Does training of Community Health Workers in diabetes lead to improved outcomes for diabetes, screening and management in low-and-middle-income-countries:A systematic review protocol

Anirudh Gaurang Gudlavalleti, Giridhara R. Babu, Suresh Kumar Kamalakannan, G V S Murthy, Nicolaas C Schaper, Onno van Schayck

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Anirudh Gaurang Gudlavalleti[1] MA; Giridhara R. Babu[2]; Suresh Kumar Kamalakannan[3]; G V S Murthy[4]; Nicolaas C Schaper[5]; Onno van Schayck[5]

[1]Maastricht University Hyderabad IN
[2]Qatar University Doha QA
[3]Northumbria University North Umbria GB
[4]Pragyaan Sustainable Health Outcomes Foundation Hyderabad IN
[5]Maastricht University Maastricht NL

Corresponding Author:
Anirudh Gaurang Gudlavalleti MA
Maastricht University
PRASHO
World Trade Centre
Hyderabad
IN

Abstract

Background: Diabetes, particularly Type 2 Diabetes Mellitus (T2DM), is a global health crisis disproportionately affecting low- and middle-income countries (LMICs). Task-shifting strategies employing Community Health Workers (CHWs) have emerged as a promising approach to address healthcare barriers in LMICs, although their effectiveness in diabetes management remains uncertain.

Objective: To establish the protocols for a systematic review assessing whether training CHWs in diabetes management leads to improved outcomes in screening and managing diabetes in LMICs.

Methods: The systematic review protocol follows the PRISMA guidelines and has been registered with PROSPERO (CRD42022341717). Eligible studies will include randomised controlled trials and meta-analyses conducted between January 2000 and December 2023, focusing on training CHWs in diabetes management in LMICs. Studies will be searched in various databases, including PubMed, Scopus, Cochrane Central, and others. The review will include studies reporting outcomes such as changes in diabetes referrals, screenings, HbA1c values, and fasting blood glucose levels. Data extraction will be independently conducted by two reviewers using a custom-made form, with discrepancies resolved by a third reviewer. Risk of bias assessment will follow Cochrane and ROBINS tools for randomized and non-randomized studies, respectively. A narrative synthesis will explore the intervention's effects and implementation factors, with subgroup analyses planned based on CHW types and demographic factors. Meta-analysis will be conducted for the outcome measures.

Results: The systematic review aims to provide comprehensive evidence on the effectiveness of training CHWs in diabetes management in LMICs. Findings will be synthesized narratively and, if feasible, through meta-analysis.

Conclusions: This systematic review protocol outlines a rigorous methodology to evaluate the impact of training CHWs in diabetes management in LMICs. By synthesizing available evidence, this review aims to present scientific evidence of the highest order for CHW training design and associated policies. Clinical Trial: The trial has been registered with PROSPERO (CRD42022341717)

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Article Title: Does training of Community Health Workers in diabetes lead to improved outcomes for diabetes, screening and management in low-and-middle-income-countries:A systematic review protocol

Authors: Anirudh G. Gudlavalleti[1,2*], Giridhara R. Babu[3], Suresh Kamalakannan[2], GVS Murthy[2], Nicolaas C. Schaper[1], Onno CP van Schayck[1]

Affiliations:

[1]Maastricht University,
[2]Pragyaan Sustainable Health Outcomes Foundation;
[3]Qatar University; gbabu@qu.edu.qa
*Corresponding Author:Name: Anirudh Gaurang Gudlavalleti; Email: anigaurang87@gmail.com/ a.gudlavalleti@maastrichtuniversity.nl; Tel.: +91-8008799816; Address: Pragyaan Sustainable Health Outcomes Foundation, 2nd Floor, World Trade Centre Shamshabad, Nanakramguda, Hyderabad-500032

Abstract:

Introduction: Diabetes is a growing concern worldwide, particularly in low- and middle-income countries (LMICs). Type 2 Diabetes Mellitus (T2DM) constitutes a significant proportion of cases and is associated with debilitating microvascular complications. T2DM is steadily increasing among the LMICs where many barriers to healthcare exist. Thus, task shifting to community health workers (CHWs) has been proposed as a solution to improve diabetes management in these settings. However, CHWs often lack the necessary training to manage diabetes effectively. Thus, a systematic review is required to present evidence of the highest degree for this intervention and this protocol aims to establish the outline for such a review. These protocols have been registered with PROSPERO at PROSPERO 2022 CRD42022341717.

Methodology: Using the PICOTS framework, this protocol outlines a systematic review aiming to evaluate the impact of training programs for CHWs in diabetes management in LMICs. Quantitative studies focusing on CHWs, diabetes training, focusing on diabetes management outcomes like HbA1c levels and fasting blood glucose levels, between January 2000 and December 2023 and found on databases like PubMed, Ovid Medline, EMBR, BASE, Google Scholar, Web of Science, etc. will be included. We will include RCTs but will include observational studies if we find less than 5 RCTs. Three reviewers will form the author committee, where two will conduct the review independently while the third will resolve all disputes. The ROB-2 tool will used for assessing the risk of bias and the GRADE approach for the meta-analysis and narrative synthesis analysis will be utilized. The results will be presented in a PRISMA diagram.

Results: The review will begin in May 2024 and conclude in three months.

Conclusion: The review will synthesize existing evidence and provide insights into the effectiveness of such programs, informing future research and practice in diabetes care in LMICs.

Introduction

Diabetes is a global epidemic that is threatening to grow exponentially and impact the lives of those affected. The International Diabetes Federation (IDF) estimates 463 million people who have Diabetes globally and projects this number increasing to 700 million by 2045)[1]. Almost, eighty per cent of the world's diabetes patients reside in low-and-middle-income countries [2]. Type 2 Diabetes Mellitus (T2DM) constitutes a majority of diabetes patients (almost 90%) and it severely affects the patients by causing microvascular

complications that are often debilitating and morbid[3]. The condition itself is a risk factor for many other conditions like stroke, cancer, tuberculosis, etc. and causes damage to critical organs like the heart, kidneys, eyes and the limbs [4][5]. The immunocompromised nature of the patients , makes them susceptible to infections and overall contributes to poorer health outcomes in them.

The Low and Middle Income Countries (LMICs) are also gradually witnessing a rise in the prevalence of the disease in rural areas[6]. The LMICs are also plagued with barriers like trained healthcare professionals who are required to cater to this growing number of diabetic patients, large distances to the health centres, lack of transport facilities, etc. often causing poorer uptake of health services[7–9].

The T2DM disease burden has increased exponentially in LMICs due to continuous upward growth in the trajectory of common risk factors responsible for T2DM. These have caused an increase in the comorbidities associated with the condition across the LMICs[10]. Similarly, the age-standardized death rates over the past decade have seen a two to three-fold increase in the LMICs, when compared to the Upper or Middle-Income countries[11]. Recent studies have shown an increase in the prevalence of T2DM in lower socio-economic areas of LMICs[6,12]. They also show that the increase in the prevalence of prediabetes is greater in these areas than the rate of increase in urban areas.[13,14]. Hence, the burden is set to increase amongst populations that have remote access to healthcare services or cannot afford the life-long management costs associated with T2DM[14–18].

Thus, a potential method of overcoming these barriers has been the use of community health workers (CHWs) for task shifting in LMICs for both infectious diseases and non-communicable diseases (NCDs) [19–27]. All such task shifting initiatives, need to ensure that the participating CHWs are provided requisite training. Most CHW studies have found them to be deficient in knowledge and associated skills and hence training them for any task-shifting initiative is critical for its success[28–31].

Where training has been provided, the results have generally been encouraging. However, such training programs have been few, and their evaluations have been rare. Evidence is found wanting for the efficiency of trained CHWs in LMICs in screening and managing patients with diabetes. Hence a systematic review is required to present evidence of the highest degree for this intervention and we propose to conduct the systematic review to understand if training of community health workers in diabetes would lead to improved

outcomes for diabetes, screening and management in low- and middle-income countries.

Thus, the objective of this paper is to establish the protocols for the systematic review.

The systematic review has been registered with PROSPERO, at PROSPERO 2022 CRD42022341717[32].

Methodology: The criteria for considering studies for the systematic review would be done according to PICOTS framework. Therefore, we would be considering the studies under the following the condition, the participants, the intervention, the comparators, the outcomes, the types of studies, the timing of the study. Along with these, the databases to be used for the search will also be considered.

Description of condition: Type 2 diabetes mellitus will be the condition of interest. It accounts for almost 90% of diabetes globally and thereby affects a larger proportion of the population suffering from it. We will consider the WHO cut-off value of 126mg/dl for fasting plasma glucose or 200 mg/dl for 2 hour post food plasma glucose to classify a person as suffering from diabetes[33]..

Description of participants: Community Health Workers (CHWs) of Low- and middle-income countries (LMICs) will be considered participants for studies/trials to be included in this review. The World Health Organization (WHO) defines a community health worker to be *members of the communities where they work, should be selected by the communities, should be answerable to the communities for their activities, should be supported by the health system but not necessarily be a part of its organization, and have shorter training than professional workers*[34]. Hence, we will include all studies which include the CHWs in LMICs. The LMICs will be defined according to the World Bank definition of economies as those with a Gross National Income (GNI) per capita between $1,136 and $4,465, calculated using the World Bank Atlas method[35]. A detailed list of the countries is given in Annexure 1.

Description of the intervention: The CHWs employed for task shifting have been found to have deficient knowledge. This can be corrected by providing them with the requisite training as training has been evidenced as an effective instrument for improving their knowledge, skills, and practices in LMICs[36,37]. Training in Type 2 Diabetes Mellitus (T2DM) management includes the systematic application of formal processes to impart knowledge and help people acquire the skills necessary for them

to perform their jobs satisfactorily. Hence, studies reporting any training related to the knowledge, skills and performance of the CHWs will be included. Some of the common aspects of training might include,

- Screening of glycemia,
- Lifestyle advice and education for patients,
- Measurement of glycemia, and
- Referral indications related to the above items.

Description of the Comparator: Standard training given to CHWs will be considered as the comparator. Therefore, any such training (whether focused on diabetes or even no training) provided to the CHWs would be included as the comparator.

Description of Studies: For the review, we will include randomised control trials as the first choice of studies, conducted between January 2000 to December 2023, in LMICs and published in English. This is due to the fact they present the highest degree of scientific evidence and the World Health Organization and the World Medical Association published their guidelines and resolutions on task shifting respectively[38,39] around this time period. If there are less than 5 such studies, we will then include observational studies as well. For the purpose of high scientific evidence, we will exclude qualitative studies .The included studies will focus on the training of CHWs in diabetes and look at diabetes management as their outcome. The details about the outcomes are detailed in the section below.

Description of Outcomes: As we wish to study the effect of the training on diabetes management, we will include studies reporting any of the following outcomes with the respective measures of effect:

- Referral for diabetes- Change in the number of referrals
- Screening for diabetes- Change in the number of screenings
- HbA1c values- Change in the mean HbA1c values
- Fasting blood glucose values- Change in the mean fasting blood glucose values

Databases for search: For our review, we would search for appropriate studies on the following databases:

- Ovid MEDLINE,
- PubMed
- Scopus,

- Cochrane Central, and
- Evidence Based Medicine Reviews,

Additionally, we will also search the bibliographies of all the trials included based on our search strategies to identify further relevant studies. We will also be searching for all pertinent grey literature as this will help us identify the case studies and reports in greater detail. This will include a search of the databases about grey literature like BASE, Google Scholar, WHO International Clinical Trials Registry Platform and World Cat. These will help us identify reports of studies conducted by private and civil society organizations or by other PhD students. The provisional search strategy for PubMed has been described in Annexure 2.

Study selection for the review: Study titles and abstracts, which will be obtained through electronic source search, will be independently read by the authors (AG & R). The articles would then be selected for eligibility, based on the criteria above. Articles that the authors find to be eligible will be retrieved in the full-text form. In case any of these articles are later found to be unsuitable for inclusion in our review, they would be mentioned separately in detail in a tabular manner, titled Table of excluded studies. The PRISMA-P[40] guidelines have been adhered to for this protocol and PRISMA guidelines will be adhered to for the conduct of the review (PRISMA-P checklist attached as Annexure-3). The full-text review will be carried out independently by both the authors (AG & R). The third author (GRB) will resolve any disagreements which might arise.

Data Extraction & Synthesis: The data extraction will be done by two reviewers independently. They will first develop a custom-made data extraction form using the Cochrane collaboration template for Randomised Controlled Trials (RCTs) & non-RCTs. This form will first be piloted with a small sample of study designs included in the review. The data will be extracted to prespecified and pre-approved sheets using Microsoft Excel. These forms will be prespecified by the authors to include a recording of the study characteristics, the outcomes of interest and all relevant information. Furthermore, these forms will be shared with the author committee members for their feedback and for them to further pilot it put on a small number of studies. Based on this the forms would either be revised or finalized. In this manner, these forms would be pre-approved and finalized. The final version of the form will be used to extract & subsequently collect data from all the

included studies by the review authors. Any disagreements will be resolved by the third reviewer.

If the data extracted is found to be limited, then we will contact the study authors for further information. Finally, we will also contact the authors of the included trials or studies to ascertain if they would like to answer any questions regarding the trials or studies. All the results will be presented in an appendix. Any missing or otherwise relevant information will be obtained from the primary authors of the original trials or studies (if needed).

Lastly, in cases of multiple publications, we will consider the final or the updated version of each study as the primary reference. This will ensure that the latest evidence is included in the review.

The following information will be extracted from the included studies:

- Training Characteristics: We will extract characteristics like the duration of training, Frequency of training, the content of training, location of training

- The outcomes as reported by the study authors and will include the following outcomes:
  - o Referral for Diabetes
  - o Screening for diabetes
  - o HbA1c scores
  - o Fasting Blood glucose values

We will use the desktop version of a software like COVIDENCE or SysRev for the extraction process.

Risk of bias (quality) assessment

We will follow the revised risk of bias version 2 (ROB) tool[41], which is a modified version of the Cochrane risk of bias tool to assess the internal validity of the included randomized controlled trials. The tool includes an assessment of sequence generation and allocation concealment, blinding of participants and outcome assessment, incomplete outcome data and selective outcome reporting.

We will use ROBINS risk of bias tool in non-randomised studies (if included) of intervention for assessing the risk of bias in non-randomised studies included in the review. This will be done at the outcome level. All three

reviewers (AGG, R and GRB) will be a part of the review. The first two will be conducting the review and in case of any disagreement which can't be resolved between them, the third reviewer will resolve the disagreement and his decision will be final. If the information available from the sources is inadequate, then we will contact the primary authors of the studies to include details to request any missing data on items that could have contributed to the risk of bias. The individual bias items will be evaluated based on the items described in the *Cochrane Handbook for Systematic Review of Interventions-version 6.1, 2020*[42].

Strategy for data synthesis

A preliminary search for studies, showed a lot of heterogeneity, in terms of the training, like the study settings, participant education, professional experience, training frequency, training duration and training content. Expecting this trend in the studies to be extracted & included, the authors will synthesize the training component narratively as per the Cochrane Handbook's suggestion.

The preliminary search also showed homogeneity in terms of the outcome results, like the mean change in fasting blood glucose values and the mean change in HbA1c values. We will perform a meta-analysis and report the results in a PRISMA- diagram[43].

The data points which the reviewers would look for synthesis are:

i. The effect of the intervention: Authors will determine if studies are estimating the same underlying treatment/intervention effect. As our review focuses on CHW training as the intervention, we will be looking if the studies are estimating the intervention effect in terms of knowledge, skills and performance of the CHWs related to diabetes, i.e. the interventions focusing on:
    - Screening
    - Referral
    - HbA1c levels &
    - Fasting blood glucose levels

Additionally, the methodology & participant(s) being studied will also be studied.

ii. The factors affecting the implementation of the study interventions.

For the continuous data points, we would use the mean difference method for meta-analysis while we would use the odds ratio and the risk ratio methods for the discrete data points. In both the cases the confidence

intervals would be 95%.

The narrative synthesis will be carried out by developing a general framework using a set of tools like MS Excel and Mendeley or Endnote. This will be executed using the following steps:

- Develop a theory of change to understand how the intervention works, why it works and for whom it best works
- Development of preliminary synthesis of findings of all the studies to be included
- Exploration of relationships across the entire data from the included studies.
- Assessment of the robustness of the synthesis.

The main narrative findings will be reported in a table titled 'Summary of Findings' by using the GRADE approach as mentioned in the Cochrane Handbook. The within-study risk of bias to assess the methodological quality, the directness of the evidence, the heterogeneity, the precision effect estimates, and the risk of publication bias will also be considered.

Eventually, a rating system to rate the quality of the evidence for each of the outcomes in terms of high, moderate, low & very low will be created. The same GRADE method will also be used for the meta-analysis findings.

Analysis of subgroups or subsets

We plan to perform subgroup analysis according to the following factors:

• Types of community health workers (nurses, lay health workers, etc.)

• Demographic factors of health workers (education, work experience, etc.)

These factors will be analysed for homogeneity or heterogeneity using the chosen software. All data would be entered in the software and tabulations would be carried out concerning each of the factors mentioned above to assess the heterogeneity/homogeneity. We would be utilizing the Q statistic and I-square methods for assessing the heterogeneity. Further relationships will be explored within the data using the aforementioned factors and the predefined outcomes. A statistical test of significance will be carried out for each of the mentioned factors and an eventual summary will be presented to showcase statistical significance (if present) based on the p-value of the association using the one-tailed test for each factor and its relationship with each outcome.

Results:

The review will be started in May 2024 and will be completed in a timeframe of 3 months. This will include the screening, abstract review, full-text review, data extraction and data synthesis.

Discussion:

Diabetes is a pressing global health challenge, particularly affecting low- and middle-income countries (LMICs), where the prevalence is rapidly increasing among sections that are unable to afford or access quality healthcare. These patients are at high risk of developing complications which affect the critical organs of the body. This combined with the delayed wound healing and their immunocompromised status, contributes to poorer outcomes for them. This underscores the importance of developing effective strategies for managing T2DM, particularly in LMICs where access to healthcare services can be limited.

One such strategy is use of community health workers (CHWs) for task shifting. CHWs, who are often members of the communities they serve, play a vital role in delivering healthcare services, including diabetes management, in LMICs. . However, CHWs lack the necessary knowledge and skills to manage diabetes and thus require training to improve their capacities. While there is some evidence to suggest that such training programs are successful in improving the CHWs knowledge, skills, and performance in diabetes management, such studies are few and their evaluations are rare. Therefore, there is a need for a systematic review to assess the impact of training programs for CHWs on diabetes outcomes in LMICs.

This protocol aims to establish the outline for such a systematic review and has been registered with PROSPERO.

Possible findings from the review may include evidence supporting the effectiveness of training programs in improving CHWs' ability to screen for diabetes, refer patients for further care, and manage diabetes-related outcomes such as HbA1c levels and fasting blood glucose values. The review may also identify gaps in the existing literature, such as the lack of rigorous evaluations of training programs or the need for more studies in certain geographical regions or among specific populations.

The limitations of the study would be possible deviations from the protocols due to unexpected results in terms of number of studies, language restrictions, type and number of studies and the quality of studies.

In conclusion, our protocol aims to establish a systematic review that will have the potential to influence

future efforts of CHW training for effective diabetes management in LMICs.

Author Contributions: Conceptualisation: A.G.G., S.K, G.R.B., N.C.S. and O.C.P.v.S. Validation: N.C.S., G.R.B. and O.C.P.v.S. Data curation: A.G.G., S.K and G.R.B. Funding acquisition: NA. Methodology: A.G.G., S.K, G.R.B., G.V.S.M., N.C.S. and O.C.P.v.S. Project administration: A.G.G. S.K. Resources: A.G.G., S.K, G.R.B. Software: NA. Supervision: S.K, G.R.B., G.V. S.M., N.C.S. and O.C.P.v.S. Writing—original draft: A.G.G. Writing—review and editing: A.G.G., S.K, G.R.B., G.V.S.M., N.C.S. and O.C.P.v.S. All authors have read and agreed to the published version of the manuscript

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Conflicts of interest: The authors do not report any conflict of interest.

Abbreviations: CHW- Community Health Worker; LMIC- Low and Middle Income Country; T2DM- Type 2 Diabetes Mellitus; RCT- Randomised Controlled Trial

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Data Availability: As the article is a protocol for a systematic review, hence there is no data. All supplementary materials are provided as annexures. In case of any queries, the corresponding author can be contacted and they will ensure the requisite query/ data is provided.

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Annexure 1: List of Low-Middle-Income-Countries defined by World Bank 2024

Angola	Jordan	Philippines
Algeria	India	Samoa
Bangladesh	Iran, Islamic Rep	São Tomé and Principe
Benin	Kenya	Senegal
Bhutan	Kiribati	Solomon Islands
Bolivia	Kyrgyz Republic	Sri Lanka
Cabo Verde	Lao PDR	Tanzania
Cambodia	Lebanon	Tajikistan
Cameroon	Lesotho	Timor-Leste
Comoros	Mauritania	Tunisia
Congo, Rep.	Micronesia, Fed. Sts.	Ukraine
Côte d'Ivoire	Mongolia	Uzbekistan
Djibouti	Morocco	Vanuatu
Egypt, Arab Rep.	Myanmar	Vietnam
Eswatini	Nepal	Zambia
Ghana	Nicaragua	Zimbabwe

Guinea	Nigeria	
Haiti	Pakistan	
Honduras	Papua New Guinea	

Annexure 2: Provisional Search Strategy for PubMed

((community health worker[MeSH Terms]) OR (community health workers[MeSH Terms])) OR (lay worker))) OR (CHW)) OR (health worker)) OR (health worker, community[MeSH Terms])) OR (health worker, village[MeSH Terms])) OR (health workers, community[MeSH Terms])) OR (ASHA)) OR (ANM)) OR (MPHW)) OR (JHA)) OR (MPW)) OR (MPHA)) AND (academic training[MeSH Terms])) OR (traini[MeSH Terms])) OR (activities, training[MeSH Terms])) OR (training)) OR (capacity building[MeSH Terms])) OR (activities, educational[MeSH Terms])) OR (activity, educational[MeSH Terms])) OR (education)) OR (hospital, teaching[MeSH Terms])) OR (hospitals, teaching[MeSH Terms])) OR (method, teaching[MeSH Terms])) OR (teaching)) OR (interactive tutorial[MeSH Terms])) OR (tutoring)) OR (coaching)) OR (supervision[MeSH Terms])) AND (effect, placebo[MeSH Terms])) OR (effects, placebo[MeSH Terms])) OR (placebo effect[MeSH Terms])) OR (placebos[MeSH Terms])) OR (placebo effects[MeSH Terms])) OR (care standard[MeSH Terms])) OR (care standards[MeSH Terms])) OR (standard training)) AND (type 2 diabetes mellitus[MeSH Terms])) OR (Typ[MeSH Terms])) OR (blood glucose[MeSH Terms])) OR (home blood glucose monitoring[MeSH Terms])) OR (monitoring, home blood

glucose[MeSH Terms])) OR (Fasting Blood Glucose)) OR (FBS)) OR (Random Blood Glucose)) OR (Random Blood Sugar)) OR (Fasting Blood Sugar)) OR (RBS)) OR (consultation and referral[MeSH Terms])) OR (hospital referral[MeSH Terms])) OR (hospital referrals[MeSH Terms])) OR (referrals, hospital[MeSH Terms])) OR (referrals[MeSH Terms])) OR (physician self referral[MeSH Terms])) OR (physician self referrals[MeSH Terms])) OR (referrals, hospital[MeSH Terms])) OR (self referrals, physician[MeSH Terms])) OR (screening))) OR (a1b hemoglobin, glycosylated[MeSH Terms])) OR (glycosylated a1b hemoglobin[MeSH Terms])) OR (glycosylated hemoglobin[MeSH Terms])) OR (HbA1c)) OR (ogtt[MeSH Terms])) OR (glucose tolerance test[MeSH Terms])) OR (glucose tolerance tests[MeSH Terms])) OR (glucose tolerance, oral[MeSH Terms])) OR (microvascular complications)) OR (DR Screening)) OR (Diabetic Retinopathy Screening)) OR (Peripheral Neuropathy Screening) AND (clinicaltrial[Filter] OR meta-analysis[Filter] OR randomizedcontrolledtrial[Filter])) AND (countries, developing[MeSH Terms])) OR (countries, developing[MeSH Terms])) OR (countries, less developed[MeSH Terms])) OR (LMIC)) OR (Low and Middle Income Country)) OR (Low and Middle Income Countries) Filters: **Clinical Trial, Clinical Trial, Phase III, Controlled Clinical Trial, Meta-Analysis, Pragmatic Clinical Trial, Randomized Controlled Trial, Systematic Review, Adult: 19+ years, from 2000/1/1 - 2023/4/1**

Annexure-3 : PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on a Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Yes
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Yes
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Yes
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Yes
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not an Amendment
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Yes
Sponsor	5b	Provide name for the review funder and/or sponsor	Not

			Applicable (NA)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	NA
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Yes
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Yes
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Yes
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Yes
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Yes
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Yes
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Yes
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Yes
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Yes
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Yes
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Yes
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Yes
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Yes
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Yes
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Yes
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Yes
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Yes

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group.

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.