SUPPLEMENTARY FILE: 1

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

Item No	Checklist item
NFORM	IATION
1a	Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in Low and Middle-Income Countries: A Systematic Review
1b	N/A
2	The study has been registered in PROSPERO and the Registration ID is CRD42021245517.
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	No NFORM 1a 1b 2

Contributions	3b	All authors were involved in the development of the selection	
		criteria, and data extraction criteria. All authors will read, provide	
		feedback and approve the final manuscript.	
Amendments	4	As the review is being carried out amendments to the search	
		strategy, selection criteria, and data extraction criteria may be	
		amended to include the most pertinent information for this	
		review's objectives. If amendments to this protocol are made, the	
		date of each amendment along with a description/rationale for the	
		change will be noted.	
Support:			
Sources	5a	Nil	
Sponsor	5b	Nil	
Role of	5c	Not Applicable.	
sponsor or			
funder			

INTRODUCTION

Rationale

Rationale: A deeper knowledge of the influence of mHealth applications in controlling blood sugar levels and managing diabetes is crucial for diabetes self-management, especially in the LMICs. Hence, this review aims to assess the effectiveness of mHealth applications in managing T2DM among the LMICs, with a focus on Indian studies because India has the highest burden of diabetes among the LMICs.

Objectives

7

- 1. To identify the effectiveness of mHealth applications in managing blood glucose levels of individuals with T2DM and
- To assess the impact of using mHealth applications in managing T2DM concerning health-promoting behavior among the LMICs in the context of India

1.

METHODS

Eligibility criteria

8 We followed the PICO concept/framework

Population (P): Adults over 18 years of age, technology literate, using a smartphone or personal computer diagnosed with type 2 diabetes mellitus based on any one of the WHO 2020 criteria for diagnosis¹⁷ i.e., HbA1c values ≥6.5% (48 mmol/mol), Fasting Blood Glucose (FBG) ≥7.0 mmol/L (126 mg/dL), Random plasma/Blood Glucose (RBS) ≥11.1 mmol/L (200 mg/dL), an Oral Glucose Tolerance Test (OGTT) ≥200 mg/dl.

Intervention (I): mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. mHealth solutions like applications or text messages, emails, video clips, graphics, and web services.

Comparison (C): the comparator groups would be the individuals who received standard hospital treatment or no hospital care and those who received an intervention.

Country comparison: impact of using diabetes self-management app among the LMICs listed by the World Bank-India in particular.

Outcomes(O): primary outcomes- clinical parameter HbA1c Secondary outcomes- adherence to medications, self-efficacy, and Health-promoting behaviour.

Information sources

9 Authors in collaboration developed search strategies using medical subject headings (MeSH) and text words related to the topic. We will search CINAHL, PubMed, Web of Science, and Scopus. Only studies with human subjects will be included.

Search strategy

10 Refer to supplementary file 2.

Study records:

Data management

11a The search results collected from the electronic databases will be exported to Endnote version X7. Duplicate studies will be removed.

Data will then be extracted, and relevant information will be extracted to an Excel spreadsheet using a data extraction tool.

Selection process

11b

Two authors will independently screen each title for inclusion in the systematic review using the eligibility criteria. Abstracts of studies included in the first stage of screening will be independently evaluated by two authors. Exclusion of the studies in this stage will be done only after expert advice and the included studies will be screened further for full text by the authors. At the full-text screening stage, if both the authors reject a study then it will be excluded and if a disagreement arises between the two authors on the inclusion or exclusion of the paper, then the disagreement will be resolved by the third reviewer or an expert and then will arrive at conclusion on including or excluding a paper based on predetermined criteria. Reasons for exclusion will be given at the full-text screening stage and the PRISMA flowchart will be used to depict the screening process. The rationale for exclusion will be provided for all the excluded studies throughout the process.

Data collection process

11c

Data extraction will be performed using a standardised pre-tested data extraction format by the authors. The data extraction form will be pilot tested by each author and will be edited based on discussion among the authors. (Refer; supplementary file-3 Data extraction format)

Any missing data in the studies included for review will be obtained by contacting the study authors of that study.

Data items

12

Bibliometric information such as Author's name, Author's affiliations, Title, Journal name, publication year, and country of conduct will be collected along with Characteristics of the included studies. Data will be extracted based on the type of study, study objectives, Inclusion criteria, participant's characteristics, Intervention details, comparator, and the study outcome.

Outcomes and prioritization

13

A detailed summary of all the included studies will include information on authors, study objectives, Inclusion criteria,

Intervention details, comparator, outcome measures, and the country will be in a narrative format.

An evaluation will be done if it is appropriate to perform a metaanalysis to assess the effectiveness of diabetic self-management apps in controlling type 2 diabetes.

Meta-analysis with a random-effects model will be performed if there is a similarity in terms of the participants, study design, comparator, and outcomes.

Risk of bias in individual studies

Two authors will independently assess the risk of bias in included studies. The Cochrane Risk of Bias (RoB 2) tool will be used to evaluate Randomised controlled trials. Risk of bias in Nonrandomized Studies of Interventions assessment tool (ROBINS-I) for Non-Randomised studies.

Data synthesis

15a

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15b

A detailed summary of all the included studies in a narrative format will be given. It will include information on authors, study objectives, Inclusion criteria, Intervention details, comparator, outcome measures, and the country. Secondly, an evaluation will be done if it is appropriate to perform a meta-analysis to assess the effectiveness of diabetic self-management applications in controlling blood sugar levels. Meta-analysis with a random-effects model will be performed if there is a similarity in terms of the participants, study design, comparator, and outcomes. The pooled estimates will be obtained separately for RCTs, and Non-RCTs (Quasi-experimental and controlled before-after studies). The summary estimates will be expressed in mean difference, standardized mean difference for continuous outcomes, and relative risk & odds ratio for categorical outcomes with 95% confidence intervals. Forest plots, I² statistic, Chi² test, and Tau² will be used to measure and assess heterogeneity among the included studies in each analysis. Meta-regression will be used to investigate heterogeneity if appropriate data is obtained. An attempt will be made to contact the study authors if data is inadequate or missing and the record will be maintained on the amount of missing data with reasons. An assessment for publication bias will be made by creating a funnel plot only if there are at least 10 studies in the meta-analysis. A narrative synthesis will be done if there are less than 10 included studies.

	15c	
	15d	
Meta-bias(es)	16	Not applicable.
Confidence in	17	Not applicable.
cumulative		
evidence		