonstrate in the conceptual model that mortality is substantially distant from the intervention of GMP, and is also subject to numerous confounders, making it an unsuitable way to assess the impact of GMP in general. However, impacts on mortality and not on direct outcomes, or vice versa, may have important implications for policymakers; therefore, we intend to include these data to inform the recommendations of the review. The secondary outcomes will not be included in the summary of findings table but will be summarised in a separate table.

Search methods for identification of studies

Electronic searches

We plan to search the following databases and trial registers. We will search MEDLINE using the strategy in Appendix 1, which we will adapt for other databases using appropriate indexing terms and syntax.

1. Cochrane Central Register of Controlled Trials Register (CENTRAL; current issue) in the Cochrane Library, which includes the Developmental, Psychosocial and Learning Problems Specialised Register.
2. MEDLINE Ovid (1946 onwards).
3. MEDLINE In-Process and Other Non-Indexed Citations Ovid (1946 onwards).
4. MEDLINE Epub Ahead of Print Ovid (current issue).
5. Embase Ovid (1974 onwards).
6. CINAHL Plus EBSCOhost (1937 onwards).
7. Global Index Medicus, World Health Organization (www.globalindexmedicus.net/).
8. Science Citation Index-Expanded, Clarivate Web of Science (1970 onwards).
9. Social Sciences Citation Index, Clarivate Web of Science(1970 onwards).
10. Conference Proceedings Citation Index - Science, Clarivate Web of Science (1990 onwards).

11. Conference Proceedings Citation Index - Social Science & Humanities, Clarivate Web of Science (1990 onwards).
12. *Cochrane Database of Systematic Reviews* (CDSR; current issue) in the Cochrane Library.
13. Epistemonikos (www.epistemonikos.org/en/).
14. ProQuest Dissertations and Theses Global (current issue).
15. ClinicalTrials.gov (clinicaltrials.gov/) (current issue).
16. World Health Organization International Clinical Trials Registry Platform (trialsearch.who.int/Default.aspx) (current issue).

Searching other resources

We will examine reference lists of included studies, systematic reviews and other reviews published since the inception of GMP in the 1980s, in order to identify relevant studies. Additionally, we will contact organisations and individual researchers working in the field for unpublished data, confidential reports and raw data from published trials. We will search OpenGrey (www.opengrey.eu/) for further unpublished data and the WHO Institutional Repository for Information Sharing (IRIS) (apps.who.int/iris/) and WHO Global database on the Implementation of Nutrition Action (GINA) (extranet.who.int/nutrition/gina/en) for relevant policy documents and studies. We will search for retractions and corrections of included studies before the review is published. Abstracts will be included during screening and, if necessary, we will contact the study authors to obtain full-text records where available.

Data collection and analysis

Selection of studies

As described in Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2021), two review authors will independently apply the inclusion criteria to all records, using Covidence (Covidence 2021). Initially, they will screen the titles and abstracts to exclude trials that clearly do not meet the inclusion criteria. If one or both of the review authors judge that the trial might be eligible for inclusion, or they require more information to judge eligibility, we will obtain the full paper. We will obtain full-text reports of all potentially eligible studies, by contacting the relevant authors if necessary, and will further assess these for inclusion using a pre-designed eligibility form based on the inclusion criteria. We will resolve different opinions about eligibility by discussion or, where necessary, by consulting with a third review author. We will produce a 'Characteristics of excluded studies' table to document reasons for excluding studies at the full-text stage (i.e those studies one may expect to be included the review but that do not quite meet inclusion criteria). We will produce a PRISMA flow diagram (Moher 2009) to summarise the entire selection process, detailing the numbers of studies identified in the search and subsequently excluded and included at each stage. We will assess inter-rater reliability using the Kappa statistic described by Landis 1977 (Higgins 2021b). If there are several published articles based on a single study, we will collate the multiple reports, so that the study rather than the report is the unit of interest.

Data extraction and management

In accordance with Chapter 5 of the *Cochrane Handbook* (Li 2021), two review authors will independently extract data using a pre-designed data extraction form in Microsoft Excel (Microsoft Excel 2018). To pilot the form, two review authors will independently perform data extraction on three studies (one for each eligible study design) and calculate inter-rater reliability. If the authors score below 80% agreement (i.e. kappa below 0.8), the necessary changes will be discussed and applied (Landis 1977). We will base the extraction form on the TIDieR-PHP tool for describing population health and policy interventions (Campbell 2018) as this will best address the issues regarding the complexity of the intervention.

In addition, socio-economic status and access to timely and quality health care are key factors in ensuring that communities access and benefit from growth monitoring and health promotion. For example, in the context of gender disempowerment, racial or ethnic discrimination and conflict leading to humanitarian crises, mothers and their children may not have equitable access to growth monitoring and health promotion. We therefore intend to apply an equity lens using the PROGRESS acronym (Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status, and Social capital), to guide data extraction for factors that would disadvantage one community accessing GMP over another (O'Neill 2013).

A full list of data to be extracted is described in Table 1. The review authors will consult with a third review author to resolve disagreements. Once the extraction process is complete, data will be compiled into RevMan Web for analysis (RevMan Web 2020). We will check all data entered into RevMan Web to ensure accuracy.

Assessment of risk of bias in included studies

Assessment of risk of bias in randomised studies

Two review authors (MT and JT) will independently assess the risk of bias in included RCTs using version 2 of the Cochrane risk of bias tool (RoB 2) (RoB 2 2021a), following guidance described by Higgins 2021c. The tool consists of the following five domains.

1. Bias arising from the randomisation process.
2. Bias due to deviations from intended interventions.
3. Bias due to missing outcome data.
4. Bias in measurement of the outcome.
5. Bias in selection of the reported result.

In case of cluster-RCTs, we will use the modified RoB 2 tool for cluster-randomised trials, which also includes the domain "bias derived from the moment of identification and recruitment of participants" (RoB 2 2021b). We will also follow the description included in the *Cochrane Handbook*, to assess bias in this type of study (Higgins 2021a). In the case of cross-over trials, we will use the modified RoB 2 tool for cross-over trials, using the signalling questions that are appropriate to first period of analysis only (RoB 2 2021c).

We will assess the risk of bias for the outcomes of the included trials that will be included in our summary of findings table, focusing on the end point of 24 months post-intervention, as this was most commonly reported in studies identified during scoping. Outcomes to be included in the RoB 2 assessment include:

1. anthropometric indicators of nutrition (such as weight, height, z-score, weight for age, height for age or weight for height);
2. improvements in children's diets and the way mothers provide milk and food (documented by external observations); and

3. health service usage (such as visit rate, vaccination rate or delayed presentation rate).

We are interested in quantifying the effect of assignment to the interventions at baseline, regardless of whether the interventions are received as intended (the 'intention-to-treat effect'). We will use the RoB 2 Excel tool to implement RoB 2 (RoB 2 2021a). For each domain, we will use the signalling questions provided by the RoB 2 tool, and answer with 'yes', 'probably yes', 'no', 'probably no' or 'no information'. The RoB 2 tool automatically generates a judgement regarding bias for each domain and overall, based on these responses. We will also check all judgements and amend them if necessary. Generally, the overall score will be based on the least favourable assessment made for any of the domains. However, if 'some concerns' arise in multiple domains, authors may decide on an overall judgement of 'high' risk of bias for that outcome. Any disagreements between the two authors for independently assessing bias will be resolved by a third author (HN). We will provide a full risk of bias table with our consensus judgement and reasoning for each domain, including answers to the signalling questions, in the supplementary data associated with the review.

Assessment of risk of bias in non-randomised studies

Two review authors will independently assess the risk of bias of included cohort and controlled before-and-after studies using the ROBINS-I tool (Sterne 2016), which involves consideration of the following bias domains.

1. Bias due to confounding.
2. Bias in selection of participants into the study.
3. Bias in classification of interventions.
4. Bias due to deviations from intended interventions.
5. Bias due to missing data.
6. Bias in measurement of outcomes.
7. Bias in selection of the reported result.

For the ROBINS-I assessment, potential confounders must be defined a priori and we anticipate these to include: age, sex, socioeconomic status, setting, seasonality and change in national policies for health/nutrition. Each domain will be judged as being at low, moderate, serious or critical risk of bias. We will decide on an overall score based on the least favourable assessment made for any of the domains. Any disagreements between the two authors for independently assessing bias will be resolved by a third author.

Measures of treatment effect

Dichotomous data

We will calculate risk ratios (RRs) with 95% confidence intervals (CIs), by dividing the number of events by the number of participants. It would be appropriate to use either the odds ratio (OR) or RR; however, the RR is more commonly used and is easier to interpret by health professionals and less likely to lead to over-estimation of effect size (Deeks 2021).

Continuous data

We will calculate mean differences (MDs) when continuous data are measured by the same scale or unit. When one outcome is assessed using different measures, we will use the standardised mean difference (SMD), calculated by dividing the difference in means by the standard deviation (SD). We will include both change and end scores in our analysis. We will report both with 95% CIs.

Highly skewed continuous data, identified from observation, will be presented in a table. We will consider the implications of any skewed data on the interpretation of results, particularly when the study size is small.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually randomised trials. We expect that study authors will have controlled for cluster randomisation, and where this has occurred, we will detail the methods the authors used in the outcome row of our data extraction form (Table 1), for inclusion in the 'Characteristics of included studies' tables. In accordance with the guidance in Chapter 23 of the *Cochrane Handbook* (Higgins 2021a), if the authors have not already controlled for clustering, we will use the intra-cluster correlation coefficients (ICCs) reported in the study. If these have not been reported, we will first contact the study authors for further information. If we do not receive a response from authors, or these data are not made available to us, we will analyse these trials using imputed ICC estimates from similar trials. With the help of ICC estimates, we will calculate the design effect and inflate the variance accordingly for use in the review. If ICC estimates from similar studies are not available, we will present unadjusted results in additional tables. It is good practice to conduct a sensitivity analysis of trials using imputed ICC estimates; however, as we aim to produce a narrative synthesis, this will not be possible. We will therefore be cautious in our interpretation of all cluster-randomised data, with a particular focus on those using imputed statistics.

Cross-over trials

Due to the nature of the complex intervention and multiple behaviour changes expected to result from the intervention (Figure 1), we do not anticipate any cross-over trials. If they are identified we will analyse data from the first period only due to the likelihood of carry-over effects from the intervention (Higgins 2021a). This approach does raise some issues regarding potential selective reporting and we will therefore be alert to this in the interpretation of results.

Non-randomised studies

In accordance with the guidance in Chapter 24 of the *Cochrane Handbook* (Reeves 2021), we will use the same measures of treatment effect as for randomised studies, along with 95% CIs. We will also extract information about how the estimate was derived (e.g. the confounders controlled for) (see Data extraction and management). If both unadjusted and adjusted intervention effects are reported, we will extract adjusted effects. If multiple adjusted estimates of intervention effect are reported, the one that is judged to minimise the risk of bias due to confounding will be chosen.

Multiple outcome measures

We will use the reductionist approach to handle any multiplicity in reporting of outcome measures (described by López-López 2018). This approach aims to reduce the data set to typically one effect size per study. We will choose the effect size based

on the following hierarchy, outlined in Chapter 3 of the *Cochrane Handbook* (McKenzie 2021a):

1. the study's primary outcome;
2. the outcome used in the sample size calculation; or
3. the outcome with the median effect.

The benefit of this approach is that it will not introduce statistical dependencies that need to be modelled or accounted for in the statistical analysis, as would be the case when using an integrative approach. However, the limitation, namely the loss of precision, will be considered in the interpretation of results. Multiplicity can be difficult to predict, and so any necessary deviations from protocol will be explained at length in the review methods.

Multiple time points

We will analyse different lengths of follow-up in separate analyses. We will group follow-up time points as follows: up to six months, up to 12 months, up to 24 months, and 24 months or more after intervention. We have chosen to include up to six months as this is most appropriate to detect changes in breastfeeding practices. The impact of improved solid feeding practices are typically observed over a longer term such as up to 12 and 24 months and longer; and these were the end-points typically reported by the studies we identified during scoping.

Studies with multiple intervention groups

In accordance with the guidance in Chapter 3 of the *Cochrane Handbook* (McKenzie 2021a), for trials with three or more arms, eligible intervention arms may be placed in different comparisons. If two or more intervention arms are in the same comparison, these groups will be combined to create a single pair-wise comparison using formulae described in the *Cochrane Handbook* (Higgins 2021b) for calculating combined sample size, mean and standard deviations.

Dealing with missing data

Following the guidance of Chapter 10 of the *Cochrane Handbook* (Deeks 2021), we will first contact corresponding authors to request clarification and data whenever the published information does not allow us to decide whether to include or exclude a study. We will also contact them to obtain missing data in order to appropriately describe the study results. We will report characteristics of, reasons for, and number of missing data for all included studies in the risk of bias tables.

If we are unable to obtain missing data, we will analyse the available data. We will contact trial authors to request information on whether or not missing data can be assumed to be 'missing at random'. The absence of data deemed 'not missing at random' may lead to bias in the reporting of results; therefore, we will address the potential impact of the missing information on the robustness of findings of the review in the discussion section.

For missing summary statistics, we will first attempt to calculate the values from available data. For example, the standard deviation can be calculated from the standard error, CI, t-statistic or P value, as described in the *Cochrane Handbook* (Higgins 2021b). However, if these data are not available, we will instead use imputation methods described in the *Cochrane Handbook* (Higgins 2021b). We will use summary statistics for the same outcome measure from other studies in the review that are comparable in measurement scale, degree of measurement error and population.

Assessment of heterogeneity

Due to the nature of narrative synthesis, we will be unable to statistically assess heterogeneity. However, we will construct detailed study characteristic tables (as detailed in Table 1) to describe the variation in study design and context, and to assess the impact of this on the robustness of results in the discussion section and GRADE assessment.

Assessment of reporting biases

Due to the nature of narrative synthesis we will be unable to formally assess publication bias by drawing funnel plots. Instead, we will describe the nature of publication of all included studies and assess the impact of this on the robustness of results in the discussion section and GRADE assessment. We will attempt to assess selective reporting bias by comparing the reported outcomes to those specified in the protocol or methods section, where available.

Data synthesis

All eligible studies will be included in the narrative synthesis irrespective of their risk of bias. Due to the substantial heterogeneity in study design and context we do not anticipate that meta-analysis will be possible. We therefore intend to summarise the data in a narrative synthesis, drawing on guidance from Chapter 12 of the *Cochrane Handbook* (McKenzie 2021b), and the recently published SWiM guidelines (Campbell 2020) that promote transparent and complete reporting. Our a priori approach to the checklist described in the SWiM guidelines (Table 2) is as follows.

1. **Item 1 (grouping studies for synthesis):** we will begin by grouping the studies, first by outcome measure, then by comparator intervention and finally by study design (e.g. RCTs, quasi-RCTs and non-randomised trials). Any changes to this order in the final review will be detailed, with reasons why.
2. **Item 2 (describe the standardised metric and transformation method used):** within each group we will select a standardised metric for reporting of the outcome measure based on what is most commonly used in the included studies. We will transform any data expressed differently to the standardised metric, according to guidance listed in Chapter 6 of the *Cochrane Handbook* (Higgins 2021b), to aid comparison and tabulation of results.
3. **Item 3 (describe the synthesis methods):** we will calculate summary statistics of intervention effect estimates (for example, median and interquartile range). In addition, we intend to calculate a direction of effect by combining P values or performing vote counting; the method that we choose will depend on the data available and we will provide a justification for any decision in the final review.
4. **Item 4 (criteria used to prioritise results for summary and synthesis):** we will not prioritise the reporting of any study over the others to avoid introducing bias due to selective reporting.
5. **Item 5 (investigation of heterogeneity in reported effects):** we will conduct an informal investigation of heterogeneity, as described in Subgroup analysis and investigation of heterogeneity.

6. **Item 6 (certainty of evidence):** we will perform a GRADE assessment for each outcome.
7. **Item 7 (data presentation methods):** we will present outcome data in tables, with a column to highlight any important issues and a further column to describe the certainty of evidence associated with the outcome. We will organise the tables first by outcome measure, then by comparator intervention and finally by study design, as in the narrative text, to aid navigation of the evidence.
8. **Item 8 (reporting results):** for each outcome and comparison group, we will describe the synthesis findings including: a list of contributing studies; description of study characteristics guided by the PROGRESS and TIDieR-PHP tools (Table 1); and a descriptive summary of effect measures, accompanied by a CI where possible and a statement regarding certainty of effect. We will discuss the perceived strengths, weaknesses, and contributions of each included study and its effects on health equity based on the data collected.
9. **Item 9 (limitations of the synthesis):** we will discuss any limitations of the synthesis, including limitations of the narrative synthesis method, deviations from protocol, limitations of the standardised metrics used and data synthesis methods, limitations or availability of data, certainty of evidence and heterogeneity of effect measures.

Subgroup analysis and investigation of heterogeneity

We will conduct an informal assessment of heterogeneity by ordering tables according to possible modifiers. These include: study design (i.e. we will separate RCTs from non-RCTs); group or individual promotion activities; and single- or multi-component promotional activities. However, we do not intend this investigation to be definitive, and we will discuss the implications of any heterogeneity in reported effects on the robustness of our results.

Sensitivity analysis

Due to the nature of narrative synthesis, we will be unable to perform any sensitivity analysis. Factors that would be investigated with such methods include the impact of: studies judged as being at high risk of bias; studies presenting imputed data (such as ICC estimates); and studies with data deemed not missing at random. Instead, we will assess the impact of these factors on the robustness of results informally in the 'Discussion' section of the final review.

Summary of findings and assessment of the certainty of the evidence

We will create a summary of findings table for the following outcomes at 24 months post-intervention, for all three potential comparisons (GMP versus GM; GMP versus general health promotion; GMP versus no intervention).

1. Anthropometric indicators of nutrition (such as weight, height, z-score, weight for age, height for age or weight for height).
2. Improvements in children's diets and the way mothers provide milk and food (documented by external observations).
3. Health service usage (such as visit rate, vaccination rate or delayed presentation rate).

Summary of findings tables are limited to seven outcomes (including multiple measures of the same outcomes). We therefore will only include the most frequently reported measure for each of the three outcomes in the tables. We will use GRADEpro GDT software to create the tables and will follow the guidance in Chapter 14 of the *Cochrane Handbook* (Schünemann 2021).

We will assess the certainty of the evidence for each outcome using the GRADE approach, which consists of five domains (risk of bias, consistency of effect, imprecision, indirectness and publication bias). The risk of bias domain will be based on the overall RoB 2 judgement. For all studies, we will start at a judgement of 'high certainty', and downgrade appropriately to 'moderate', 'low' or 'very low' certainty when serious concerns arise from the five domains listed above. In the new ROBINS-I tool, non-randomised studies start as representing 'high certainty' evidence, as is typically observed with RCTs. However, the evidence from non-randomised studies will generally be downgraded by two levels due to the inherent risk of bias associated with the lack of randomisation, such as confounding and selection bias. We therefore expect a lower certainty of evidence for non-randomised trials compared to RCTs. We will justify all decisions to downgrade the certainty of evidence in the footnotes of each table. Two review authors will independently assess the certainty of evidence and will consult a third author to resolve any disagreements.

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ADDITIONAL TABLES

Table 1. Data extraction form

Methods	First author name, year of publication, study design and PICO (population, intervention, comparator, outcome); for non-randomised studies, we will also extract information on confounding variables and any attempts by the author to mitigate against these
Participants	Sample size, age range and mean, gender distribution of children. Occupation, gender/sex, education status and social capital of parents**
Brief name*	Brief name or phrase that describes the intervention
Why*	Logic, mechanism and/or rationale of the intervention, clearly linking intervention elements to the expected effects on immediate or longer term outcomes (or both)
What materials*	Materials used in the intervention, such as: informational materials; nature and value of any benefits provided; any physical resources or infrastructure provided as part of the intervention
What and how*	How the intervention was planned, established, and intended to be delivered, including what promotional activities were included, how activities such as counselling were delivered (e.g. face-to-face or through educational materials, individual or group-based, and topics covered)
Who provided*	Description of those involved in the planning, delivery and monitoring of the intervention, including organisations involved, and training and expertise of staff
Where*	Type of location (e.g. health centre or community-based), geographical scope (e.g. national, regional, local). Historical, cultural, socioeconomic, religious or political context**
When and how often*	When the intervention was implemented, how long it remained in place, and, if applicable, the number, duration, and scheduling of occasions
Planned variation*	Description and reasoning; and the reason for any variation or tailoring that was planned or allowed for in the design of the intervention
Unplanned variation*	Description and reasoning; and the reason for any unplanned variation or modifications in the intervention (eg, between different locations, geographical areas, population subgroups, or over time) that were made after the intervention commenced
How well*	Strategies used or actions taken to ensure that the intervention was delivered as intended). Distinguishing between intervention failure and implementation failure
Outcomes	1. Anthropometric indicators of nutrition (such as weight, height, z-score, weight for age, height for age or weight for height) 2. Observed feeding practices (improvements in children's diets and the way mothers provide milk and food, documented by external observations) 3. Health service usage (such as visit rate, vaccination rate or delayed presentation rate) 4. Frequency and severity of childhood illnesses 5. Mortality We will also include information on how the study authors controlled for cluster randomisation.
Funding sources	Names of institutions and companies providing funding

Table 1. Data extraction form *(Continued)*

Conflicts of interest	Any statement provided by the author

*Adapted from the TIDieR-PHP tool. We will refer to the full tool for guidance when performing data extraction.
**Adapted from PROGRESS lens

Table 2. SWiM reporting checklist

SWiM reporting item	Item description
1 Grouping studies for synthesis	1a) Provide a description of, and rationale for, the groups used in the synthesis (e.g. groupings of populations, interventions, outcomes, study design)
	1b) Detail and provide rationale for any changes made subsequent to the protocol in the groups used in the synthesis
2 Describe the standardised metric and transformation methods used	Describe the standardised metric for each outcome. Explain why the metric(s) was chosen and describe any methods used to transform the intervention effects, as reported in the study, to the standardised metric, citing any methodological guidance consulted
3 Describe the synthesis methods	Describe and justify the methods used to synthesise the effects for each outcome when it was not possible to undertake a meta-analysis of effect estimates
4 Criteria used to prioritise results for summary and synthesis	Where applicable, provide the criteria used, with supporting justification, to select the particular studies, or a particular study, for the main synthesis or to draw conclusions from the synthesis (e.g. based on study design, risk of bias assessments, directness in relation to the review question)
5 Investigation of heterogeneity in reported effects	State the method(s) used to examine heterogeneity in reported effects when it was not possible to undertake a meta-analysis of effect estimates and its extensions to investigate heterogeneity
6 Certainty of evidence	Describe the methods used to assess the certainty of the synthesis findings
7 Data presentation methods	Describe the graphical and tabular methods used to present the effects (eg, tables, forest plots, harvest plots)
	Specify key study characteristics (eg, study design, risk of bias) used to order the studies, in the text and any tables or graphs, clearly referencing the studies included
8 Reporting results	For each comparison and outcome, provide a description of the synthesised findings and the certainty of the findings. Describe the result in language that is consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis
9 Limitations of the synthesis	Report the limitations of the synthesis methods used and/or the groupings used in the synthesis and how these affect the conclusions that can be drawn in relation to the original review question

Adapted from Campbell 2020

APPENDICES

Appendix 1. MEDLINE search strategy

Database: Ovid MEDLINE(R)

Lines 55 to 56 are filters to help identify studies relevant to LMIC which were developed in 2020 by Cochrane Effective Practice and Organisation of Care (EPOC) Cochrane EPOC 2020.

1 exp infant/
2 exp child/
3 (infant$ or baby or babies or child$ or boy$ or girl$ or preschool$ or pre-school$).tw,kf.
4 or/1-3
5 growth/
6 Child development/
7 Anthropometry/
8 Nutrition Surveys/
9 (growth adj3 (assess$ or chart$ or measur$ or monitor$)).tw,kf.
10 (anthropometric adj3 (growth or indicator$ or measure$ or monitor$ or surveillance)).tw,kf.
11 (age$ and ((weight or length or height) adj1 (chart$ or measur$ or monitor$ or surveillance))).tw,kf.
12 z score$.tw,kf.
13 or/5-12
14 Child Health Services/
15 Health Education/ and Parents/
16 Health Education/ and Caregivers/
17 Health Survey/
18 Health Promotion/ and Parents/
19 Health Promotion/ and Caregivers/
20 Education, Nonprofessional/ and Parents/
21 Education, Nonprofessional/ and Caregivers/
22 parenting education/
23 exp Parents/ed [Education]
24 Counseling/ and Parents/
25 Counseling/ and Caregivers/
26 Nutrition assessment/
27 Preventive Health Services/
28 health services.tw,kf.
29 ((mother$ or father$ or parent$ or carer$ or caregiver$ or care-giver$) adj3 (advice or advised or counsel$ or educat$ or knowledge or learn$)).tw,kf.
30 (health adj3 (advice or advised or counsel$ or education$ or knowledge or promot$)).tw,kf.
31 (nutrition$ adj3 (advice or advised or counsel$ or education$ or knowledge or promot$)).tw,kf.
32 or/14-31
33 13 and 32
34 (growth monitoring and promotion).tw,kf.
35 (integrated adj2 nutrition).tw,kf.
36 (GMP adj15 nutrition$).tw,kf.
37 or/33-36
38 4 and 37
39 randomized controlled trial.pt.
40 controlled clinical trial.pt.
41 randomi#ed.ab.
42 placebo$.ab.
43 drug therapy.fs.
44 randomly.ab.
45 trial.ab.
46 groups.ab.
47 cohort studies/ or follow-up studies/ or longitudinal studies/ or prospective studies/ or retrospective studies/
48 (cohort$ or longitudinal$ or prospectiv$ or retrospectiv$ or (follow$ adj1 up)).tw,kf.
49 Controlled Before-After Studies/
50 (controlled or control group or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or cba design$ or cba stud$ or comparative stud$ or evaluation stud$ or program$ evaluation or program$ effectiveness).tw,kf.
51 or/39-50
52 exp animals/ not humans.sh.
53 51 not 52
54 38 and 53
55 (afghanistan or albania or algeria or american samoa or angola or "antigua and barbuda" or antigua or barbuda or argentina or armenia or armenian or aruba or azerbaijan or bahrain or bangladesh or barbados or republic of belarus or belarus or byelarus or belorussia or byelorussian or belize or british honduras or benin or dahomey or bhutan or bolivia or "bosnia and herzegovina" or bosnia or herzegovina or botswana or bechuanaland or brazil or brasil or bulgaria or burkina faso or burkina fasso or upper volta or burundi or urundi or cabo verde or cape verde or cambodia or kampuchea or khmer republic or cameroon or cameron or cameroun or central african republic or ubangi shari or chad or chile or china or colombia or comoros or comoro islands or iles comores or mayotte or democratic republic of the

congo or democratic republic congo or congo or zaire or costa rica or "cote d'ivoire" or "cote d' ivoire" or cote divoire or cote d ivoire or ivory coast or croatia or cuba or cyprus or czech republic or czechoslovakia or djibouti or french somaliland or dominica or dominican republic or ecuador or egypt or united arab republic or el salvador or equatorial guinea or spanish guinea or eritrea or estonia or eswatini or swaziland or ethiopia or fiji or gabon or gabonese republic or gambia or "georgia (republic)" or georgian or ghana or gold coast or gibraltar or greece or grenada or guam or guatemala or guinea or guinea bissau or guyana or british guiana or haiti or hispaniola or honduras or hungary or india or indonesia or timor or iran or iraq or isle of man or jamaica or jordan or kazakhstan or kazakh or kenya or "democratic people's republic of korea" or republic of korea or north korea or south korea or korea or kosovo or kyrgyzstan or kirghizia or kirgizstan or kyrgyz republic or kirghiz or laos or lao pdr or "lao people's democratic republic" or latvia or lebanon or lebanese republic or lesotho or basutoland or liberia or libya or libyan arab jamahiriya or lithuania or macau or macao or republic of north macedonia or macedonia or madagascar or malagasy republic or malawi or nyasaland or malaysia or malay federation or malaya federation or maldives or indian ocean islands or indian ocean or mali or malta or micronesia or federated states of micronesia or kiribati or marshall islands or nauru or northern mariana islands or palau or tuvalu or mauritania or mauritius or mexico or moldova or moldovian or mongolia or montenegro or morocco or ifni or mozambique or portuguese east africa or myanmar or burma or namibia or nepal or netherlands antilles or nicaragua or niger or nigeria or oman or muscat or pakistan or panama or papua new guinea or new guinea or paraguay or peru or philippines or philipines or phillipines or phillippines or poland or "polish people's republic" or portugal or portuguese republic or puerto rico or romania or russia or russian federation or ussr or soviet union or union of soviet socialist republics or rwanda or ruanda or samoa or pacific islands or polynesia or samoan islands or navigator island or navigator islands or "sao tome and principe" or saudi arabia or senegal or serbia or seychelles or sierra leone or slovakia or slovak republic or slovenia or melanesia or solomon island or solomon islands or norfolk island or norfolk islands or somalia or south africa or south sudan or sri lanka or ceylon or "saint kitts and nevis" or "st. kitts and nevis" or saint lucia or "st. lucia" or "saint vincent and the grenadines" or saint vincent or "st. vincent" or grenadines or sudan or suriname or surinam or dutch guiana or netherlands guiana or syria or syrian arab republic or tajikistan or tadjikistan or tadzhikistan or tadzhik or tanzania or tanganyika or thailand or siam or timor leste or east timor or togo or togolese republic or tonga or "trinidad and tobago" or trinidad or tobago or tunisia or turkey or turkmenistan or turkmen or uganda or ukraine or uruguay or uzbekistan or uzbek or vanuatu or new hebrides or venezuela or vietnam or viet nam or middle east or west bank or gaza or palestine or yemen or yugoslavia or zambia or zimbabwe or northern rhodesia or global south or africa south of the sahara or sub-saharan africa or subsaharan africa or africa, central or central africa or africa, northern or north africa or northern africa or magreb or maghrib or sahara or africa, southern or southern africa or africa, eastern or east africa or eastern africa or africa, western or west africa or western africa or west indies or indian ocean islands or caribbean or central america or latin america or "south and central america" or south america or asia, central or central asia or asia, northern or north asia or northern asia or asia, southeastern or southeastern asia or south eastern asia or southeast asia or south east asia or asia, western or western asia or europe, eastern or east europe or eastern europe or developing country or developing countries or developing nation? or developing population? or developing world or less developed countr* or less developed nation? or less developed population? or less developed world or lesser developed countr* or lesser developed nation? or lesser developed population? or lesser developed world or under developed countr* or under developed nation? or under developed population? or under developed world or underdeveloped countr* or underdeveloped nation? or underdeveloped population? or underdeveloped world or middle income countr* or middle income nation? or middle income population? or low income countr* or low income nation? or low income population? or lower income countr* or lower income nation? or lower income population? or underserved countr* or underserved nation? or underserved population? or underserved world or under served countr* or under served nation? or under served population? or under served world or deprived countr* or deprived nation? or deprived population? or deprived world or poor countr* or poor nation? or poor population? or poor world or poorer countr* or poorer nation? or poorer population? or poorer world or developing econom* or less developed econom* or lesser developed econom* or under developed econom* or underdeveloped econom* or middle income econom* or low income econom* or lower income econom* or low gdp or low gnp or low gross domestic or low gross national or lower gdp or lower gnp or lower gross domestic or lower gross national or lmic or lmics or third world or lami countr* or transitional countr* or emerging economies or emerging nation?).ti,ab,sh,kf.

56 (afghan or afghans or afghani or albanian? or algerian? or american samoan? or angolan? or antiguan? or barbudan? or argentine? or argentinian? or argentinean? or armenian? or aruban? or azerbaijani? or bahraini? or bangladeshi? or bangalees or bajan? or belarusian? or byelorussian? or belizean? or beninese? or bhutanese or bolivian? or bosnian? or botswana or batswana or brazilian? or brasilian? or bulgarian? or burkinabe or burkinese or burundian? or cape verdean? or cabo verdean? or cambodian? or khmer or cameroonian? or central african? or chadian? or chilean? or chinese or colombian? or comorian? or congolese or costa rican? or ivorian? or croatian? or cuban? or cypriot? or czech? or djiboutian? or dominican? or ecuadorian? or egyptian? or salvadoran? or equatorial guinean? or equatoguinean? or eritrean? or estonian? or swazi? or swati? or ethiopian? or fijian or gabonese or gabonaise or gambian? or georgian? or ghanaian? or gibraltarian? or greek? or grenadian? or guamanian? or guatemalan? or guinean? or bissau guinean? or guyanese or haitian? or honduran? or hungarian? or indian? or indonesian? or iranian? or iraqian? or iraqi? or manx or jamaican? or jordanian? or kazakhstani? or kenyan? or kirabati or kirabatian? or north korean? or korean? or kosovar? or kosovan? or kyrgyz* or lao or laotian? or latvian? or lebanese or lesothan? or lesothonian? or mosotho or basotho or liberian? or libyan? or lithuanian? or macanese or macedonian? or malagasy or madagascan? or malawian? or malaysian? or maldivian? or malian? or maltese or marshallese? or mauritanian? or mauritian? or mexican? or micronesian? or moldovan? or mongolian? or mongol or montenegrin? or moroccan? or mozambican? or burmese or myanmar or namibian? or nauruan? or nepali or nepalese or netherlands antillean? or nicaraguan? or nigerien? or nigerian? or northern mariana islander? or mariana? or omani? or pakistani? or palauan? or palestinian* or panamanian? or papua new guinean? or paraguayan? or peruvian? or philippine? or philipine? or phillipine? or phillippine? or filipino? or filipina? or polish or pole or poles or portuguese or puerto rican? or romanian? or russian? or soviet people or soviet population or rwandan? or rwandese or ruandan? or ruandese or samoan? or sao tomean? or santomean? or saudi arabian? or saudi? or senegalese or serbian? or montenegrin? or seychellois or seychelloise? or sierra leonean? or slovak? or slovene? or solomon islander? or somali? or south african? or south sudanese or sri lankan? or ceylonese or kittitian? or nevisian? or saint lucian? or vincentian? or sudanese or surinamese? or syrian? or tajik? or tajikistani? or tadjik? or tadjikistani? or tanzanian? or

tanganyikan? or thai or timorese? or togolese or tongan? or trinidadian? or tobagonian? or tunisian? or turk? or turkish or turkmen? or tuvaluan? or ugandan? or ukrainian? or uruguayan? or uzbek? or vanuatu* or venezuelan? or vietnamese or yemeni? or yemenite? or yemenese or yugoslav? or yugoslavian? or zambian? or zimbabwean?).ti,ab,sh,kf.
57 or/55-56
58 54 and 57

Appendix 2. Countries categorised as low- and middle-income by the World Bank

Correct to 2019 (World Bank 2020).

Afghanistan
Albania
Algeria
American
Angola
Argentina
Armenia
Azerbaijan
Bangladesh
Belarus
Belize
Benin
Bhutan
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Bulgaria
Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Central African Republic
Chad
China
Colombia
Comoros
Congo, Democtratic Repuplic
Congo, Republic
Costa Rica
Côte d'Ivoire
Cuba
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt, Arab Republic
El Salvador
Equatorial Guinea
Eritrea Mali
Eswatini
Ethiopia
Fiji
Gabon
Gambia, The
Georgia
Ghana
Grenada
Guatemala
Guinea

Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia
Iran, Islamic Republic
Iraq
Jamaica
Jordan St Vincent and the Grenadines
Kazakhstan
Kenya
Kiribati
Korea, Democratic People's Republic
Kosovo
Kyrgyz
Lao People's Democratic Republic
Lebanon
Lesotho
Liberia Sudan
Libya
Madagascar
Malawi
Malaysia
Maldives
Marshall Islands
Mauritania
Mexico
Micronesia, Federated States
Moldova
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nepal
Nicaragua
Niger
Nigeria
North Macedonia
Pakistan
Papua New Guinea
Paraguay
Peru
Philippines
Republic
Russian Federation
Rwanda
Samoa
Samoa
São Tomé and Principe
Senegal
Serbia
Sierra Leone
Solomon Islands
Somalia
South Africa
South Sudan
Sri Lanka
Saint Lucia
Suriname

Syrian Arab Republic
Tajikistan
Tanzania
Thailand
Timor-Leste
Togo
Tonga
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
Ukraine
Uzbekistan
Vanuatu
Venezuela, Republic
Vietnam
West Bank and Gaza
Yemen, Republic
Zambia
Zimbabwe

CONTRIBUTIONS OF AUTHORS

MT is the guarantor for the review and revised the new version of the protocol, including both the Background and Methods sections.

QL and QL developed the original version of this protocol (Liu 2017) and approved subsequent revisions.

HN provided guidance and feedback on the Background and Methods sections, in collaboration with MT.

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