

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

# **BMJ Open**

## Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in LMICs: A Systematic Review Protocol

lournali	RM1 Open
Journal:	
Manuscript ID	bmjopen-2021-060108
Article Type:	Protocol
Date Submitted by the Author:	15-Dec-2021
Complete List of Authors:	dsouza, sherize; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Shetty, Sahana; Manipal Academy of Higher Education, Dept. Endocrinology, Kasturba Medical College Hospital, MAHE venne, Julien; Manipal Academy of Higher Education, Digital Health and wellbeing, Prasanna School of Public Health Pundir , Prachi ; Manipal Academy of Higher Education, Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Rajkhowa, Priyobrat; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health; Maastricht University, Prasanna School of Public Health Research Institute, Department of International Health, CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Jean Monnet Chair in European Public Health, Department of International Health
Keywords:	PUBLIC HEALTH, Information management < BIOTECHNOLOGY & BIOINFORMATICS, DIABETES & ENDOCRINOLOGY, PREVENTIVE MEDICINE, NUTRITION & DIETETICS, Epidemiology < TROPICAL MEDICINE

## SCHOLARONE<sup>™</sup> Manuscripts

Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in LMICs: A Systematic Review

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

## Abstract

Introduction: There are a variety of mobile health applications available to monitor an individual's health or lifestyle to make it convenient and easy to access healthcare facilities at home. Despite the growing number of mobile applications, the evidence from research on normalising HbA1c levels with the use of these applications remains a mystery to many of them. As a result, the goal of this research is to see, how effective are the diabetic self-management applications on controlling type 2 diabetes? And To compare the evidence obtained among the LMICs

Methods and analysis: The electronic databases included for search will be PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials and additional sources of the search will be grey literature available on diabetes management websites, and reference lists of included studies. Studies published in the English language in indexed and peer-reviewed sources and additional sources will be considered. Studies reporting the effectiveness of mobile applications in the management of Type 2 diabetes in the LMICs will be eligible for inclusion. Editorials, letters, commentaries, conference and workshop reports, and articles in languages other than English, will be excluded.

The Population-Intervention-Comparison Outcomes (PICO) Framework and the PRISMA statement 2021, will be used for reporting this systematic review.

Data analysis will be done by narrative synthesis, and a meta-analysis may be conducted if we come across homogenous data for the outcome.

Ethics and dissemination: As this study is a systematic review, we will not be recruiting any participants for the study and hence will not require ethical approval. The dissemination of the summary of the study results will be done at the conferences.

**Keywords:** mobile health application, self-management applications, and type 2 diabetes mellitus

Prospero registration ID: CRD42021245517

## Article summary:

Strengths of the study:

1. There are no systematic reviews published particularly focusing on self-managing type 2 diabetes with the help of mhealth technologies among the Low and Middle income countries.

elie

2. The study findings are intended to support and generalize the factors obtained among the LMICs

Limitations of the study are:

1. The study isn't funded and hence will limit to only articles published in the English language

2. The geographical area under study will be limited to only low and middle-income countries specifically in the context of India since the trial is conducted representing the Indian population only.

#### Introduction

'Diabetes' is a term used to describe a group of diseases characterized by elevated blood glucose levels. It is caused by a lack of insulin production or function, or both, which may occur for various reasons and lead to protein and lipid metabolic disorders <sup>1</sup>. Various scientific studies have established that adequate blood glucose regulation minimizes the long-term effects of type 2 diabetes. Due to multiple circumstances, adolescents often fail to meet their blood glucose goals to the required level. But their deep inclination towards technology provides an opportunity for the delivery of innovative selfmanagement interventions. A slew of issues plagues the delivery of healthcare in low and middle-income countries (LMICs). In 57 developing countries, the World Health Organization (WHO) estimates a 4.3 million healthcare worker shortage, resulting in understaffed hospitals, limited patient access to care, and a significant patient-physician contact gap, especially in rural areas <sup>2</sup>. To bridge this gap in terms of diabetes management, self-management app can play a pivotal role in India and the LMICs. The use of mobile health tools to help people manage chronic diseases is on the rise, but evidence of their effectiveness is mixed<sup>3</sup>. Patients with diabetes are increasingly using mobile technology for health (mHealth) interventions to help improve self-management: however, these interventions have not been implemented by a large number of patients, and dropout rates are common. In the management of diabetes, patient personality traits may play a key role in app adoption and active usage <sup>4</sup>.

#### **BMJ** Open

Diabetes has become so common in low- and middle-income countries (LMICs) that four out of every five people with diabetes now live in these countries, and the rate of diabetes is increasing in poorer communities <sup>5</sup>. Diabetes currently affects 336 million people in lowand middle-income countries (LMIC) <sup>6&7.</sup> Even in India, diabetes is rapidly growing and has reached the status of a potential epidemic, with more than 72.9 million diabetics currently diagnosed and projected to rise to 134.3 million by the year 2045, as reported by International Diabetes Federation (IDF) <sup>8</sup>. To manage diabetes and bridge the gap in terms of diabetes self-management among the LMICs, as well as to prioritise research agendas, public health interventions, and policies, a better understanding of the effect of mHealth in controlling and managing diabetes is indispensable. This review aims to assess the effectiveness of diabetic self-management applications on controlling type 2 diabetes in LMICs.

The global burden of type 2 diabetes mellitus (T2DM) continues to rise, with T2DM estimated to affect over 9% of the global population by 2035. The rising prevalence of T2DM will put pressure on healthcare systems to properly manage these individuals so that diabetes complications are avoided. Optimizing patient outcomes by combining medications with self-management of glycemic control and other risk variables could be a better approach. There is an increasing number of smartphone applications meant to help T2DM patients manage their condition, but only a few have been thoroughly tested<sup>9</sup>. mHealth applications are used in the self-management of type 2 diabetes mellitus along with standard care. The interventions may also include other forms of mHealth solutions like texting, emailing, video clips, and graphics. To find the evidence on how the use of mobile applications has impacted the health and self-management of type 2 diabetes among the individuals affected. Hence, our study objective is to understand-How effective are the diabetic self-management applications on controlling type 2 diabetes? And comparing the evidence obtained among the LMICs

ð

text

#### **Review Questions**

1. Are diabetic self-management applications effective in controlling diabetes among the type 2 diabetic individuals?

2. To find out the impact on behavioral outcomes due to use of Diabetic self-management applications?

## Methods

The PRISMA 2020 statement; an updated guideline for reporting systematic reviews<sup>10</sup> will be used for reporting the review and the population-intervention-comparisonoutcomes (PICO) framework will be used for defining the methods of the review. (Refer; supplementary file 1- PRISMA checklist).

Criteria for considering studies for this review

## Types of studies

Study design: The following study designs will be included: Randomized controlled trials (RCTs) to understand the effectiveness of the diabetic self-management app on the health of the app users, and Non Randomized controlled trials (NRCTs) like the Quasiexperimental studies, and controlled before after studies. We will exclude observational studies, conference papers, editorials, and other studies without any mobile app interventions in them.

## Type of participants

Individuals with type 2 diabetes mellitus in the LMICs as listed in the World Bank Organization and individuals who fulfill the WHO criteria for being diagnosed with T2DM, with no age restrictions on the population.

**Patient and public involvement:** patients and the public were not involved in any way in this study.

## Type of interventions

**Digital health**: The use of digital, mobile, and wireless technologies to support the achievement of health objectives. Digital health describes the general use of information and communications technologies (ICT) for health and is inclusive of both mHealth and eHealth<sup>11</sup>.

EHealth: is the use of information and communication technologies (ICT) for health.

The unprecedented spread of mobile technologies as well as advancements in their innovative application to address health priorities have evolved into a new field of eHealth, known as mHealth.

*mHealth:* The Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices<sup>12</sup>.

From the context of our study, the term mHealth refers to the mobile applications used in the self-management of type 2 diabetes mellitus. The interventions may also include other simpler forms of mHealth solutions like texting, emailing, video clips, graphics, and web services.

Type of Comparison: the comparator groups would be the individuals who received standard hospital treatment or no hospital care and who received an intervention.

## Type of outcome measures

**BMJ** Open

Primary outcomes

• Clinical outcome (HbA1c at 3months, 6 months, and over 1 year)

[A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives.<sup>13</sup>]

Secondary outcomes:

- Adherence to diabetic self-management applications and medication: The studies
  must have reported using any of the standard survey tools to record daily
  medication intake and app usage during the follow-up for a year.
- Self-efficacy with adherence to mHealth applications: Self-efficacy is defined as "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations." - Albert Bandura <sup>14, 15</sup>. The studies must have done a subjective evaluation of the individual's willingness to use the self-management applications to manage t2dm and those who are confident to follow in their near future.
- Behavior change- If the study participants during their follow-up period adapted the positive change in behavior towards achieving better health, like opting for a healthy diet, regular moderate exercising, brisk walking, reducing/ managing their stress levels. Will be checked across the quality of life improvement index if any done in the studies<sup>16</sup>.

Search methods for identification of studies

PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites, and reference lists of included studies. (Refer; supplementary file 2- Search strategies)

## Data extraction and management

We will be using endnote library version X7 for screening and downloading the full-text articles and Microsoft Excel 2013 will be used for data extraction of the full-text articles. 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 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 (Refer supplementary file 1) will be used to depict the screening process.

The rationale for exclusion will be provided for all the excluded studies throughout the process. 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 through contacting the study authors of that particular study.

#### Assessment of risk of bias in included studies

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<sup>17</sup>. Risk of bias in Non-randomized Studies of Interventions assessment tool (ROBINS-I) for Non Randomised studies<sup>18</sup>. The quality of the included studies will be assessed by using the Newcastle Ottawa Scale (NOS) for cross-sectional studies<sup>19</sup>.

#### Data synthesis

Firstly, we will provide a detailed summary of all the included studies in a narrative format. 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. Secondly, an evaluation will be done if it is appropriate to perform a metaanalysis to assess the effectiveness of diabetic self-management applications on 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. The results 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, I<sup>2</sup> statistic, Chi<sup>2</sup> test, and Tau<sup>2</sup> will be used to measure and assess heterogeneity among the included studies in each analysis. Meta-regression will be used to investigate heterogeneity if needed. An attempt will be made to contact 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

Protected by copyright, including for uses related to text

and

data mining, AI training, and similar technologies

> synthesis will be done if there are less than 10 included studies. All the analyses will be conducted in STATA 16.

> Description of primary and secondary outcomes, whether adherence to diabetic selfmanagement applications and medication has improved or not, Behavior change will be noted with the quality of life improvement index and self-efficacy will be checked following the improvement in managing T2DM. Listing out various measurement tools and devices used for judging the above-mentioned outcomes.

## Subgroup analysis

Subgroup analysis will be performed for the following if appropriate

Table 1

1) Duration of the intervention	<ul> <li>3 months</li> <li>6 months</li> <li>1 year</li> </ul>
2) Across the regions (LMIC's)	Comparing study effectiveness within the LMICs
3) Age groups	The most effective rate of using the Diabetic self- management app in age groups as classified by UN
4) Gender	Male/ Females

#### **BMJ** Open

## Author affiliations:

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

Email id of authors:

- 1. sherize.merlin@learner.manipal.edu
- 2. sahana.shetty@manipal.edu
- 3. julien.venne@manipal.edu
- 4. prachipundir2012@gmail.com
- 5. priyobrat.rajkhowa@learner.manipal.edu
- 6. melissa.glenda1@gmail.com
- 7. helmut.brand@manipal.edu

Email id for correspondence: helmut.brand@manipal.edu

**Ethics and dissemination:** The study will be a systematic review of the published articles from different recognised and accessible databases and will not recruit any human participants directly, therefore, ethical clearance is not applicable. The dissemination of the final review findings will be done in a national or international conference and will be published in an indexed peer-reviewed journal.

**Author Contributions:** HB is the corresponding author, SMD, SS, JV, PP, PR and SMD conceptualized the study. SMD, SS, JV, PP, PR MGL and HB drafted the manuscript. 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.

Acknowledgments: Not applicable.

**Funding:** This research received no specific grant from any funding agency in the public, commercial or not-for-profit sector

Conflicts of interest: There is no conflict of interest in this project.

Supplemental material: Supplementary materials are enclosed as 1, 2 and 3

## References:

	BMJ Open
1.	Diagnosis and classification of diabetes mellitus. Diabetes Care. 2013 Ja 36(SUPPL.1): S67-74.
2.	Mahmud N, Rodriguez J, Nesbit J. A text message-based intervention to brid the healthcare communication gap in the rural developing world. Technolo and Health Care. 2010 Jan 1; 18(2):137-44.3.
3.	Dugas M, Crowley K, Gao GG, Xu T, Agarwal R, Kruglanski AW, et al. Individu differences in regulatory mode moderate the effectiveness of a pilot mHea trial for diabetes management among older veterans. PLoS One. 201 13(3):e0192807.
4.	Su J, Dugas M, Guo X, GAO G. Influence of personality on mHealth use patients with diabetes: Prospective pilot study. JMIR mHealth uHealth. 20 Aug; 8(8):e17709.
5.	Dunachie S, Chamnan P. The double burden of diabetes and global infection low and middle-income countries. Trans R Soc Trop Med Hyg. 2019 Fe 113(2):56–64.
6.	IDF. IDF Diabetes Atlas Eighth [Internet]. Dunia : IDF. 2017 [cited 2021 Mar 2 p. 168. Available from: https://diabetesatlas.org/en/sections/worldwide-toll- diabetes.html
7.	Worldwide trends in diabetes since 1980: a pooled analysis of 751 population based studies with 4.4 million participants. Lancet (London, England). 2016 A 387(10027):1513–30.
8.	International Diabetes Federation - Home. (2019). Retrieved fro

BMJ Open

- 9. Agarwal, P., Mukerji, G., Desveaux, L., Ivers, N. M., Bhattacharyya, O., Hensel, J. M., Shaw, J., Bouck, Z., Jamieson, T., Onabajo, N., Cooper, M., Marani, H., Jeffs, L., & Bhatia, R. S. (2019). Mobile App for Improved Self-Management of Type 2 Diabetes: Multicenter Pragmatic Randomized Controlled Trial. JMIR *mHealth and uHealth*, 7(1), e10321. https://doi.org/10.2196/10321 10. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. DOI: 10.1136/BMJ.n71 11. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment. Geneva: World Health Organization; 2016. License: CC BY-NC-SA 3.0 IGO. 12. WHO, mHealth: New horizons for health through mobile technologies: a second global survey on eHealth. ISBN 978 92 4 156425 0. 2011 13. for Centers Disease Control and Prevention, https://www.cdc.gov/learnmorefeelbetter/programs/diabetes.htm Bandura A. Self-efficacy. The Corsini encyclopedia of psychology. 2010 Jan 14. 30:1-3. 15. Bandura A. Self-Efficacy in Changing Societies. Cambridge University Press; 1997. 16. Behaviour Change Models and Strategies. Updated: 01 July 2014. https://www.eufic.org/en/healthy-living/article/motivating-behaviour-change
  - 17. Jonathan AC Sterne. ROBINS-I: a tool for assessing risk of bias in nonrandomised studies of interventions, BMJ 2016; 355 doi:

to text

ining, Al training, and similar technologies

Protected by copyright, including for uses related

https://doi.org/10.1136/bmj.i4919 (Published BMJ 12 October 2016). 2016;355:i4919 18. Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterneon behalf of the RoB2 Development Group. Revised Cochrane risk-of-bias tool for randomized trials (August 2019). 19. Wells, G. A., Shea, B., O'Connell, D., Peterson, J., Welch, V., et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. 2011. http://www.ohri.ca/programs/clinical\_epidemiology/oxford.asp 

## **SUPPLEMENTARY FILE: 1**

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

Section and topic	ltem No	Checklist item
ADMINISTRATIVE IN	FORMA	TION
Title:	C	4
Identification	1a	Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in LMICs: A Systematic Review (Refer; page no. 1)
Update	1b	N/A
Registration	2	The study has been registered in PROSPERO and the Registration ID is CRD42021245517. (Refer; page no. 1)
Authors:		
Contact	3a	<ul> <li>Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi</li> <li>Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut</li> <li>Brand<sup>1, 6</sup></li> <li>1. Department of Health Policy, Prasanna School of Public Health,</li> <li>Manipal Academy of Higher Education.</li> <li>2. Department of Endocrinology, Kasturba Medical College Hospital,</li> <li>MAHE, Manipal, India.</li> <li>3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE,</li> <li>Manipal, India</li> <li>4. Public Health Evidence South Asia (PHESA), Prasanna School of</li> <li>Public Health, Manipal Academy of Higher Education.</li> <li>5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill,</li> <li>Shillong, Meghalaya.</li> <li>6. Department of International Health, Care and Public Health</li> <li>Research Institute – CAPHRI, Faculty of Health Medicine and Life</li> <li>Sciences, Maastricht University, Maastricht, The Netherlands.</li> </ul>

		Email id of authors:
		<ol> <li>sharu2690@gmail.com</li> <li>sahana.shetty@manipal.edu</li> <li>julien.venne@manipal.edu</li> <li>prachipundir2012@gmail.com</li> <li>priyobrat.rajkhowa@learner.manipal.edu</li> <li>melissa.glenda1@gmail.com</li> <li>helmut.brand@manipal.edu</li> </ol> Email id for correspondence: helmut.brand@manipal.edu (Refer: page no. 8)
Contributions	3b	All authors were involved in development of the selection criteria, and data extraction criteria. All authors will read, provide feedback and approve the final manuscript. (Refer; page no. 8)
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 reviews 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 sponsor or funder	5c	Not Applicable.
INTRODUCTION		
Rationale	6	Despite the growing number of mobile apps, the evidence from research on normalising HbA1c levels with the use of these apps remains a mystery to many of them. As a result, the goal of this research is to see, how effective are the diabetic self-management apps on controlling type 2 diabetes? And To compare the evidence obtained among the LMICs (Refer; page no. 2)

Objectives	7	Review question: how effective are the diabetic self-management apps on controlling type 2 diabetes? And To compare the evidence obtained among the LMICs (Refer; page no. 3)
METHODS		
Eligibility criteria	8	We followed PICOconcept/framework Population (P): Individuals with type 2 diabetes mellitus in the LMICs as listed in the World Bank organization and individuals who fulfill the WHO criteria for being diagnosed with T2DM, with no age restrictions on the population. Intervention (I): mobile phones, patient monitoring devices, persona digital assistants (PDAs), and other wireless devices. mHealth solutions like texting, emailing, 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 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 parameters like HbA1c Secondary outcomes- adherence to medications, self-efficacy and behavior changes. (Refer; page no. 3 onwards)
Information sources	9	Authors in collaboration developed search strategies using medica subject headings (MeSH) and text words related to the topic. We wil search CINAHL complete, PubMed, Web of Science, and Scopus. Only studies with human subjects will be included. (Refer; page no. 5)
Search strategy	10	Refer supplementary file 2.
Study records:		
Data management	11a	The search results collected from the electronic databases will be exported to endnote version 20. Duplicate studies will be removed. Data will then be extracted, and relevant information will be extracted to Excel spreadsheet using a data extraction tool. (Refer; page no. 6)

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Selection process Data collection process	Two authors will independently s systematic review using the eligibili in the first stage of screening will authors. Exclusion of the studies in advice and the included studies will authors. At the full-text screening s then it will be excluded and if a authors on inclusion or exclusion or be resolved by the third reviewer conclusion on including or exclud criteria. Reasons for exclusion will be and the PRISMA flowchart will be us rationale for exclusion will be p throughout the process. (Refer; pa Data extraction format by the au be pilot tested by each author ar among the authors. (Refer; supp Any missing data in the studies in	screen each title for inclusion in th ty criteria. Abstracts of studies include II be independently evaluated by tw this stage will be done only after expen I be screened further for full text by th stage, if both the authors reject a stud disagreement arises between the tw f the paper, then the disagreement will r or an expert and then will arrive a ling a paper based on predetermine be given at the full-text screening stag sed to depict the screening process. Th provided for all the excluded studie ge no. 6) ned using a standardised pre-teste uthors. The data extraction form wi nd will be edited based on discussio lementary file 3) included for review will be obtaine
Data items	through contacting the study aut Bibliometric information such as Title, Journal name, publication collected along with Characterist be extracted based on the type criteria, participant's chara comparator, and the study outco	Author's name, Author's affiliations n year, country of conduct will b tics of the included studies. Data wi of study, study objectives, Inclusio acteristics, Intervention details ome. (Refer; supplementary file 3)
Outcomes and prioritization	A detailed summary of all the inc information on authors, study of Intervention details, comparator country will be in a narrative for An evaluation will be done if it is analysis to assess the effectivene apps on controlling type 2 diabet	cluded studies will include ojectives, Inclusion criteria, r, outcome measures, and the mat. appropriate to perform a meta- ess of diabetic self-management tes. (Refer; page no. 5)

		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. (Refer; page no. 6&7)
Risk of bias in individual studi	14 es	Authors will independently assess the risk of bias in included studies The Cochrane Risk of Bias (RoB 2) tool will be used to evaluat Randomised controlled trials (Julian PT Higgins, et. al., 2019). Risk of bias in Non-randomized Studies of Interventions assessment too (ROBINS-I) for Non Randomised studies – case-control and cohor studies (Jonathan AC Sterne, et. al., 2016). The quality of the include studies will be assessed by using the Newcastle Ottawa Scale (NOS for cross-sectional studies (Wells, G. A., et. al., 2011). (Refer; page no 6)
Data synthesis	15a 15b 15c	A detailed summary of all the included studies in a narrative forma. The results 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, statistic, Chi <sup>2</sup> test, and Tau <sup>2</sup> will be used to measure and assess heterogeneity among the included studies in each analysis. Meta regression will be used to investigate heterogeneity if needed. (Refer page no. 6&7)
	15d	
Confidence in cumulative	16	Not applicable.

6

## Supplementary file: 2

## II. Search Strategy

Database	Search strategy	Hits
PubMed	(("diabetes mellitus, type 2"[MeSH Terms] OR "self- management/education"[MeSH Major Topic]) AND "Mobile Applications"[MeSH Major Topic] AND "english"[Language] AND "english"[Language]) AND ((fha[Filter]) AND (clinicaltrial[Filter] OR randomized controlled trial[Filter] OR review[Filter]) AND (humans[Filter]) AND (english[Filter]))	58
World Bank list of low and middle- income countries included in the study	"low and middle income countr*"[Title/Abstract] OR "LMIC"[Title/Abstract] OR "Afghanistan"[Title/Abstract] OR "Afghanistan"[MeSH Terms] OR "albania"[MeSH Terms] OR "albania"[Title/Abstract] OR "algeria"[Title/Abstract] OR "algeria"[MeSH Terms] OR "american samoa"[MeSH Terms] OR "american samoa"[Title/Abstract] OR "Angola"[Title/Abstract] OR "Angola"[MeSH Terms] OR "argentina"[MeSH Terms] OR "argentina"[Title/Abstract] OR "argentina"[MeSH Terms] OR "argentina"[Title/Abstract] OR "argentina"[Title/Abstract] OR "armenia"[MeSH Terms] OR "azerbaijan"[MeSH Terms] OR "azerbaijan"[Title/Abstract] OR "bangladesh"[MeSH Terms] OR "azerbaijan"[MeSH Terms] OR "azerbaijan"[Title/Abstract] OR "bangladesh"[MeSH Terms] OR "republic of belarus"[MeSH Terms] OR "belarus"[Title/Abstract] OR "belize"[MeSH Terms] OR "belarus"[Title/Abstract] OR "butan"[MeSH Terms] OR "belarus"[Title/Abstract] OR "butan"[MeSH Terms] OR "BENIN"[Title/Abstract] OR "butan"[MeSH Terms] OR "BENIN"[Title/Abstract] OR "butan"[MeSH Terms] OR "BENIN"[Title/Abstract] OR "butan"[MeSH Terms] OR "BENIN"[Title/Abstract] OR "bolivia"[Title/Abstract] OR ("BOSNIA AND HERZEGOVINA"[MeSH Terms] OR ("BOSNIA AND HERZEGOVINA"[All Fields]) OR "BOSNIA AND HERZEGOVINA"[All Fields] OR "bosnia"[All Fields]) AND	1,476,962

2	
2	
3	
4	
5	
6	
7	
/	
8	
9	
10	
11	
11	
12	
13	
14	
15	
10	
16	
17	
18	
19	
20	
20	
21	
22	
23	
2J 24	
24	
25	
26	
27	
20	
20	
29	
30	
31	
27	
22	
33	
34	
35	
36	
20	
37	
38	
39	
40	
-TU 1	
41	
42	
43	
44	
 //	
45	
46	
47	
<u>4</u> 8	
40	
49	
50	
51	
52	
52	
22	
54	
55	
56	
50	
57	
58	
59	

"BOSNIA AND HERZEGOVINA"[MeSH Terms]) OR "BOSNIA
AND HERZEGOVINA"[Title/Abstract] OR
"botswana"[MeSH Terms] OR "botswana"[Title/Abstract]
OR "brazil"[MeSH Terms] OR "brazil"[Title/Abstract] OR
"bulgaria"[MeSH Terms] OR "bulgaria"[Title/Abstract] OR
"burkina faso"[MeSH Terms] OR "burkina
faso"[Title/Abstract] OR "burundi"[MeSH Terms] OR
"burundi"[Title/Abstract] OR "cabo verde"[MeSH Terms]
OR "cabo verde"[Title/Abstract] OR "cambodia"[MeSH
Terms] OR "cambodia"[Title/Abstract] OR
"cameroon"[MeSH Terms] OR
"cameroon"[Title/Abstract] OR "central african
republic"[MeSH Terms] OR "central african
republic"[Title/Abstract] OR "chad"[MeSH Terms] OR
"chad"[Title/Abstract] OR "china"[MeSH Terms] OR
"china"[Title/Abstract] OR "colombia"[MeSH Terms] OR
"colombia"[Title/Abstract] OR "comoros"[MeSH Terms]
OR "comoros"[Title/Abstract] OR ((("congo"[MeSH
Terms] OR "congo"[All Fields]) AND "dem"[All Fields])
AND "rep"[Title/Abstract]) OR "costa rica"[MeSH Terms]
OR "costa rica"[Title/Abstract] OR "cote d ivoire"[MeSH
Terms] OR "cote d ivoire"[Title/Abstract] OR
"cuba"[MeSH Terms] OR "cuba"[Title/Abstract] OR
"djibouti"[MeSH Terms] OR "djibouti"[Title/Abstract] OR
"dominica"[MeSH Terms] OR "dominica"[Title/Abstract]
OR "dominican republic"[MeSH Terms] OR "dominican
republic"[Title/Abstract] OR "ecuador"[MeSH Terms] OR
"ecuador"[Title/Abstract] OR "el salvador"[MeSH Terms]
OR "el salvador"[Title/Abstract] OR "equatorial
guinea"[MeSH Terms] OR "equatorial
guinea"[Title/Abstract] OR "egypt"[MeSH Terms] OR
"arab republic of egypt"[Title/Abstract] OR
"eritrea"[MeSH Terms] OR "eritrea"[Title/Abstract] OR
"ethiopia"[MeSH Terms] OR "ethiopia"[Title] OR
"fiji"[MeSH Terms] OR "fiji"[Title/Abstract] OR
"gabon"[MeSH Terms] OR "gabon"[Title/Abstract] OR
"gambia"[MeSH Terms] OR "gambia"[Title/Abstract] OR

("georgia"[MeSH Terms] OR "georgia republic"[MeSH
Terms) OR georgia [III.ie/Abstract] OR gnana [MeSH
Termsj OR "ghana"(Title/Abstractj OR "grenada"(MeSH
Terms OR "grenada"[Title/Abstract] OR
"guatemala"[MeSH Terms] OR
"guatemala"[Title/Abstract] OR "guinea bissau"[MeSH
Terms] OR "guinea bissau"[Title/Abstract] OR
"guyana"[MeSH Terms] OR "guyana"[Title] OR
"haiti"[MeSH Terms] OR "haiti"[Title] OR
"honduras"[MeSH Terms] OR "honduras"[Title/Abstract]
OR "India"[MeSH Terms] OR "India"[Title/Abstract] OR
"indonesia"[MeSH Terms] OR "indonesia"[Title/Abstract]
OR "iran"[MeSH Terms] $OR$ "iran"[Title/Abstract] $OR$
"iamaica"[MeSH Terms] OR "iamaica"[Title/Abstract] OP
"iordan"[MeSH Terms] OP "iordan"[Title/Abstract] OP
jordan [iviesii reinis] OK jordan [inie/Abstract] OK
jordan [WeSH Terms] OK jordan [Title] OK
"kazakhstan"[MeSH Terms] OR
"kazakhstan"[Title/Abstract] OR "kenya"[MeSH Terms]
OR "kenya"[Title] OR "micronesia"[MeSH Terms] OR
"kiribati"[Title] OR "democratic people s republic of
korea"[MeSH Terms] OR "democratic people s republic of
korea"[Title/Abstract] OR "kosovo"[MeSH Terms] OR
"kosovo"[Title/Abstract] OR "kyrgyzstan"[MeSH Terms]
OR "kyrgyz republic"[Title/Abstract] OR "lao
pdr"[Title/Abstract] OR "lebanon"[MeSH Terms] OR
"lebanon"[Title/Abstract] OR "lesotho"[MeSH Terms] OR
"lesotho"[Title/Abstract] OR "liberia"[MeSH Terms] OR
"liberia"[Title] OR "libya"[MeSH Terms] OR
"libya"[Title/Abstract] OP "madagasear"[MoSH Torms] OP
"madagascar"[Title/Abstract] OP "malawi"[MoSH Terms]
OR malawi [Title] OR malaysia [Iviesh Terms] OR
"malaysia"[Title/Abstract] OR "indian ocean
islands"[MeSH Terms] OR "maldives"[Title] OR
"Mali"[MeSH Terms] OR "Mali"[Title/Abstract] OR
"micronesia"[MeSH Terms] OR "marshall
islands"[Title/Abstract] OR "mauritania"[MeSH Terms] OR
"mauritania"[Title/Abstract] OR "mauritius"[MeSH

1	
2	
3	
4	
5	
6	
7	
/ 0	
0	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
20	
∠ı 22	
∠∠ วว	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
20	
2/	
38	
39	
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	
51	
57	
52	
55 Γ 4	
54	
55	
56	
57	
58	
59	
60	

Terms] OR "mauritius"[Title] OR "mexico"[MeSH Terms]OR "mexico"[Title/Abstract] OR "micronesia"[MeSHTerms] OR "micronesia"[Title/Abstract] OR"moldova"[MeSH Terms] OR "moldova"[Title/Abstract]OR "mongolia"[MeSH Terms] OR "montenegro"[MeSHTerms] OR "montenegro"[MeSHTerms] OR "montenegro"[Title/Abstract] OR"morocco"[MeSH Terms] OR "morocco"[Title/Abstract]OR "mozambique"[MeSH Terms] OR"mozambique"[Title/Abstract] OR "myanmar"[MeSHTerms] OR "myanmar"[Title/Abstract] OR
OR "mexico"[Title/Abstract] OR "micronesia"[MeSH Terms] OR "micronesia"[Title/Abstract] OR "moldova"[MeSH Terms] OR "moldova"[Title/Abstract] OR "mongolia"[MeSH Terms] OR "mongolia"[Title/Abstract] OR "montenegro"[MeSH Terms] OR "montenegro"[Title/Abstract] OR "morocco"[MeSH Terms] OR "morocco"[Title/Abstract] OR "mozambique"[MeSH Terms] OR "mozambique"[Ittle/Abstract] OR "myanmar"[MeSH Terms] OR "myanmar"[Title/Abstract] OR
Terms]OR"micronesia"[Title/Abstract]OR"moldova"[MeSH Terms]OR"moldova"[Title/Abstract]OR"mongolia"[MeSH Terms]OR"mongolia"[Title/Abstract]OR"montenegro"[MeSHTerms]OR"montenegro"[Title/Abstract]OR"morocco"[MeSH Terms]OR"morocco"[Title/Abstract]OROR"mozambique"[MeSH Terms]OR"mozambique"[MeSHTerms]OR"myanmar"[MeSHTerms]OR"myanmar"[MeSH
"moldova"[MeSH Terms] OR "moldova"[Title/Abstract]OR"mongolia"[MeSH Terms]OR"mongolia"[Title/Abstract]OR"montenegro"[MeSHTerms]OR"montenegro"[Title/Abstract]OR"morocco"[MeSH Terms]OR"morocco"[Title/Abstract]OR"mozambique"[MeSH Terms]OR"mozambique"[Title/Abstract]OR"mozambique"[MeSHTerms]OR"myanmar"[MeSHTerms]OR"myanmar"[Title/Abstract]
OR"mongolia"[MeSHTerms]OR"mongolia"[Title/Abstract]OR"montenegro"[MeSHTerms]OR"montenegro"[Title/Abstract]OR"morocco"[MeSHTerms]OR"morocco"[Title/Abstract]OR"mozambique"[MeSHTerms]OR"mozambique"[Title/Abstract]OR"myanmar"[MeSHTerms]OR"myanmar"[Title/Abstract]OR
<pre>"mongolia"[Title/Abstract] OR "montenegro"[MeSH Terms] OR "montenegro"[Title/Abstract] OR "morocco"[MeSH Terms] OR "morocco"[Title/Abstract] OR "mozambique"[MeSH Terms] OR "mozambique"[Title/Abstract] OR "myanmar"[MeSH Terms] OR "myanmar"[Title/Abstract] OR</pre>
Terms] OR "montenegro"[Title/Abstract] OR "morocco"[MeSH Terms] OR "morocco"[Title/Abstract] OR "mozambique"[MeSH Terms] OR "mozambique"[Title/Abstract] OR "myanmar"[MeSH Terms] OR "myanmar"[Title/Abstract] OR
"morocco"[MeSH Terms] OR "morocco"[Title/Abstract] OR "mozambique"[MeSH Terms] OR "mozambique"[Title/Abstract] OR "myanmar"[MeSH Terms] OR "myanmar"[Title/Abstract] OR
OR "mozambique"[MeSH Terms] OR "mozambique"[Title/Abstract] OR "myanmar"[MeSH Terms] OR "myanmar"[Title/Abstract] OR
<ul> <li>"mozambique"[Title/Abstract] OR "myanmar"[MeSH</li> <li>Terms] OR "myanmar"[Title/Abstract] OR</li> </ul>
Terms] OR "myanmar"[Title/Abstract] OR
"namibia"[MeSH Terms] OR "namibia"[Title/Abstract] OR
"nepal"[MeSH Terms] OR "nepal"[Title/Abstract] OR
"nicaragua"[MeSH Terms] OR "nicaragua"[Title/Abstract]
OR "niger"[MeSH Terms] OR "niger"[Title/Abstract] OR
"nigeria"[MeSH Terms] OR "nigeria"[Title/Abstract] OR
"republic of north macedonia"[MeSH Terms] OR
"macedonia"[Title/Abstract] OR "pakistan"[MeSH Terms]
OR "pakistan"[Title/Abstract] OR "panama"[MeSH Terms]
OR "panama"[Title/Abstract] OR "papua new
guinea"[MeSH Terms] OR "papua new
guinea"[Title/Abstract] OR "paraguay"[MeSH Terms] OR
"paraguay"[Title/Abstract] OR "peru"[MeSH Terms] OR
"peru"[Title/Abstract] OR "philippines"[MeSH Terms] OR
"philippines"[Title/Abstract] OR "romania"[MeSH Terms]
OR "romania"[Title/Abstract] OR "russia"[MeSH Terms]
OR "russian federation"[Title/Abstract] OR
"rwanda"[MeSH Terms] OR "rwanda"[Title/Abstract] OR
"samoa"[MeSH Terms] OR "samoa"[Title/Abstract] OR
"sao tome and principe"[WeSH Terms] OR ("sao
tome"[IItle/Abstract] AND "principe"[IItle/Abstract]) OR
senegai [MeSH Terms] OR senegai [Title/Abstract] OR
serbia livies i rennsj. OR serbia (i nie/Abstract) OR "sjorra loopo"[MoSH Torma] OB "sjorra
Sierra ieurie [iviesn rernis] UK Sierra
"solomon islands"[Titlo/Abstract] OP "somalia"[Mosu
Terms] OR "somalia"[Title/Abstract] OR "south

Total	1AND 2	8
	"zimbabwe"[Title/Abstract]	
	"zimbabwe"[MeSH Terms] OR	
	"zambia"[MeSH Terms] OR "zambia"[MeSH Terms] OR	
	"vemen"[MeSH Terms] OR "vemen"[Title/Abstract] OR	
	bank"[Title/Abstract] AND "gaza"[Title/Abstract]) OR	
	OR "vietnam"[Title/Abstract] OR ("west	
	OR "vanuatu"[Title/Abstract] OR "vietnam"[MeSH Terms]	
	"uzbekistan"[Title/Abstract] OR "vanuatu"[MeSH Terms]	
	"uzbekistan"[MeSH Terms] OR	
	Terms] OR "ukraine"[Title/Abstract] OR	
	Terms] OR "uganda"[Title/Abstract] OR "ukraine"[MeSH	
	Terms] OR "tuvalu"[Title/Abstract] OR "uganda"[MeSH	
	"turkmenistan"[Title/Abstract] OR "micronesia"[MeSH	
	"turkmenistan"[MeSH Terms] OR	
	"turkey"[MeSH Terms] OR "turkey"[Title/Abstract] OR	
	"Tunisia"[MeSH Terms] OR "Tunisia"[Title/Abstract] OR	
	"Tonga"[MeSH Terms] OR "Tonga"[Title/Abstract] OR	
	"togo"[MeSH Terms] OR "togo"[Title/Abstract] OR	
	Ieste"[MeSH Terms] OR "timor leste"[Title/Abstract] OR	
	Terms OR "thailand"[Title/Abstract] OR "timor	
	Termsj OR "tanzania" [Title/Abstract] OR "thailand" [MeSH	
	OR tajikistan [Title/Abstract] OR tanzania [Mesh	
	Pepublic [Title/Abstract]) OR tajikistan [WeSH Terms]	
	"ropublic"[Title/Abstract]) OD "toil/istan"[MaSU Terma]	
	"syrians"[All Fields]) AND "arb"[All Fields]) AND	
	"mesocricetus"[All Fields] OR "svrian"[All Fields] OR	
	OR ((("mesocricetus"[MeSH Terms] OR	
	"suriname"[MeSH Terms] OR "suriname"[Title/Abstract]	
	Terms] OR "south sudan"[Title/Abstract] OR	
	grenadines"[Title/Abstract]) OR "south sudan"[MeSH	
	vincent"[Title/Abstract] AND "the	
	"saint vincent and the grenadines"[MeSH Terms] OR ("st	
	"saint lucia"[MeSH Terms] OR "st lucia"[Title/Abstract] OR	
	lanka"[MeSH Terms] OR "sri lanka"[Title/Abstract] OR	
	"Sudan"[MeSH Terms] OR "Sudan"[Title/Abstract] OR "sri	

## Supplementary file: 3

## III. Data extraction from

Title of the study	
Authors	
Year of the study conducted	
Year of publication	
Doi & Journal	
Objectives of the study	
Participant characteristics	Number of participants
· · ·	Age
	Gender
	Ethnicity
	Socioeconomic group
	Educational status
	Duration of T2DM
Total number of participants	
Setting/ context/ country	Low-income country
	Lower Middle-income country
	Upper Middle-income country
World Bank Region	South Asia
	Sub-Saharan Africa
	East Asia and Pacific
	Europe and Central Asia
	Latin America and the Caribbean
	The Middle East and North Africa
	North America
Description of intervention for type 2	M health application
diabetes	Infographics
	Video clips
	Text messages
	Others – to be specified
Search details	Year
Source	IndMED
	Medline Plus
	OpenMED

	Ovid Medline
	PubMed / MEDLINE
	Scopus
	Web of Science
	Other Bibliographical Databases
Range of years included	No limit
No of included studies	
Type of studies included	RCT
	Quasi-experimental study
	Case-control
	Cohort
	Controlled trial
Comparator	Duration of the intervention
	Across the regions (LMIC's)
	Age groups
	Gender
Analysis	
Method of analysis	
follow up sessions	
Outcome assessed	Primary
	secondary
Results/ findings	
Significance	9
Heterogeneity if done	

**BMJ** Open

## **BMJ Open**

## Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in Low and Middle-Income Countries: A Systematic Review

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-060108.R1
Article Type:	Protocol
Date Submitted by the Author:	28-Jun-2022
Complete List of Authors:	dsouza, sherize; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Shetty, Sahana; Manipal Academy of Higher Education, Dept. Endocrinology, Kasturba Medical College Hospital, MAHE venne, Julien; Manipal Academy of Higher Education, Digital Health and wellbeing, Prasanna School of Public Health Pundir , Prachi ; Manipal Academy of Higher Education, Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Rajkhowa, Priyobrat; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health; Maastricht University, Department of International Health, Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health, Research Institute, Jean Monnet Chair in European Public Health, Department of International Health
<b>Primary Subject Heading</b> :	Public health
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Evidence based practice
Keywords:	PUBLIC HEALTH, Information management < BIOTECHNOLOGY & BIOINFORMATICS, DIABETES & ENDOCRINOLOGY, PREVENTIVE MEDICINE, NUTRITION & DIETETICS, Epidemiology < TROPICAL MEDICINE
	•

1	
2	
3	
4	SCHOLARONE"
5	Manuscripts
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
4/	
48	
49	
50	
51	
52	
53	
54 FF	
55 56	
20 57	
5/	
28 50	
57 60	For peer review only - http://bmiopen.bmi.com/site/about/quidelines.xbtml
00	i or peer review only integry only openionly one about guidelines. Anthin

## EFFECTIVENESS OF SELF-MANAGEMENT APPLICATIONS IN IMPROVING CLINICAL HEALTH OUTCOMES AND ADHERENCE AMONG DIABETIC INDIVIDUALS IN LOW AND MIDDLE-INCOME **COUNTRIES: A SYSTEMATIC REVIEW**

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- 6. Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

## Postal and E-mail addresses of the corresponding author

Prof. Dr. Helmut Brand, Founding Director, Prasanna School of Public Health, Manipal Academy

of Higher Education, Manipal 576104, Udupi, Karnataka, India. Ph: 0824 2923157

Email: helmut.brand@manipal.edu / helmut.brand@maastrichtuniversity.nl

**Total word count in main text** – 3130 (excluding references and supplementary files/tables)

Total number of references: 25, word count - 705

Number of supplementary files - 3

Total word count of all three supplementary files -2136

#### Abstract

Introduction: There are a variety of mobile health applications available to monitor an individual's health or lifestyle to make it convenient and easy to access healthcare facilities at home. Despite the growing number of mobile applications, the evidence from research on normalising HbA1c levels (HbA1C is defined as "estimated average blood glucose") with the use of these applications remains a mystery. The burden of type 2 diabetes mellitus (T2DM) is high in Low- and Middle-Income Countries (LMICs), with the highest-burden in the Indian population. The objective of the research is to identify how effective are the diabetic self-management applications (DSMA) in controlling the blood glucose levels of individuals with T2DM and to find the impact of DSMA in managing T2D in LMICs.

Methods and analysis: The electronic databases included for search are PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites, and reference lists of included studies. Studies published in the English language in indexed and peer-reviewed sources will be considered. Studies reporting the effectiveness of mobile applications in the management of T2D in the LMICs will be eligible for inclusion. The Population-Intervention-Comparison Outcomes (PICO) Framework and the PRISMA statement 2021, will be used for reporting this systematic review. Data analysis will be carried out using narrative synthesis, and a meta-analysis may be conducted if we come across homogenous data for the outcome.

Ethics and dissemination: As this study is a systematic review, we will not be recruiting any participants for the study and hence will not require ethical approval. The study summary will be disseminated at a conference.

Keywords: mobile health application, mHealth, self-management applications, type 2 diabetes mellitus

Prospero registration ID: CRD42021245517

BMJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

#### **Article summary:**

#### Strengths of the study:

- 1. There are no similar systematic reviews published particularly focusing on self-managing type 2 diabetes with the help of mHealth technologies in the Low and Middle-income countries.
- 2. The study findings intend to support and generalize the factors obtained among the LMICs

## Limitations of the study:

- 1. The exclusion of articles in languages other than English and articles behind a paywall may introduce a minor selection bias in the review, however, this could not be prevented because it is a non-funded study.
- 2. The geographical area under study will be limited to Low and Middle-Income Countries (LMICs) specifically in the context of India since India has the highest burden of diabetes among the LMICs and the systematic review findings may be used to inform future primary research in India

#### Introduction

'Diabetes' is a term used to describe a group of diseases characterized by elevated blood glucose levels. It is caused by a lack of insulin production or function, or both, which may occur for various reasons and lead to protein and lipid metabolic disorders<sup>1</sup>. Various scientific studies have established that adequate blood glucose regulation minimizes the long-term effects of type 2 diabetes. Increasing inclination towards technology provides an opportunity for the delivery of innovative self-management interventions. The global burden of type 2 diabetes mellitus (T2DM) continues to rise, with T2DM estimated to affect over 9% of the global population by 2035<sup>2</sup>.

Type 2 Diabetes in LMICs: A slew of issues plagues the delivery of healthcare in low and middleincome countries (LMICs). Where four out of every five people with diabetes now live in these

#### BMJ Open

countries, and the rate of diabetes is increasing in poorer communities <sup>3</sup>. In 57 developing countries, the World Health Organization (WHO) estimates a 4.3 million healthcare worker shortage, resulting in understaffed hospitals, limited patient access to care, and a significant patient-physician contact gap, especially in rural areas <sup>4</sup>. To bridge this gap in terms of diabetes management, self-management apps can play a pivotal role in India and the LMICs. The use of mobile health tools to help people manage chronic diseases is on the rise, but evidence of their effectiveness is mixed<sup>5</sup>. Patients with diabetes are increasingly using mobile technology for health (mHealth) interventions to help improve self-management; however, these interventions have not been implemented by many patients, and dropout rates are common.

Measures to control Type 2 Diabetes: The rising prevalence of T2DM has put pressure on healthcare systems to properly manage these individuals so that diabetes complications are avoided. Optimizing patient outcomes by combining medications with self-management of glycemic control and other risk variables could be a better approach. To help people keep blood sugar within the normal range (i.e., <= 5.7% of the HbA1c) the American Diabetes Association also recommends: engaging in weight management activities, eating a nutritious diet, getting regular exercise, smoking cessation, and stress reduction as the key factors to achieve normal glycemic levels.

Once diabetes has progressed to the extreme levels, dietary adjustments and lifestyle modifications alone are no longer sufficient to maintain appropriate blood sugar levels, and doctors may urge a person to take medications. However, for older adults diagnosed with diabetes and whose blood sugar is marginally high, drugs may or may not be required<sup>6</sup>. Along with dietary adherence, behavioral factors such as "Self-efficacy" have proved to be the most significant predictive factor of HbA1c, Physical activity for Body Mass Index (BMI), and glucose self-monitoring for Fasting Blood Glucose (FBG) in leading a healthy lifestyle<sup>7</sup>. In recent years, there are an increasing number of smartphone applications that are meant to help T2DM patients manage their condition, but only a few have been thoroughly evaluated among the general population globally<sup>8</sup>.

eHealth: is the use of information and communication technologies (ICT) for health.

The unprecedented spread of mobile technologies as well as advancements in their innovative application to address health priorities have evolved into a new field of eHealth, known as mHealth.

mHealth: The Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices<sup>9</sup>.

A mHealth application used in the self-management of type 2 diabetes mellitus, along with standard care- a study conducted in India in the year 2017, has proved that the users of the study with "Gather m-Health app" as an intervention given to the participants of the study improved medication adherence and Blood glucose testing accuracy over 6 months of the study<sup>10</sup> Evidence generated by another Indian study using a mHealth application "DIAGURU" mainly focused on lifestyle modification and medication management over 6 months suggesting, that technological approaches can be used as a public health measure to improve the quality of life of patients with type 2 Diabetes Mellitus<sup>11</sup>.

Non-exercise Activity Thermogenesis (NEAT) a smartphone intervention used to reduce the health consequences of sedentary behavior, provided an opportunity to intervene and improve the health of a large proportion of the population in Chicago<sup>12</sup>. Although there might be a few barriers to the use of remote mHealth technologies in self-managing type 2 diabetes with poor technology literacy<sup>13,</sup> desired elements such as blood sugar monitoring, instructional content, personalised feedback, reminders, and goal setting were thought to be beneficial<sup>14</sup>. The interventions may also include other forms of mHealth solutions like texting, emailing, video clips, and graphics. To find the evidence on how the use of mobile applications has impacted the health of type 2 diabetic individuals. Few of the proven interventions leading to more effective control of diabetes were reported<sup>15</sup>.

Rationale: A deeper knowledge of the influence of mHealth applications in controlling blood sugar levels and managing diabetes is crucial to manage diabetes in terms of diabetic selfmanagement in the LMICs, as well as to prioritize research agendas, and policies. Hence, this
review aims to assess the effectiveness of diabetic self-management applications in managing type 2 diabetes in LMICs, with a focus on Indian studies because India has the highest burden of diabetes among the LMICs, and our systematic review findings may be used to inform future primary research related to the diabetes self-management in India.

#### **Review Questions**

1. Are diabetic self-management applications effective in controlling blood glucose levels among individuals with type 2 diabetes mellitus in LMICs?

2. What is the impact of using Diabetic self-management applications in managing type 2 diabetes in LMICs in the context of India?

## Methods

The PRISMA 2020 statement; an updated guideline for reporting systematic reviews<sup>16</sup> will be used for reporting the review and the Population-Intervention-Comparison-Outcomes (PICO) framework will be used for defining the methods of the review. (Refer; to supplementary file 1-PRISMA checklist). The systematic review protocol was registered on the international prospective register of systematic reviews, PROSPERO, with the registration number CRD42021245517.

#### Criteria for considering studies for this review

#### Types of studies:

*Study design:* Randomized controlled trials (RCTs), Non-Randomized controlled trials (NRCTs) like the Quasi-experimental studies, and controlled before-after studies will be included. All observational studies, conference papers, editorials, reports, and other studies without any mobile app interventions in them will be excluded.

*Year of publication:* we will include publications matching our criteria from the year 2015 to 2022. As the search strategy yielded publications from the year 2015 onwards.

*Type of participants:* 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 diagnosis<sup>17</sup> 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.

*FBG:* Fasting means not having anything to eat or drink (except water) for at least 8 hours before the test. Diabetes is diagnosed at FBG of greater than or equal to 126 mg/dl.

*RBS:* This test is a blood check at any time of the day when an individual has severe diabetes symptoms (Diabetes is diagnosed at blood glucose of greater than or equal to 200 mg/dl.

*OGTT:* A two-hour test that checks your blood glucose levels before and two hours after you drink a special sweet drink. Diabetes is diagnosed at two-hour blood glucose  $\geq$  200 mg/dl<sup>18</sup>.

**Patient and public involvement:** patients and the public will not be involved in any way in this study.

#### Type of interventions

Digital health: The use of digital, mobile, and wireless technologies to support the achievement of health objectives. Digital health describes the general use of information and communications technologies (ICT) for health and is inclusive of both mHealth and eHealth<sup>19</sup>. From the context of our study, the term mHealth refers to the mobile applications used in the self-management of T2DM. The interventions may also include other simpler forms of mHealth solutions like texting, emailing, video clips, graphics, and web services.

**Type of Comparison:** the comparator groups would be the individuals who received standard hospital treatment or no hospital care and who received an intervention.

Type of outcome measures: Primary outcomes include,

- Clinical outcome (HbA1c at 3 months interval): [A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives<sup>20</sup>]
   Secondary outcomes include,
  - Adherence to diabetic self-management applications and medication: The studies must have reported using any of the standard survey tools to record daily medication intake and app usage during the follow-up for a year.
  - Self-efficacy with adherence to mHealth applications: Self-efficacy is defined as "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations." - Albert Bandura <sup>21, 22</sup>. The studies must have done a subjective evaluation of the individual's willingness to use the self-management applications to manage t2dm and those who are confident to follow in their near future.
  - Behavior change: If the study participants during their follow-up period adapted a positive change in behavior towards achieving better health, like opting for a healthy diet, regular moderate exercising, brisk walking, and reducing/ managing their stress levels. Will be checked across the quality of life improvement index if any done in the studies <sup>23</sup>.

**Search methods for identification of studies:** PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites. Forward citation search will be undertaken for any key references identified and reference lists of included studies (Refer to supplementary file 2- 'Search strategies' for more search information).

We will be using Endnote library version X7 for screening and downloading the full-text articles and Microsoft Excel 2013 will be used for data extraction of the full-text articles. 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 (Refer to supplementary file 1) will be used to depict the screening process. The rationale for exclusion will be provided for all the excluded studies throughout the process.

**Data extraction and management:** Data extraction will be performed using a standardized pretested 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. The data extraction form will include information on citation details, characteristics of the studies, location, region, population, intervention, the effectiveness of an intervention, and the information on outcome and the main findings (Refer to 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 with a minimum waiting period of two weeks for their reply. In the event of no response from the authors of the study, a decision will be taken by the team of authors of the systematic review.

**Assessment of risk of bias in included 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<sup>24</sup>. Risk of bias in Non-randomized Studies of Interventions assessment tool (ROBINS-I) for Non-Randomised studies<sup>25</sup>.

**Data synthesis:** Firstly, we will provide a detailed summary of all the included studies in a narrative format. 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, l<sup>2</sup> statistic, Chi<sup>2</sup> test, and Tau<sup>2</sup> 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 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. All the analyses will be conducted in Review Manager 5.3 and STATA 16.

Description of primary and secondary outcomes, whether adherence to diabetic selfmanagement applications and medication has improved or not, Behavior change will be noted with the quality of life improvement index and self-efficacy will be checked following the improvement in managing T2DM. Listing out various measurement tools and devices used for judging the above-mentioned outcomes.

**Subgroup analysis:** Subgroup analysis will be performed for the following if appropriate. Sensitivity analysis will be performed if we find out any uncertainties in one or more input variables that may lead to uncertainties among other output variables.

Subgroup analysis will be performed for the following:

- Duration of the given intervention (3 months intervals up to a year)
- Comparing study effectiveness within the LMICs
- The most effective rate of using the Diabetic self-management app in age groups as classified by the UN

• Gender

#### **Author affiliations:**

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup> Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

**Ethics and dissemination:** The study will be a systematic review of the published articles from different recognised and accessible databases and will not recruit any human participants directly, therefore, ethical clearance is not applicable. The dissemination of the final review findings will be done at a national or international conference and will be published in an indexed peer-reviewed journal.

**Author Contributions:** HB is the corresponding author, SMD, SS, JV, PP, MGL, PR, and HB conceptualized the study. SMD, SS, JV, PP, MGL, PR, and HB drafted the manuscript. 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.

Protected by copyright, including for uses related to text

**Funding:** This research received no specific grant from any funding agency in the public, commercial or not-for-profit sector

**Conflicts of interest:** There is no conflict of interest in this project.

Supplemental material: Supplementary materials are enclosed as 1, 2 and 3

Patient and public involvement: patients and the public were not involved in any way in this study

## **References:**

- 1. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes care. 2013 Jan;36(Suppl 1):S67.
- 2. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw J, Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-management of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealth and uHealth. 2019 Jan 10;7(1):e10321.
- Dunachie S, Chamnan P. The double burden of diabetes and global infection in low and 3. middle-income countries. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2019 Feb 1;113(2):56-64.
- 4. Mahmud N, Rodriguez J, Nesbit J. A text message-based intervention to bridge the healthcare communication gap in the rural developing world. Technology and Health Care. 2010 Jan 1;18(2):137-44.
- 5. Dugas M, Crowley K, Gao GG, Xu T, Agarwal R, Kruglanski AW, et al. Individual differences in regulatory mode moderate the effectiveness of a pilot mHealth trial for diabetes management among older veterans. PLoS One. 2018; 13(3):e0192807.

- West M. Controlling type 2 diabetes: With and without medication [Internet]. Medicalnewstoday.com. 2021. Available from: https://www.medicalnewstoday.com/articles/how-to-control-type-2-diabetes
- Brown SA, García AA, Brown A, Becker BJ, Conn VS, Ramírez G, Winter MA, Sumlin LL, Garcia TJ, Cuevas HE. Biobehavioral determinants of glycemic control in type 2 diabetes: a systematic review and meta-analysis. Patient education and counseling. 2016 Oct 1;99(10):1558-67.
- 8. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw J, Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-management of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealth and uHealth. 2019 Jan 10;7(1):e10321.
- 9. World Health Organization. mHealth: new horizons for health through mobile technologies. mHealth: new horizons for health through mobile technologies.. 2011.
- 10. Kleinman NJ, Shah A, Shah S, Phatak S, Viswanathan V. Improved medication adherence and frequency of blood glucose self-testing using an m-Health platform versus usual care in a multisite randomized clinical trial among people with type 2 diabetes in India. Telemedicine and e-Health. 2017 Sep 1;23(9):733-40.
- Kumar DS, Prakash B, Chandra BS, Kadkol PS, Arun V, Thomas JJ. An android smartphone-based randomized intervention improves the quality of life in patients with type 2 diabetes in Mysore, Karnataka, India. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2020 Sep 1;14(5):1327-32.
- Pellegrini CA, Hoffman SA, Daly ER, Murillo M, Iakovlev G, Spring B. Acceptability of smartphone technology to interrupt sedentary time in adults with diabetes. Translational behavioral medicine. 2015 Sep 1;5(3):307-14.
- 13. Alvarado MM, Kum HC, Coronado KG, Foster MJ, Ortega P, Lawley MA. Barriers to remote health interventions for type 2 diabetes: a systematic review and proposed classification scheme. Journal of medical Internet research. 2017 Feb 13;19(2):e6382.

#### **BMJ** Open

g W, Yuan S, Hol for individuals ealth. 2016 Sep 1 ton KR, Crowley th coaching for tiers in Digital H MJ, McKenzie MJ, McKenzie aff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Organ S://www.diabet ld Health Organ tical guide to co ers ention. https:/	tz BE. Explor with type 2 o 1;22(9):733- AP, Vence type 2 diabo lealth. 2021; JE, Bossuyt F Brennan SE ng systemat nization. Diag ganization: C ADA. es.org/diabo nization. Mon onducting res for	ring the challeng diabetes living in 8. N, Underwood R etes: randomize 3. PM, Boutron I, H E, Chou R. The R cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva	es and opport rural commur (, Morris G, Ke d controlled tr offmann TC, N PRISMA 2020 s ematic reviews agement of typ and. 2020. 2022. sis luating digital sment.	unities of health hities. Telemedia elly J, Landry MJ rial of healthy a Aulrow CD, Shar statement: an u . 2021 Dec;10(1 be 2 diabetes (H Available health interver	n mobile cine and J. Digital It home. mseer L, updated L):1-1. HEARTS- from: ntions: a
s for individuals salth. 2016 Sep : ton KR, Crowley th coaching for tiers in Digital H MJ, McKenzie aff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Organ s://www.diabet ld Health Organ tical guide to co ers ention. https:/	with type 2 of 1;22(9):733-3 7 AP, Vence type 2 diabor lealth. 2021; JE, Bossuyt F Brennan SE ng systemat nization. Diag ganization: C ADA. es.org/diabor nization. Mon onducting res for	diabetes living in 8. N, Underwood H etes: randomize 3. PM, Boutron I, H E, Chou R. The H cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	k rural commur K, Morris G, Ke d controlled tr offmann TC, N PRISMA 2020 = ematic reviews agement of typ and. 2020. 2022. sis luating digital sment.	hities. Telemedia elly J, Landry MJ rial of healthy a Aulrow CD, Shar statement: an a . 2021 Dec;10(1 pe 2 diabetes (H Available health interver	cine and J. Digital It home. mseer L, updated L):1-1. HEARTS- from: ntions: a
ealth. 2016 Sep : ton KR, Crowley th coaching for tiers in Digital H MJ, McKenzie aff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Organ s://www.diabet ld Health Organ tical guide to co ers ention. https:/	1;22(9):733-3 v AP, Vence type 2 diabo lealth. 2021; JE, Bossuyt F Brennan SE ng systemat nization. Diag ganization. Diag ganization. Diag song diabo nization. Mon nducting res for	8. N, Underwood H etes: randomize 3. PM, Boutron I, H E, Chou R. The H cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	K, Morris G, Ke d controlled tr offmann TC, N PRISMA 2020 a ematic reviews agement of typ and. 2020. 2022. sis luating digital ssment.	elly J, Landry M. rial of healthy a Aulrow CD, Shar statement: an o . 2021 Dec;10(1 pe 2 diabetes (H Available health interver	J. Digital It home. Inseer L, Updated L):1-1. HEARTS- from: Itions: a
ton KR, Crowley th coaching for tiers in Digital H MJ, McKenzie aff JM, Akl EA, eline for reporti Id Health Organ Vorld Health Organ s://www.diabet Id Health Organ tical guide to co ers ention. https:/	v AP, Vence type 2 diabo lealth. 2021; JE, Bossuyt F Brennan SE ng systemat nization. Diag ganization. Diag ganization. Diag sonization. Diag dization. Mon nducting res for	N, Underwood H etes: randomize 3. PM, Boutron I, H E, Chou R. The H cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	K, Morris G, Ke d controlled tr offmann TC, M PRISMA 2020 a ematic reviews agement of typ and. 2020. 2022. sis luating digital sment.	elly J, Landry M. rial of healthy a Aulrow CD, Shan statement: an o . 2021 Dec;10(1 be 2 diabetes (H Available health interver	J. Digital at home. mseer L, updated L):1-1. HEARTS- from: ntions: a
th coaching for tiers in Digital F MJ, McKenzie aff JM, Akl EA, eline for reporti Id Health Organ Vorld Health Organ s://www.diabet Id Health Organ tical guide to co ers ention. https://	type 2 diabo lealth. 2021; JE, Bossuyt F Brennan SE ng systemat nization. Diag ganization. Diag ganization. Diag sonization. Diag nization. Mon nducting res for	etes: randomize 3. PM, Boutron I, H , Chou R. The F cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	d controlled tr offmann TC, N PRISMA 2020 a amatic reviews agement of typ and. 2020. 2022. sis luating digital sment.	rial of healthy a Aulrow CD, Shar statement: an r . 2021 Dec;10(1 be 2 diabetes (H Available health interver	nt home. mseer L, updated L):1-1. HEARTS- from: ntions: a
tiers in Digital F MJ, McKenzie laff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Org nosis   s://www.diabet ld Health Organ tical guide to co ers ention. https:/	lealth. 2021; JE, Bossuyt F Brennan SE Ing systemat nization. Diag ganization: C ADA. es.org/diabe nization. Mon onducting res for	3. M, Boutron I, H C, Chou R. The F cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	loffmann TC, N PRISMA 2020 s ematic reviews agement of typ and. 2020. 2022. sis luating digital	Aulrow CD, Shai statement: an i . 2021 Dec;10(1 pe 2 diabetes (F Available health interver	mseer L, updated L):1-1. HEARTS- from: ntions: a
e MJ, McKenzie laff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Org nosis   s://www.diabet ld Health Organ tical guide to co ers ention. https:/	JE, Bossuyt F Brennan SE ng systemat iization. Diag ganization: C ADA. es.org/diabe iization. Mon inducting res for	PM, Boutron I, H E, Chou R. The F cic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	loffmann TC, N PRISMA 2020 ematic reviews agement of typ and. 2020. 2022. sis luating digital ssment.	Aulrow CD, Shai statement: an i . 2021 Dec;10(1 pe 2 diabetes (F Available health interver	mseer L, updated L):1-1. HEARTS- from: ntions: a
laff JM, Akl EA, eline for reporti ld Health Organ Vorld Health Org nosis   s://www.diabet ld Health Organ tical guide to co ers ention. https:/	Brennan SE ng systemat nization. Diag ganization: C ADA. es.org/diabe nization. Mon nducting res for	E, Chou R. The F ic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	PRISMA 2020 ematic reviews agement of typ and. 2020. 2022. sis luating digital	statement: an 1 . 2021 Dec;10(1 pe 2 diabetes (H Available health interver	updated L):1-1. HEARTS- from: ntions: a
eline for reporti Id Health Organ Vorld Health Org nosis   s://www.diabet Id Health Organ tical guide to co ers ention. https://	ing systemat nization. Diag ganization: C ADA. es.org/diabe nization. Mon onducting res for	ic reviews. Syste gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	ematic reviews agement of typ and. 2020. 2022. sis luating digital	. 2021 Dec;10(1 oe 2 diabetes (H Available health interver	l):1-1. HEARTS- from: itions: a
Id Health Orgar Vorld Health Org nosis   s://www.diabet Id Health Organ tical guide to co ers ention. https://	ization. Diag ganization: C ADA. es.org/diabe ization. Mor inducting res for	gnosis and mana Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	agement of typ and. 2020. 2022. sis luating digital	pe 2 diabetes (I Available health interver	from: tions: a
Vorld Health Or nosis   s://www.diabet ld Health Organ tical guide to co ers ention. https://	ganization: C ADA. es.org/diabe nization. Mor onducting res for	Geneva, Switzerl Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	and. 2020. 2022. sis luating digital	Available health interver	from: ntions: a
nosis   s://www.diabet ld Health Organ tical guide to co ers ention. https://	ADA. es.org/diabe nization. Mor onducting res for	Diabetes.org. etes/a1c/diagnos nitoring and eva search and asses	2022. sis Iluating digital sment.	Available health interver	from: ntions: a
s://www.diabet ld Health Organ tical guide to co ers ention. https://	es.org/diabe nization. Mor onducting res for	etes/a1c/diagno nitoring and eva search and asses	sis Iluating digital Isment.	health interver	ntions: a
ld Health Organ tical guide to co ers ention. https://	nization. Mon anducting res for	nitoring and eva search and asses	luating digital sment.	health interver	ntions: a
tical guide to co ers ention. https://	onducting res	search and asses	sment.		
ers ention. https://	for	Disease			
ention. https://		Disease	Co	ontrol	and
,	//www.cdc.g	gov/learnmorefe	elbetter/prog	rams/diabetes.ł	htm
lura A. Self-effic	cacy. The Co	orsini encycloped	lia of psycholo	ogy. John Wiley	& Sons,
doi. 2010;10(97	8047047921	.6):1-3.			
lura A, Watts R	E. Self-effica	icy in changing s	ocieties. Caml	oridge Universit	ty Press;
′.					
viour Change N	Models and	Strategies [Inter	net]. Eufic.org	. 2014. Availab	le from:
s://www.eufic.c	org/en/healt	hy-living/article,	/motivating-be	haviour-change	5
ne JA, Hernán M	/IA, Reeves I	BC, Savović J, Be	rkman ND, Vis	swanathan M, H	lenry D,
an DG, Ansari N	MT, Boutron	I, Carpenter JR.	ROBINS-I: a to	ool for assessin	g risk of
in non-randomi	sed studies	of interventions.	. bmj. 2016 Oc	t 12;355.	
		terne IA on hel	nalf of the RoB	32 Development	t Group.
ins JP, Savović J	, Page MJ, S				
	an DG, Ansari I in non-randomi	an DG, Ansari MT, Boutron in non-randomised studies	an DG, Ansari MT, Boutron I, Carpenter JR. in non-randomised studies of interventions. ins JP, Savović J, Page MJ, Sterne JA. on bel	an DG, Ansari MT, Boutron I, Carpenter JR. ROBINS-I: a to in non-randomised studies of interventions. bmj. 2016 Oc ins JP, Savović J, Page MJ, Sterne JA. on behalf of the RoE	an DG, Ansari MT, Boutron I, Carpenter JR. ROBINS-I: a tool for assessin in non-randomised studies of interventions. bmj. 2016 Oct 12;355. ins JP, Savović J, Page MJ, Sterne JA. on behalf of the RoB2 Developmen <sup>.</sup>

# 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\*

Section and topic	ltem No	Checklist item
ADMINISTRATIVE I	NFORM	IATION
Title:	C	6
Identification	1a	Effectiveness of self-management applications in improving clinica health outcomes and adherence among diabetic individuals in Low and Middle-Income Countries: A Systematic Review
Update	1b	N/A
Registration	2	The study has been registered in PROSPERO and the Registration ID is CRD42021245517.
Authors:		
Contact	3a	<ul> <li>Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup></li> <li>Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.</li> <li>Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India</li> <li>Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.</li> <li>Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.</li> </ul>

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	6	A deeper knowledge of the influence of mHealth applications is controlling blood sugar levels and managing diabetes is crucial to manage diabetes in terms of diabetic self-management in the LMIC as well as to prioritize research agendas, and policies. Hence, the review aims to assess the effectiveness of diabetic self-management applications in managing type 2 diabetes in LMICs, with a focus of Indian studies because India has the highest burden of diabete among the LMICs, and our systematic review findings may be use to inform future primary research related to the diabetes self management in India.
Objectives	7	<ol> <li>To identify how effective are the diabetic self-management applications on controlling the blood glucose levels of individuals with type 2 diabetes mellitus and</li> <li>To find the impact of diabetic self-management application in managing type 2 diabetes in LMICs, specifically in the Indian context</li> </ol>

2	
3	
4	
5	
ر ح	
0	
7	
8	
9	
10	
11	
12	
12	
13	
14	
15	
16	
17	
18	
10	
19	
20	
21	
22	
23	
24	
25	
25	
26	
27	
28	
29	
30	
31	
21	
32	
33	
34	
35	
36	
37	
20	
20	
39	
40	
41	
42	
43	
ΔΔ	
 //	
45	
46	
47	
48	
49	
50	
50	
21	
52	
53	
54	
55	
56	
57	
57	
58	
59	
60	

		BMJ Open
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 diagnosis <sup>17</sup> 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 behavior changes.
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	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 studie included in the first stage of screening will be independently evaluated by two authors. Exclusion of the studies in this stage wi be done only after expert advice and the included studies will be
		screened further for full text by the authors. At the full-text screenin 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 of exclusion of the paper, then the disagreement will be resolved by the third reviewer or an expert and then will arrive at conclusion of including or excluding a paper based on predetermined criteria Reasons for exclusion will be given at the full-text screening stag and the PRISMA flowchart will be used to depict the screenin process. The rationale for exclusion will be provided for all th excluded studies throughout the process.
Data collection process	11c	Data extraction will be performed using a standardised pre-teste data extraction format by the authors. The data extraction form wi be pilot tested by each author and will be edited based on discussio among the authors. (Refer; supplementary file-3 Data extractio 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' affiliations, Title, Journal name, publication year, and country of conduct will be collected along with Characteristics of the includer studies. Data will be extracted based on the type of study, stud objectives, Inclusion criteria, participant's characteristics Intervention details, comparator, and the study outcome.
Outcomes and	13	A detailed summary of all the included studies will include

ו ר	
2	
2	
4 5	
5	
0	
/	
ð	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	
51	
52	
52	
54	
54	
55	
50	
5/ 50	
58	

60

		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 meta-
		analysis 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,
Risk of blas in	14	I wo authors will independently assess the risk of bias in included
individual studies		studies. The Cochrane Risk of Blas (ROB 2) tool will be used to
		randomized Studies of Interventions assessment tool (ROBINS-I) for
		Non-Randomised studies.
Data synthesis	15a	N
	15b	A detailed summary of all the included studies in a narrative format
		will be given It will include information on authors, study objectives
	ļ	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, l <sup>2</sup> statistic,
		Chi <sup>2</sup> test, and Tau <sup>2</sup> 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

	inadec	juate or missing and the record will be maintained on the
	amour	nt of missing data with reasons. An assessment for publication
	bias w	ill be made by creating a funnel plot only if there are at leas
	10 stu	dies in the meta-analysis. A narrative synthesis will be done
	therea	are less than 10 included studies.
	150	
	15d	
Meta-bias(es)	16 Not ap	plicable.
Confidence in	17 Not ap	plicable.
cumulative evidence		
	For peer review only	http://hmiopen.hmi.com/site/about/quidelings.yhtml
	I ULDEELLEVIEW UTIV -	http://phillopen.phil.com/site/about/quideiiiies.Xiitiiii

# Supplementary file: 2

#### II. Search Strategy

Database	Search strategy	Hits
PubMed	(("diabetes mellitus, type 2"[MeSH Terms] OR "self- management/education"[MeSH Major Topic]) AND "Mobile Applications"[MeSH Major Topic] AND "english"[Language] AND "english"[Language]) AND ((fha[Filter]) AND (clinicaltrial[Filter] OR randomized controlled trial[Filter] OR review[Filter]) AND (humans[Filter]) AND (english[Filter]))	65
World Bank list of low and middle- income countries included in the study (OR)	Afghanistan, Albania, Algeria, American Samoa, 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, dem. Rep., Congo, rep., Costa Rica, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, Arab Rep., El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Fiji, Gabon, Gambia, the Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran, Islamic Rep. Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Korea, dem. People's rep. Kosovo, Kyrgyz, republic, Lao pdr, Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia, fed. Sts., Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, North Macedonia, Pakistan, Panama, Papua new guinea, Paraguay, Peru, Philippines, Romania, Russian Federation, Rwanda, Samoa, Sao tome and Principe,	7,361,793

	South Africa, South Sudan, Sri Lanka, St. Lucia, St. Vincent, and the Grenadines, Sudan, Suriname, Syrian Arab Republic, Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Yemen, rep., Zambia and Zimbabwe	
Total 1AND 2 (2015-2022)	("diabetes mellitus, type 2"[MeSH Terms] OR "self management/education"[MeSH Major Topic]) AND "Mobile Applications"[MeSH Major Topic] AND "english"[Language] AND "english"[Language] AND ("hasabstract"[All Fields] AND ("clinical trial"[Publication Type] OR "randomized controlled trial"[Publication Type] OR "review"[Publication Type]) AND "humans"[MeSH Terms] AND "english"[Language]) AND ("afghanistan"[All Fields] OR "Albania"[All Fields] OR "Algeria"[All Fields] OR "American"[All Fields] OR "Argentina"[All Fields] OR "American"[All Fields] OR "Argentina"[All Fields] OR "Armenia"[All Fields] OR "Argentina"[All Fields] OR "Bangladesh"[All Fields] OR "Azerbaijan"[All Fields] OR "Bangladesh"[All Fields] OR "Belarus"[All Fields] OR "Belize"[All Fields] OR "Belarus"[All Fields] OR "Bosnia"[All Fields] OR "Benin"[All Fields] OR "Bosnia"[All Fields] OR "Brazil"[All Fields] OR "Bulgaria"[All Fields] OR "Brazil"[All Fields] OR "Bangladesh"[All Fields] OR "Brazil"[All Fields] OR "Bosnia"[All Fields] OR "Brazil"[All Fields] OR "Cabo"[All Fields] OR "Burkina"[All Fields] OR "Cabo"[All Fields] OR "Burkina"[All Fields] OR "Cabo"[All Fields] OR "Cameroon"[All Fields] OR "Cambodia"[All Fields] OR "Cameroon"[All Fields] OR "Central"[All Fields] OR "Chad"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Republic"[All Fields] OR "Congo"[All Fields] OR "Republic"[All Fields] OR "Congo"[All Fields] OR "Republic"[All Fields] OR "Costa"[All Fields] OR "Republic"[All Fields] OR "Costa"[All Fields] OR "Republic"[All Fields] OR "Costa"[All Fields] OR "Republic"[All Fields] OR "Dominican"[All Fields] OR "Egypt"[All Fi	19

1	
2	
	"Guinea"[All Fields] OR "Eritrea"[All Fields] OR
5	"Eswatini"[All Eields] OR "Ethionia"[All Eields] OR
6	
7	"Fiji"[All Fields] OR "Gabon"[All Fields] OR "Gambia"[All
8	Fields] OR "Georgia"[All Fields] OR "Ghana"[All Fields]
9	OR "Grenada" [All Fields] OR "Guatemala" [All Fields] OR
10	"Guinea"[All Fields] OR "Guinea-Bissau"[All Fields] OR
11	"Guvana"[All Fields] OR "Haiti"[All Fields] OR
12	"Hondurge"[All Fields] OR "India"[All Fields] OR
13	
14	"Indonesia"[All Fields] OR "Iran"[All Fields] OR
15	"Islamic"[All Fields] OR "rep"[All Fields] OR "Iraq"[All
16	Fields] OR "Jamaica"[All Fields] OR "Jordan"[All Fields]
17	OR "Kazakhstan"[All Fields] OR "Kenva"[All Fields] OR
18	"Kiribati"[All Fields] OB "Korea"[All Fields] OB "dem"[All
19	Kinbati [Air Heids] OK Korea [Air Heids] OK deni [Air
20	rielasj uk People's [All Fields] UK rep [All Fields] UK
21	"Kosovo"[All Fields] OR "Kyrgyz"[All Fields] OR
22	"Republic"[All Fields] OR "Lao"[All Fields] OR "pdr"[All
23	Fields] OR "Lebanon" [All Fields] OR "Lesotho" [All Fields]
24	OB "Liberia"[All Fields] OB "Libya"[All Fields] OB
25	"Madagasaar" [All Fields] OR "Malawi" [All Fields] OR
26	Madagascar [All Fields] OR Malawi [All Fields] OR
27	"Malaysia"[All Fields])
28	Translations
29	fha[Filter]: hasabstract
30	clinicaltrial[Filter]: clinical trial [PT]
31	randomized controlled trial[Filter]: randomized
3Z 22	
27	controlled trial [PT]
25	review[Filter]: review [PT]
36	humans[Filter]: humans[MH]
37	english[Filter]: english [LA]
38	
39	
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	

# Supplementary file: 3

#### III. Data extraction from

Title of the study         Authors         The Year of the study conducted         Year of publication         Doi & Journal         Objectives of the study         Participant characteristics         Total number of participants         Setting/ context/ country	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Authors         The Year of the study conducted         Year of publication         Doi & Journal         Objectives of the study         Participant characteristics         Total number of participants         Setting/ context/ country	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
The Year of the study conducted Year of publication Doi & Journal Objectives of the study Participant characteristics Total number of participants Setting/ context/ country	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Year of publication Doi & Journal Objectives of the study Participant characteristics Total number of participants Setting/ context/ country	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Doi & Journal Objectives of the study Participant characteristics Total number of participants Setting/ context/ country	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Objectives of the study Participant characteristics Total number of participants	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM Low-income country
Participant characteristics Total number of participants	Number of participants Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Total number of participants Setting/ context/ country	Age Gender Ethnicity Socioeconomic group Educational status Duration of T2DM
Total number of participants	Gender Ethnicity Socioeconomic group Educational status Duration of T2DM Low-income country
Total number of participants	Ethnicity Socioeconomic group Educational status Duration of T2DM Low-income country
Total number of participants	Socioeconomic group Educational status Duration of T2DM Low-income country
Total number of participants	Educational status Duration of T2DM Low-income country
Total number of participants	Duration of T2DM Low-income country
Total number of participants	Low-income country
Setting/ context/ country	Low-income country
secting, context, country	
	Lower Middle-income country
	Upper Middle-income country
World Bank Region	South Asia
	Sub-Saharan Africa
	East Asia and the Pacific
	Europe and Central Asia
	Latin America and the Caribbean
	The Middle East and North Africa
	North America
Description of intervention for type 2	M health application
diabetes	Infographics
	Video clips
	Text messages
	Others – to be specified
Search details	Year
Source	IndMED
	Medline Plus
	OpenMED

Page 2	26 of 25 መ
	MJ Ope
	n: first
	publish
	ied as 1
	0.1136/ Protec
	bmjope ted by
	n-2021- copyrig
	060108 ht, inclu
	on 15 N Iding fo
	lovemb Ense r uses i
	er 2022 eigneme related
	Downl ent Sup to text a
	oaded f erieur (/ and dat:
	rom htt ABES) a minin
	p://bmj g, Al tra
	open.br iining, a
	nj.com/ Ind sim
	on Jun Ilar tech
	e 12, 20 Inologi
	)25 at A es.
	gence E
	Bibliog
	raphiqu
	le de l

	Ovid Medline
	PubMed / MEDLINE
	Scopus
	Web of Science
	Other Bibliographical Databases
The range of years included	No limit
No of included studies	
Type of studies included	RCT
	Quasi-experimental study
	Case-control
	Cohort
	Controlled trial
Comparator	Duration of the intervention
	Across the regions (LMICs)
	Age groups
	Gender
Analysis	
Method of analysis	
ollow up sessions	
Outcome assessed	Primary
	secondary
Results/ findings	
Significance	4
Heterogeneity if done	
Study Limitations	<b>O</b> .
Study Limitations	0.

# **BMJ Open**

# Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in Low and Middle-Income Countries: A Systematic Review

lournal:	BM1 Open
Manuscript ID	bmjopen-2021-060108.R2
Article Type:	Protocol
Date Submitted by the Author:	01-Aug-2022
Complete List of Authors:	dsouza, sherize; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Shetty, Sahana; Manipal Academy of Higher Education, Dept. Endocrinology, Kasturba Medical College Hospital, MAHE venne, Julien; Manipal Academy of Higher Education, Digital Health and wellbeing, Prasanna School of Public Health Pundir , Prachi ; Manipal Academy of Higher Education, Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Rajkhowa, Priyobrat; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health; Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health, Research Institute, Jean Monnet Chair in European Public Health, Department of International Health
<b>Primary Subject Heading</b> :	Public health
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Evidence based practice
Keywords:	PUBLIC HEALTH, Information management < BIOTECHNOLOGY & BIOINFORMATICS, DIABETES & ENDOCRINOLOGY, PREVENTIVE MEDICINE, NUTRITION & DIETETICS, Epidemiology < TROPICAL MEDICINE
	•

1	
2	
3	
4	SCHOLARONE**
5	Manuscripts
7	
8	
9	
10	
11	
12	
14	
15	
16	
1/	
19	
20	
21	
22	
23	
25	
26	
27	
20 29	
30	
31	
32	
33 34	
35	
36	
37	
38 39	
40	
41	
42	
43 ΔΔ	
45	
46	
47	
48 49	
50	
51	
52	
53	
54 55	
56	
57	
58	
אכ 60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

# EFFECTIVENESS OF SELF-MANAGEMENT APPLICATIONS IN IMPROVING CLINICAL HEALTH OUTCOMES AND ADHERENCE AMONG DIABETIC INDIVIDUALS IN LOW AND MIDDLE-INCOME **COUNTRIES: A SYSTEMATIC REVIEW**

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- 6. Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

# Postal and E-mail addresses of the corresponding author

Prof. Dr. Helmut Brand, Founding Director, Prasanna School of Public Health, Manipal Academy

of Higher Education, Manipal 576104, Udupi, Karnataka, India. Ph: 0824 2923157

Email: helmut.brand@manipal.edu / helmut.brand@maastrichtuniversity.nl

**Total word count in main text** – 2731 (excluding references and supplementary files/tables)

Total number of references: 28, word count - 820

Number of supplementary files - 3

Total word count of all three supplementary files -2099

Introduction: A variety of mobile health applications are available to monitor an individual's health or lifestyle to make it convenient to access healthcare facilities at home. Despite the growing number of mobile applications, the evidence from research on normalizing HbA1c levels (HbA1C is defined as "estimated average blood glucose") but the use of these applications remains a mystery. The burden of Type 2 diabetes mellitus (T2DM) is high in Low- and Middle-Income Countries (LMICs), with the highest burden in the Indian population. Our objective is 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

Methods and analysis: The electronic databases included for search are PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites, and reference lists of included studies. Studies published in the English language in indexed and peer-reviewed sources will be considered. Studies reporting the effectiveness of mobile applications in the management of T2D in LMICs will be eligible for inclusion. The Population-Intervention-Comparison Outcomes (PICO) Framework and the PRISMA statement 2021, will be used for reporting. Data analysis will be carried out using narrative synthesis, and a meta-analysis may be conducted if we come across homogenous data for the outcome.

Ethics and dissemination: As this study is a systematic review, we will not be recruiting any participants for the study and hence will not require ethical approval. The study summary will be disseminated at a conference.

Keywords: mobile health application, mHealth, self-management applications, type 2 diabetes mellitus

Prospero registration ID: CRD42021245517

#### Article summary:

Strengths of the study:

- 1. Novelty of the systematic review topic
- 2. Adherence to mHealth applications and Positive behavioral outcomes will be evaluated

Limitations of the study:

- 1. The exclusion of articles in languages other than English and articles behind a paywall
- 2. The geographical area of the study will be limited to Low and Middle-Income Countries (LMICs)

#### Introduction

'Diabetes' is a term used to describe a group of diseases characterized by elevated blood glucose levels. It is caused by a lack of insulin production or function, or both, which may occur for various reasons and lead to protein and lipid metabolic disorders<sup>1</sup>. Various scientific studies have established that adequate blood glucose regulation minimizes the long-term effects of type 2 diabetes. Increasing inclination towards technology provides an opportunity for the delivery of innovative self-management interventions. The global burden of type 2 diabetes mellitus (T2DM) continues to rise, with T2DM estimated to affect over 9% of the global population by 2035<sup>2</sup>. The use of mobile health tools to help people manage chronic diseases is on the rise, but evidence of their effectiveness is mixed<sup>3</sup>. An overview and a scoping review were conducted to understand the Impact of mobile health (mHealth) Interventions among chronic diabetic patients showed improving glycemic control using diverse mHealth interventions<sup>4&5</sup>. Another trial proved to have improved behavioral outcomes among diabetic individuals<sup>6</sup>. People with diabetes are increasingly using mobile technology for health (mHealth) interventions to help improve selfmanagement; however, these interventions have not been implemented by many patients, and dropout rates are common.

Page 5 of 26

#### **BMJ** Open

Type 2 Diabetes in LMICs: A slew of issues plagues the delivery of healthcare in low and middleincome countries (LMICs). Where four out of every five people with diabetes now live in these countries, and the rate of diabetes is increasing in poorer communities<sup>7</sup>. In 57 developing countries, the World Health Organization (WHO) estimates a 4.3 million healthcare worker shortage, resulting in understaffed hospitals, limited patient access to care, and a significant patient-physician contact gap, especially in rural areas <sup>8</sup>. To bridge this gap in terms of diabetes management, self-management apps can play a pivotal role in India and the LMICs. To understand how mHealth apps aid in diabetes management, knowing what is meant by eHealth is important.

eHealth: is the use of information and communication technologies (ICT) for health.

The unprecedented spread of mobile technologies as well as advancements in their innovative application to address health priorities have evolved into a new field of eHealth, known as mHealth.

mHealth: The Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices<sup>9</sup>.

A mHealth application used in the self-management of T2DM, along with standard care- a study conducted in India in the year 2017, has proved that the users of the study with "Gather m-Health app" as an intervention given to the participants of the study improved medication adherence and Blood glucose testing accuracy over 6 months of the study<sup>10</sup> Evidence generated by another Indian study using a mHealth application "DIAGURU" mainly focused on lifestyle modification and medication management over 6 months suggesting, that technological approaches can be used as a public health measure to improve the quality of life of patients with type 2 Diabetes Mellitus<sup>11</sup>.

Non-exercise Activity Thermogenesis (NEAT) a smartphone intervention used to reduce the health consequences of sedentary behavior, provided an opportunity to intervene and improve

# Page 6 of 26 BMJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

#### **BMJ** Open

the health of a large proportion of the population in  $Chicago^{12}$ . Although there might be a few barriers to the use of remote mHealth technologies in self-managing type 2 diabetes with poor technology literacy<sup>13,</sup> desired elements such as blood sugar monitoring, instructional content, personalized feedback, reminders, and goal setting were thought to be beneficial<sup>14</sup>. The interventions may also include other forms of mHealth solutions like texting, emailing, video clips, and graphics. To find evidence on how the use of mobile applications has impacted the health of type 2 diabetic individuals. Few of the proven interventions leading to more effective control of diabetes were reported<sup>15</sup>.

Measures to control T2DM: The rising prevalence of T2DM has put pressure on healthcare systems to properly manage diabetic individuals so that diabetes complications are avoided. Optimizing patient outcomes by combining medications with self-management of glycemic control and other risk variables could be a better approach. To help people keep blood sugar within the normal range (i.e., <= 5.7% of the HbA1c) the American Diabetes Association also recommends: engaging in weight management activities, eating a nutritious diet, getting regular exercise, smoking cessation, and stress reduction as the key factors to achieve normal glycemic levels.

Once diabetes has progressed to extreme levels, dietary adjustments and lifestyle modifications alone are no longer sufficient to maintain appropriate blood sugar levels, and doctors may urge a person to take medications. However, for older adults diagnosed with diabetes and whose blood sugar is marginally high, drugs may or may not be required<sup>16</sup>. Along with dietary adherence, behavioral factors such as "Self-efficacy" have proved to be the most significant predictive factor of HbA1c, Physical activity for Body Mass Index (BMI), and glucose self-monitoring for Fasting Blood Glucose (FBG) in leading a healthy lifestyle<sup>17</sup>. In recent years, there are an increasing number of smartphone applications that are meant to help T2DM patients manage their condition, but only a few have been thoroughly evaluated among the general population globally<sup>18</sup>.

#### **Review Questions**

1. Are mHealth applications effective in managing blood glucose levels among individuals with type 2 diabetes mellitus in LMICs?

2. What is the impact of using mHealth applications in managing T2DM concerning healthpromoting behavior among the LMICs in the context of India?

**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.

#### Methods

The PRISMA 2020 statement; an updated guideline for reporting systematic reviews<sup>19</sup> will be used for reporting the review and the Population-Intervention-Comparison-Outcomes (PICO) framework will be used for defining the methods of the review. (Refer; to supplementary file 1-PRISMA checklist). The systematic review protocol was registered on the international prospective register of systematic reviews, PROSPERO, with the registration number CRD42021245517.

#### Criteria for considering studies for this review

#### Types of studies:

*Study design:* Randomized controlled trials (RCTs), Non-Randomized controlled trials (NRCTs) like the Quasi-experimental studies, and controlled before-after studies will be included. Observational studies, conference papers, editorials, reports, and other studies without any mobile app interventions in them will be excluded.

*Year of publication:* we will include publications matching our criteria from the year 2015 to 2022. As the search strategy yielded publications from the year 2015 onwards.

*Type of participants:* 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 diagnosis<sup>20</sup> i.e., HbA1c values  $\geq$ 6.5% (48 mmol/mol), Fasting Blood Glucose (FBG)  $\geq$ 7.0 mmol/L (126 mg/dL), Random plasma/Blood Glucose (RBS)  $\geq$ 11.1 mmol/L (200 mg/dL), Oral Glucose Tolerance Test (OGTT)  $\geq$ 200 mg/dl.

*FBG:* Fasting means not having anything to eat or drink (except water) for at least 8 hours before the test. Diabetes is diagnosed at FBG of greater than or equal to 126 mg/dl.

*RBS:* This test is a blood check at any time of the day when an individual has severe diabetes symptoms (Diabetes is diagnosed at blood glucose of greater than or equal to 200 mg/dl.

*OGTT:* A two-hour test that checks your blood glucose levels before and two hours after you drink a special sweet drink. Diabetes is diagnosed at two-hour blood glucose  $\geq$  200 mg/dl <sup>21</sup>.

Patient and public involvement: patients and the public will not be involved in any way in this study.

# Type of interventions

Digital health: The use of digital, mobile, and wireless technologies to support the achievement of health objectives. Digital health describes the general use of information and communications technologies (ICT) for health and is inclusive of both mHealth and eHealth<sup>22</sup>. From the context of our study, the term mHealth refers to the mobile applications used in the self-management of T2DM. The interventions may also include other simpler forms of mHealth solutions like texting, emailing, video clips, graphics, and web services.

**Type of Comparison:** the comparator groups would be the individuals who received standard hospital treatment or no hospital care and who received an intervention.

Type of outcome measures: Primary outcomes include,

Clinical outcome (HbA1c at 3 months interval): [A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives<sup>23</sup>]

Secondary outcomes include,

- Adherence to diabetic self-management applications and medication: The studies must have reported using any of the standard survey tools to record daily medication intake and app usage during the follow-up for a year.
- Self-efficacy with adherence to mHealth applications: Self-efficacy is defined as "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations." - Albert Bandura<sup>24, 25</sup>. The studies must have done a subjective evaluation of the individual's willingness to use the self-management applications to manage T2DM and those who are confident to follow in their near future.
- Health promoting behavior: If the study participants during their follow-up period adapted a positive change in behavior towards achieving better health, like opting for a healthy diet, regular moderate exercising, brisk walking, and reducing/ managing their stress levels. Will be checked across the guality of life improvement index if any done in the studies <sup>26</sup>. Health-promoting behavior changes will not be limited to nutrition, physical exercise/ activity, or regular/ frequency of blood glucose monitoring.

Search methods for identification of studies: PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites. Forward citation search will be undertaken for any key references identified and reference lists of included studies (Refer to supplementary file 2- 'Search strategies' for more search information).

BMJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

We will be using Endnote library version X7 for screening and downloading the full-text articles and Microsoft Excel 2013 will be used for data extraction of the full-text articles. 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 fulltext screening stage and the PRISMA flowchart (Refer to supplementary file 1) will be used to depict the screening process. The rationale for exclusion will be provided for all the excluded studies throughout the process.

**Data extraction and management:** Data extraction will be performed using a standardized pretested 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. The data extraction form will include information on citation details, characteristics of the studies, location, region, population, intervention, the effectiveness of an intervention, and the information on outcome and the main findings (Refer to 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 with a minimum waiting period of two weeks for their reply. In the event of no response from the authors of the study, a decision will be taken by the team of authors of the systematic review.

**Assessment of risk of bias in included 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<sup>27</sup>. Risk of bias in Non-randomized Studies of Interventions assessment tool (ROBINS-I) for Non-Randomised studies<sup>28</sup>.

Page 11 of 26

#### **BMJ** Open

Data synthesis: Firstly, we will provide a detailed summary of all the included studies in a narrative format. 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 randomeffects 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, I<sup>2</sup> statistic, Chi<sup>2</sup> test, and Tau<sup>2</sup> 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. All the analyses will be conducted in Review Manager 5.3 and STATA 16.

Description of primary and secondary outcomes, whether adherence to diabetic selfmanagement applications and medication has improved or not, Behavior change will be noted with the quality of life improvement index and self-efficacy will be checked following the improvement in managing T2DM. Listing out various measurement tools and devices used for judging the above-mentioned outcomes.

**Subgroup analysis:** Subgroup analysis will be performed for the following if appropriate. Sensitivity analysis will be performed if we find out any uncertainties in one or more input variables that may lead to uncertainties among other output variables.

Subgroup analysis will be performed for the following:

• Duration of the given intervention (3 months intervals up to a year)

BMJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

- Comparing study effectiveness within the LMICs
- The most effective rate of using the Diabetic self-management app in age groups as classified by the UN
- Gender

# Author affiliations:

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup> Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

**Ethics and dissemination:** The study will be a systematic review of the published articles from different recognised and accessible databases and will not recruit any human participants directly, therefore, ethical clearance is not applicable. The dissemination of the final review findings will be done at a national or international conference and will be published in an indexed peer-reviewed journal.

**Author Contributions:** HB is the corresponding author, SMD, SS, JV, PP, MGL, PR, and HB conceptualized the study. SMD, SS, JV, PP, MGL, PR, and HB drafted the manuscript. All authors

Acknowledgments: Not applicable.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sector

**Conflicts of interest:** There is no conflict of interest in this project.

Supplemental material: Supplementary materials are enclosed as 1, 2 and 3

Patient and public involvement: patients and the public were not involved in any way in this study ele.

# **References:**

- 1. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes care. 2013 Jan;36(Suppl 1):S67.
- 2. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw J, Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-management of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealth and uHealth. 2019 Jan 10;7(1):e10321.
- 3. Dugas M, Crowley K, Gao GG, Xu T, Agarwal R, Kruglanski AW, et al. Individual differences in regulatory mode moderate the effectiveness of a pilot mHealth trial for diabetes management among older veterans. PLoS One. 2018; 13(3):e0192807.
- 4. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR

Mhealth Uhealth. 2018 Jan 17;6(1):e23. doi: 10.2196/mhealth.8873. PMID: 29343463; PMCID: PMC5792697.

- Eberle C, Löhnert M, Stichling S. Effectiveness of Disease-Specific mHealth Apps in Patients With Diabetes Mellitus: Scoping Review. JMIR Mhealth Uhealth. 2021 Feb 15;9(2):e23477. doi: 10.2196/23477. PMID: 33587045; PMCID: PMC7920757.
- 6. Boels AM, Rutten G, Zuithoff N, de Wit A, Vos R. Effectiveness of diabetes selfmanagement education via a smartphone application in insulin treated type 2 diabetes patients - design of a randomised controlled trial ('TRIGGER study'). BMC Endocr Disord. 2018 Oct 22;18(1):74. doi: 10.1186/s12902-018-0304-9. PMID: 30348142; PMCID: PMC6196442.
- Dunachie S, Chamnan P. The double burden of diabetes and global infection in low and middleincome countries. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2019 Feb 1;113(2):56-64.
- Mahmud N, Rodriguez J, Nesbit J. A text message-based intervention to bridge the healthcare communication gap in the rural developing world. Technology and Health Care. 2010 Jan 1;18(2):137-44.
- 9. World Health Organization. mHealth: new horizons for health through mobile technologies. mHealth: new horizons for health through mobile technologies.. 2011.
- 10. Kleinman NJ, Shah A, Shah S, Phatak S, Viswanathan V. Improved medication adherence and frequency of blood glucose self-testing using an m-Health platform versus usual care in a multisite randomized clinical trial among people with type 2 diabetes in India. Telemedicine and e-Health. 2017 Sep 1;23(9):733-40.
- Kumar DS, Prakash B, Chandra BS, Kadkol PS, Arun V, Thomas JJ. An android smartphone-based randomized intervention improves the quality of life in patients with type 2 diabetes in Mysore, Karnataka, India. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2020 Sep 1;14(5):1327-32.
- Pellegrini CA, Hoffman SA, Daly ER, Murillo M, Iakovlev G, Spring B. Acceptability of smartphone technology to interrupt sedentary time in adults with diabetes. Translational behavioral medicine. 2015 Sep 1;5(3):307-14.

13.

14.

15.

16.

17.

18.

19.

20.

21.

1 2 3

4 5

6 7

8

9 10

11 12

13 14

15 16

17

22 23

24 25

26 27

28

29 30

31 32

33 34

35 36

37 38

39

40 41

42 43

44 45

46 47

48 49

50

51

52

60

#### **BMJ** Open

Alvarado MM, Kum HC, Coronado KG, Foster MJ, Ortega P, Lawley MA. Barriers t	:0
remote health interventions for type 2 diabetes: a systematic review and propose	d
classification scheme. Journal of medical Internet research. 2017 Feb 13;19(2):e6382	2.
Peng W, Yuan S, Holtz BE. Exploring the challenges and opportunities of health mobil	le
apps for individuals with type 2 diabetes living in rural communities. Telemedicine an	ıd
e-Health. 2016 Sep 1;22(9):733-8.	
Azelton KR, Crowley AP, Vence N, Underwood K, Morris G, Kelly J, Landry MJ. Digita	al
health coaching for type 2 diabetes: randomized controlled trial of healthy at home	e.
Frontiers in Digital Health. 2021;3.	
West M. Controlling type 2 diabetes: With and without medication [Internet]	:].
Medicalnewstoday.com. 2021. Available from	- n:
https://www.medicalnewstoday.com/articles/how-to-control-type-2-diabetes	
Brown SA, García AA, Brown A, Becker BJ, Conn VS, Ramírez G, Winter MA, Sumlin LI	L,
Garcia TJ, Cuevas HE. Biobehavioral determinants of glycemic control in type	2
diabetes: a systematic review and meta-analysis. Patient education and counseling	g.
2016 Oct 1;99(10):1558-67.	5
Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw .	J,
Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-managemen	nt
of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealt	th
and uHealth. 2019 Jan 10;7(1):e10321.	
Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, Shamseer I	L,
Tetzlaff JM, Akl EA, Brennan SE, Chou R. The PRISMA 2020 statement: an update	d
guideline for reporting systematic reviews. Systematic reviews. 2021 Dec;10(1):1-1.	
World Health Organization. Diagnosis and management of type 2 diabetes (HEARTS	S-
D). World Health Organization: Geneva, Switzerland. 2020.	
Diagnosis   ADA. Diabetes.org. 2022. Available from	n:
https://www.diabetes.org/diabetes/a1c/diagnosis	
1	4
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

四
- 22. World Health Organization. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment.
  - 23. Centers for Disease Control and Prevention, https://www.cdc.gov/learnmorefeelbetter/programs/diabetes.htm
  - Bandura A. Self-efficacy. The Corsini encyclopedia of psychology. John Wiley & Sons, 24. Inc. doi. 2010;10(9780470479216):1-3.
- 25. Bandura A, Watts RE. Self-efficacy in changing societies. Cambridge University Press; 1997.
- 26. Behaviour Change Models and Strategies [Internet]. Eufic.org. 2014. Available from: https://www.eufic.org/en/healthy-living/article/motivating-behaviour-change
- 27. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. bmj. 2016 Oct 12;355.
- 28. Higgins JP, Savović J, Page MJ, Sterne JA. on behalf of the RoB2 Development Group. Revised Cochrane risk-of-bias tool for randomized trials (RoB 2). 2019 Jul.

iez oni

SUPPLEMENTARY FI	SUPPLEMENTARY FILE: 1 I. PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*			
I. PRISMA-I Protocols protocol*				
Section and topic	ltem No	Checklist item		
ADMINISTRATIVE IN	FORM	ΛΑΤΙΟΝ		
Title:	C	4		
Identification	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		
Update	1b	N/A		
Registration	2	The study has been registered in PROSPERO and the Registration II is CRD42021245517.		
Authors:				
Contact	3а	<ul> <li>Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup></li> <li>Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Department of Endocrinology, Kasturba Medical College Hospita MAHE, Manipal, India.</li> <li>Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India</li> <li>Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.</li> <li>Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.</li> </ul>		

2	
2	
5	
4	
5	
6	
7	
8	
9	
10	
10	
11	
12	
13	
14	
15	
16	
17	
17	
18	
19	
20	
21	
22	
23	
23	
24	
25	
26	
27	
28	
29	
30	
21	
21	
32	
33	
34	
35	
36	
37	
20	
20	
39	
40	
41	
42	
43	
44	
15	
C+	
46	
47	
48	
49	
50	
51	
51	
52	
53	
54	
55	
56	
57	
50	
50	
59	
60	

		BMJ Open
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	6	<b>Rationale:</b> 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	<ol> <li>To identify the effectiveness of mHealth applications in managing blood glucose levels of individuals with T2DM and</li> <li>To assess the impact of using mHealth applications in managing T2DM concerning health-promoting behavior among the LMICs in the context of India</li> </ol>

		1.
METHODS		
Eligibility criteria	8	We followed the PICO concept/framework
		Population (P): Adults over 18 years of age, technology literate, us a smartphone or personal computer diagnosed with type 2 diabe mellitus based on any one of the WHO 2020 criteria for diagnos i.e., HbA1c values ≥6.5% (48 mmol/mol), Fasting Blood Glucose (FB ≥7.0 mmol/L (126 mg/dL), Random plasma/Blood Glucose (R ≥11.1 mmol/L (200 mg/dL), an Oral Glucose Tolerance Test (OG ≥200 mg/dl.
		Intervention (I): mobile phones, patient monitoring device personal digital assistants (PDAs), and other wireless device mHealth solutions like applications or text messages, emails, vice clips, graphics, and web services.
		Comparison (C): the comparator groups would be the individu who received standard hospital treatment or no hospital care a those who received an intervention.
		Country comparison: impact of using diabetes self-management a 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, a Health-promoting behaviour.
Information sources	9	Authors in collaboration developed search strategies using medic 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	11a	The search results collected from the electronic databases will be

		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 of exclusion of the paper, then the disagreement will be resolved by the third reviewer or an expert and then will arrive at conclusion or 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 o 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	13	A detailed summary of all the included studies will include
prioritization		information on authors, study objectives. Inclusion criteria

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

59

Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.	MJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de l
--	--

	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 meta
	analysis 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	14 Two authors will independently assess the risk of bias in include
individual studies	studies. The Cochrane Risk of Bias (RoB 2) tool will be used to
	Provide the second s
	randomized Studies of Interventions assessment tool (ROBINS-I)
	Non-Randomised studies.
Data synthesis	15a
	15b A detailed summary of all the included studies in a narrative for
	will be given. It will include information on authors, study object
	Inclusion criteria, Intervention details, comparator, outc
	measures, and the country. Secondly, an evaluation will be done
	is appropriate to perform a meta-analysis to assess the effective
	of diabetic self-management applications in controlling blood s
	levels. Meta-analysis with a random-effects model will be perfor
	if there is a similarity in terms of the participants, study des
	comparator, and outcomes. The pooled estimates will be obta
	separately for RCTs, and Non-RCTs (Quasi-experimental
	controlled before-after studies). The summary estimates wil
	expressed in mean difference, standardized mean difference
	continuous outcomes, and relative risk & odds ratio for catego
	continuous outcomes, and relative risk & outs ratio for catego
	outcomes with 95% confidence intervals. Forest plots, I <sup>2</sup> stati
	Chi <sup>2</sup> test, and Tau <sup>2</sup> will be used to measure and assess heteroger
	among the included studies in each analysis. Meta-regression wi
	used to investigate heterogeneity if appropriate data is obtained
	attempt will be made to contact the study authors if dat
	attempt win be made to contact the study authors in dat

		BMJ Open
		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.
evidence		

## Supplementary file: 2

### II. Search Strategy

Database	Search strategy	Hits
PubMed	(("diabetes mellitus, type 2"[MeSH Terms] OR "self- management/education"[MeSH Major Topic]) AND "Mobile Applications"[MeSH Major Topic] AND "english"[Language] AND "english"[Language]) AND ((fha[Filter]) AND (clinicaltrial[Filter] OR randomized controlled trial[Filter] OR review[Filter]) AND (humans[Filter]) AND (english[Filter]))	65
World Bank list of low and middle- income countries included in the study (OR)	Afghanistan, Albania, Algeria, American Samoa, 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, dem. Rep., Congo, rep., Costa Rica, Cote d'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, Arab Rep., El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Fiji, Gabon, Gambia, the Georgia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, India, Indonesia, Iran, Islamic Rep. Iraq, Jamaica, Jordan, Kazakhstan, Kenya, Kiribati, Korea, dem. People's rep. Kosovo, Kyrgyz, republic, Lao pdr, Lebanon, Lesotho, Liberia, Libya, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Mexico, Micronesia, fed. Sts., Moldova, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, North Macedonia, Pakistan, Panama, Papua new guinea, Paraguay, Peru, Philippines, Romania, Russian Federation, Rwanda, Samoa, Sao tome and Principe,	7,361,793

	Senegal, Serbia, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, St. Lucia, St. Vincent, and the Grenadines, Sudan, Suriname, Syrian Arab Republic, Tajikistan, Tanzania, Thailand, Timor- Leste, Togo, Tonga, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Yemen, rep., Zambia and Zimbabwe	
Total 1AND 2 (2015-2022)	("diabetes mellitus, type 2"[MeSH Terms] OR "self management/education"[MeSH Major Topic]) AND "Mobile Applications"[MeSH Major Topic] AND "english"[Language] AND "english"[Language] AND ("hasabstract"[All Fields] AND ("clinical trial"[Publication Type] OR "review"[Publication Type]) AND "humans"[MeSH Terms] AND "english"[Language]) AND ("afghanistan"[All Fields] OR "Albania"[All Fields] OR "Algeria"[All Fields] OR "American"[All Fields] OR "Argentina"[All Fields] OR "American"[All Fields] OR "Argentina"[All Fields] OR "Armenia"[All Fields] OR "Argentina"[All Fields] OR "Angola"[All Fields] OR "Argentina"[All Fields] OR "Bangladesh"[All Fields] OR "Belarus"[All Fields] OR "Belize"[All Fields] OR "Belarus"[All Fields] OR "Bosnia"[All Fields] OR "Benin"[All Fields] OR "Bosnia"[All Fields] OR "Bolivia"[All Fields] OR "Bosnia"[All Fields] OR "Brazil"[All Fields] OR "Bosnia"[All Fields] OR "Brazil"[All Fields] OR "Bosnia"[All Fields] OR "Brazil"[All Fields] OR "Cabo"[All Fields] OR "Burundi"[All Fields] OR "Cabo"[All Fields] OR "Cameroon"[All Fields] OR "Cabo"[All Fields] OR "Cameroon"[All Fields] OR "Central"[All Fields] OR "Congo"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Comoros"[All Fields] OR "Congo"[All Fields] OR "Republic"[All Fields] OR "Costa"[All Fields] OR "Republic"[All Fields] OR "Costa"[All Fields] OR "Republic"[All Fields] OR "Dominican"[All Fields] OR "Republic"[All Fields] OR "	19

"Guinea"[All Fields] OR "Eritrea"[All Fields] OR
"Eswatini"[All Fields] OR "Ethiopia"[All Fields] OR
"Fiji"[All Fields] OR "Gabon"[All Fields] OR "Gambia"[All
Fieldel OD "Coercie" [All Fieldel OD "Chane" [All Fieldel
Fieldsj OK Georgia [All Fields] OK Ghana [All Fields]
OR "Grenada"[All Fields] OR "Guatemala"[All Fields] OR
"Guinea"[All Fields] OR "Guinea-Bissau"[All Fields] OR
"Guyana"[All Fields] OR "Haiti"[All Fields] OR
"Honduras"[All Fields] OR "India"[All Fields] OR
"Indonesia"[All Fields] OR "Iran"[All Fields] OR
"Islamic"[All Fields] OR "rep"[All Fields] OR "Iraq"[All
Fieldel OD "Jamaica" [All Fieldel OD "Jardan" [All Fieldel
OR "Kazakhstan"[All Fields] OR "Kenya"[All Fields] OR
"Kiribati"[All Fields] OR "Korea"[All Fields] OR "dem"[All
Fields] OR "People's"[All Fields] OR "rep"[All Fields] OR
"Kosovo"[All Fields] OR "Kyrgyz"[All Fields] OR
"Republic"[All Fields] OR "Lao"[All Fields] OR "pdr"[All
Fields] OR "Lebanon"[All Fields] OR "Lesotho"[All Fields]
OP "Liberia"[All Eiolde] OP "Libya"[All Eiolde] OP
"Iviadagascar" [All Fields] OK "Ivialawi" [All Fields] OK
"Malaysia"[All Fields])
Translations
fha[Filter]: hasabstract
clinicaltrial[Filter]: clinical trial [PT]
randomized controlled trial[Filter]: randomized
controlled trial [PT]
review[Eilter]: review [DT]
numans[Filter]: numans[IVIH]
english[Filter]: english [LA]

# Supplementary file: 3

# III. Data extraction from

Title of the study	
Authors	
The Year of the study conducted	
Year of publication	
Doi & Journal	
Objectives of the study	
Participant characteristics	Number of participants
<u> </u>	Age
	Gender
	Ethnicity
	Socioeconomic group
	Educational status
	Duration of T2DM
Total number of participants	
Setting/ context/ country	Low-income country
	Lower Middle-income country
	Upper Middle-income country
World Bank Region	South Asia
	Sub-Saharan Africa
	East Asia and the Pacific
	Europe and Central Asia
	Latin America and the Caribbean
	The Middle East and North Africa
	North America
Description of intervention for type 2	M health application
diabetes	Infographics
	Video clips
	Text messages
	Others – to be specified
Search details	Year
Source	IndMED
	Medline Plus
	OpenMED

Med / MEDLINE ous o of Science er Bibliographical Databases imit si-experimental study e-control ort trolled trial
ous o of Science er Bibliographical Databases imit si-experimental study e-control ort trolled trial
o of Science er Bibliographical Databases imit si-experimental study e-control ort trolled trial
er Bibliographical Databases imit si-experimental study e-control ort trolled trial
imit si-experimental study e-control ort trolled trial
si-experimental study e-control ort trolled trial
si-experimental study e-control ort trolled trial
si-experimental study e-control ort trolled trial
e-control ort trolled trial
ort trolled trial
trolled trial
ation of the intervention
oss the regions (LMICs)
groups
der
hary
ondary
4
4
-

# **BMJ Open**

# Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in Low and Middle-Income Countries: A Systematic Review

Journal:	BMJ Open		
Manuscript ID	bmjopen-2021-060108.R3		
Article Type:	Protocol		
Date Submitted by the Author:	12-Sep-2022		
Complete List of Authors:	dsouza, sherize; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Shetty, Sahana; Manipal Academy of Higher Education, Dept. Endocrinology, Kasturba Medical College Hospital, MAHE venne, Julien; Manipal Academy of Higher Education, Digital Health and wellbeing, Prasanna School of Public Health Pundir , Prachi ; Manipal Academy of Higher Education, Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Rajkhowa, Priyobrat; Manipal Academy of Higher Education, Health Policy, Prasanna School of Public Health; Maastricht University Care and Public Health Research Institute, Department of International Health, CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands Lewis, Melissa; Indian Institutes of Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health Brand, Helmut; Manipal Academy of Higher Education, Prasanna School of Public Health; Maastricht University Care and Public Health, Research Institute, Jean Monnet Chair in European Public Health, Department of International Health		
<b>Primary Subject Heading</b> :	Public health		
Secondary Subject Heading:	Diabetes and endocrinology, Health services research, Evidence based practice		
Keywords:	PUBLIC HEALTH, Information management < BIOTECHNOLOGY & BIOINFORMATICS, DIABETES & ENDOCRINOLOGY, PREVENTIVE MEDICINE, NUTRITION & DIETETICS, Epidemiology < TROPICAL MEDICINE		
	•		

1	
2	
3	
4	SCHOLARONE <sup>™</sup>
5	Manuscripts
6	Handscripts
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
10	
17	
10	
د ا 20	
20	
∠ I ⊃⊃	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	
40	
41	
42	
43	
44	
45	
46	
47	
48	
49	
50	
51	
52	
53	
54	
55	
56	
57	
58	
59	— I I., // I I., // I I. /// / / // / / / / / / / / / /
60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

# EFFECTIVENESS OF SELF-MANAGEMENT APPLICATIONS IN IMPROVING CLINICAL HEALTH OUTCOMES AND ADHERENCE AMONG DIABETIC INDIVIDUALS IN LOW AND MIDDLE-INCOME COUNTRIES: A SYSTEMATIC REVIEW

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

# Postal and E-mail addresses of the corresponding author

Prof. Dr. Helmut Brand, Founding Director, Prasanna School of Public Health, Manipal Academy

of Higher Education, Manipal 576104, Udupi, Karnataka, India. Ph: 0824 2923157

Email: helmut.brand@manipal.edu / helmut.brand@maastrichtuniversity.nl

Total word count in main text – 2789 (excluding abstract, references, supplementary files/tables)

**Total number of references:** 28, word count – 820

Number of supplementary files - 3

Total word count of all three supplementary files -1925

#### Abstract

Page 3 of 25

#### **BMJ** Open

Introduction: A variety of mobile health applications are available to monitor an individual's health or lifestyle to make it convenient to access healthcare facilities at home. Despite the growing number of mobile applications, the evidence from research on normalizing HbA1c levels (HbA1C is defined as "estimated average blood glucose") but the use of these applications remains a mystery. The burden of Type 2 diabetes mellitus (T2DM) is high in Low- and Middle-Income Countries (LMICs), with the highest burden in the Indian population. Our objective is 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

Methods and analysis: The electronic databases included for search are PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites, and reference lists of included studies. Studies published in the English language in indexed and peer-reviewed sources will be considered. Studies reporting the effectiveness of mobile applications in the management of T2D in LMICs will be eligible for inclusion. The Population-Intervention-Comparison Outcomes (PICO) Framework and the PRISMA statement 2021, will be used for reporting. Data analysis will be carried out using narrative synthesis, and a meta-analysis may be conducted if we come across homogenous data for the outcome.

Ethics and dissemination: As this study is a systematic review, we will not be recruiting any participants for the study and hence will not require ethical approval. The study summary will be disseminated at a conference.

Keywords: mobile health application, mHealth, self-management applications, type 2 diabetes mellitus

Prospero registration ID: CRD42021245517

#### Article Summary:

Strengths of the study:

- 1. Effectiveness of using mHealth apps on HbA1c levels
- 2. Adherence to mHealth applications and Positive behavioral outcomes will be evaluated

Limitations of the study:

- 1. The exclusion of articles in languages other than English and articles behind a paywall
- 2. The geographical area of the study will be limited to Low and Middle-Income Countries (LMICs)

#### Introduction

'Diabetes' is a term used to describe a group of diseases characterized by elevated blood glucose levels. It is caused by a lack of insulin production or function, or both, which may occur for various reasons and lead to protein and lipid metabolic disorders<sup>1</sup>. Various scientific studies have established that adequate blood glucose regulation minimizes the long-term effects of type 2 diabetes. Increasing inclination towards technology provides an opportunity for the delivery of innovative self-management interventions. The global burden of type 2 diabetes mellitus (T2DM) continues to rise, with T2DM estimated to affect over 9% of the global population by 2035<sup>2</sup>. The use of mobile health tools to help people manage chronic diseases is on the rise, but evidence of their effectiveness is mixed<sup>3</sup>. An overview and a scoping review were conducted to understand the Impact of mobile health (mHealth) Interventions among chronic diabetic patients showed improving glycemic control using diverse mHealth interventions<sup>4&5</sup>. Another trial proved to have improved behavioral outcomes among diabetic individuals<sup>6</sup>. People with diabetes are increasingly using mobile technology for health (mHealth) interventions to help improve selfmanagement; however, these interventions have not been implemented by many patients, and dropout rates are common.

Type 2 Diabetes in LMICs: A slew of issues plagues the delivery of healthcare in low and middleincome countries (LMICs). Where four out of every five people with diabetes now live in these

countries, and the rate of diabetes is increasing in poorer communities<sup>7</sup>. In 57 developing countries, the World Health Organization (WHO) estimates a 4.3 million healthcare worker shortage, resulting in understaffed hospitals, limited patient access to care, and a significant patient-physician contact gap, especially in rural areas <sup>8</sup>. To bridge this gap in terms of diabetes management, self-management apps can play a pivotal role in India and the LMICs. To understand how mHealth apps aid in diabetes management, knowing what is meant by eHealth is important.

eHealth: the use of information and communication technologies (ICT) for health.

The unprecedented spread of mobile technologies as well as advancements in their innovative application to address health priorities have evolved into a new field of eHealth, known as mHealth.

mHealth: The Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices<sup>9</sup>.

A mHealth application used in the self-management of T2DM, along with standard care- a study conducted in India in the year 2017, has proved that the users of the study with "Gather m-Health app" as an intervention given to the participants of the study improved medication adherence and Blood glucose testing accuracy over 6 months of the study<sup>10</sup> Evidence generated by another Indian study using a mHealth application "DIAGURU" mainly focused on lifestyle modification and medication management over 6 months suggesting, that technological approaches can be used as a public health measure to improve the quality of life of patients with type 2 Diabetes Mellitus<sup>11</sup>.

Non-exercise Activity Thermogenesis (NEAT) a smartphone intervention used to reduce the health consequences of sedentary behavior, provided an opportunity to intervene and improve the health of a large proportion of the population in Chicago<sup>12</sup>. Although there might be a few barriers to the use of remote mHealth technologies in self-managing type 2 diabetes with poor

technology literacy<sup>13,</sup> desired elements such as blood sugar monitoring, instructional content, personalized feedback, reminders, and goal setting were thought to be beneficial<sup>14</sup>. The interventions may also include other forms of mHealth solutions like texting, emailing, video clips, and graphics. To find evidence on how the use of mobile applications has impacted the health of type 2 diabetic individuals. Few of the proven interventions leading to more effective control of diabetes were reported<sup>15</sup>.

Measures to control T2DM: The rising prevalence of T2DM has put pressure on healthcare systems to properly manage diabetic individuals so that diabetes complications are avoided. Optimizing patient outcomes by combining medications with self-management of glycemic control and other risk variables could be a better approach. To help people keep blood sugar within the normal range (i.e., <= 5.7% of the HbA1c) the American Diabetes Association also recommends: engaging in weight management activities, eating a nutritious diet, getting regular exercise, smoking cessation, and stress reduction as the key factors to achieve normal glycemic levels.

Once diabetes has progressed to extreme levels, dietary adjustments and lifestyle modifications alone are no longer sufficient to maintain appropriate blood sugar levels, and doctors may urge a person to take medications. However, for older adults diagnosed with diabetes and whose blood sugar is marginally high, drugs may or may not be required<sup>16</sup>. Along with dietary adherence, behavioral factors such as "Self-efficacy" have proved to be the most significant predictive factor of HbA1c, Physical activity for Body Mass Index (BMI), and glucose self-monitoring for Fasting Blood Glucose (FBG) in leading a healthy lifestyle<sup>17</sup>. In recent years, there are an increasing number of smartphone applications that are meant to help T2DM patients manage their condition, but only a few have been thoroughly evaluated among the general population globally<sup>18</sup>.

#### **Review Questions**

**BMJ** Open

1. Are mHealth applications effective in managing blood glucose levels among individuals with type 2 diabetes mellitus in LMICs?

2. What is the impact of using mHealth applications in managing T2DM concerning healthpromoting behavior among the LMICs in the context of India?

**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 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.

#### Methods

The PRISMA 2020 statement; an updated guideline for reporting systematic reviews<sup>19</sup> will be used for reporting the review and the Population-Intervention-Comparison-Outcomes (PICO) framework will be used for defining the methods of the review. (Refer; to supplementary file 1-PRISMA checklist). The systematic review protocol was registered on the international prospective register of systematic reviews, PROSPERO, with the registration number CRD42021245517.

#### Criteria for considering studies for this review

Types of studies:

*Study design:* Randomized controlled trials (RCTs), Non-Randomized controlled trials (NRCTs) like the Quasi-experimental studies, and controlled before-after studies will be included. Observational studies, conference papers, editorials, reports, and other studies without any mobile app interventions in them will be excluded.

*Year of publication:* we will include publications matching our criteria from the year 2016 to 2022. As the search strategy yielded publications from the year 2016 onwards.

*Type of participants:* 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 diagnosis<sup>20</sup> 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), Oral Glucose Tolerance Test (OGTT) ≥200 mg/dl.

*FBG:* Fasting means not having anything to eat or drink (except water) for at least 8 hours before the test. Diabetes is diagnosed at FBG of greater than or equal to 126 mg/dl.

*RBS:* This test is a blood check at any time of the day when an individual has severe diabetes symptoms (Diabetes is diagnosed at blood glucose of greater than or equal to 200 mg/dl.

*OGTT:* A two-hour test that checks your blood glucose levels before and two hours after you drink a special sweet drink. Diabetes is diagnosed at two-hour blood glucose  $\geq$  200 mg/dl <sup>21</sup>.

Patient and public involvement: patients and the public will not be involved in any way in this study.

# Type of interventions

Digital health: The use of digital, mobile, and wireless technologies to support the achievement of health objectives. Digital health describes the general use of information and communications technologies (ICT) for health and is inclusive of both mHealth and eHealth<sup>22</sup>. From the context of our study, the term mHealth refers to the mobile applications used in the self-management of T2DM. The interventions may also include other simpler forms of mHealth solutions like texting, emailing, video clips, graphics, and web services.

**Type of Comparison:** the comparator groups would be the individuals who received standard hospital treatment or no hospital care and who received an intervention.

Type of outcome measures: Primary outcomes include,

- Clinical outcome (HbA1c at 3 months interval): [A hemoglobin A1c (HbA1c) test measures the amount of blood sugar (glucose) attached to hemoglobin. An HbA1c test shows what the average amount of glucose attached to hemoglobin has been over the past three months. It's a three-month average because that's typically how long a red blood cell lives<sup>23</sup>]
   Secondary outcomes include,
  - Adherence to diabetic self-management applications and medication: The studies must have reported using any of the standard survey tools to record daily medication intake and app usage during the follow-up for a year.
  - Self-efficacy with adherence to mHealth applications: Self-efficacy is defined as "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations." - Albert Bandura <sup>24, 25</sup>. The studies must have done a subjective evaluation of the individual's willingness to use the self-management applications to manage T2DM and those who are confident to follow in their near future.
  - Health promoting behavior: If the study participants during their follow-up period adapted a positive change in behavior towards achieving better health, like opting for a healthy diet, regular moderate exercising, brisk walking, and reducing/ managing their stress levels. Will be checked across the quality of life improvement index if any done in the studies <sup>26</sup>. Health-promoting behavior changes will not be limited to nutrition, physical exercise/ activity, or regular/frequent blood glucose monitoring.

**Search methods for identification of studies:** PubMed, Ovid Medline, EBSCO, CINAHL, Scopus, Web of Science, the Cochrane Central Register of Controlled Trials, and additional sources of the search will be grey literature available on diabetes management websites. Forward citation search will be undertaken for any key references identified and reference lists of included studies (Refer to supplementary file 2- 'Search strategies' for more search information).

We will be using Endnote library version X7 for screening and downloading the full-text articles and Microsoft Excel 2013 will be used for data extraction of the full-text articles. 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 fulltext screening stage and the PRISMA flowchart (Refer to supplementary file 1) will be used to depict the screening process. The rationale for exclusion will be provided for all the excluded studies throughout the process.

**Data extraction and management:** Data extraction will be performed using a standardized pretested 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. The data extraction form will include information on citation details, characteristics of the studies, location, region, population, intervention, the effectiveness of an intervention, and the information on outcome and the main findings (Refer to 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 with a minimum waiting period of two weeks for their reply. In the event of no response from the authors of the study, a decision will be taken by the team of authors of the systematic review.

**Assessment of risk of bias in included 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<sup>27</sup>. Risk of bias in Non-randomized Studies of Interventions assessment tool (ROBINS-I) for Non-Randomised studies<sup>28</sup>.

Page 11 of 25

#### **BMJ** Open

Data synthesis: Firstly, we will provide a detailed summary of all the included studies in a narrative format. 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 randomeffects 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, I<sup>2</sup> statistic, Chi<sup>2</sup> test, and Tau<sup>2</sup> 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. All the analyses will be conducted in Review Manager 5.3 and STATA 16.

Description of primary and secondary outcomes, whether adherence to diabetic selfmanagement applications and medication has improved or not, Behavior change will be noted with the quality of life improvement index and self-efficacy will be checked following the improvement in managing T2DM. Listing out various measurement tools and devices used for judging the above-mentioned outcomes.

**Subgroup analysis:** Subgroup analysis will be performed for the following if appropriate. Sensitivity analysis will be performed if we find out any uncertainties in one or more input variables that may lead to uncertainties among other output variables.

Subgroup analysis will be performed for the following:

• Duration of the given intervention (3 months intervals up to a year)

BMJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

- Comparing study effectiveness within the LMICs
- The most effective rate of using the Diabetic self-management app in age groups as classified by the UN
- Gender

# Author affiliations:

Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup> Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup>

- 1. Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.
- 2. Department of Endocrinology, Kasturba Medical College Hospital, MAHE, Manipal, India.
- 3. Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India
- 4. Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.
- 5. Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.
- Department of International Health, Care and Public Health Research Institute CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.

**Ethics and dissemination:** The study will be a systematic review of the published articles from different recognised and accessible databases and will not recruit any human participants directly, therefore, ethical clearance is not applicable. The dissemination of the final review findings will be done at a national or international conference and will be published in an indexed peer-reviewed journal.

**Author Contributions:** HB is the corresponding author, SMD, SS, JV, PP, MGL, PR, and HB conceptualized the study. SMD, SS, JV, PP, MGL, PR, and HB drafted the manuscript. All authors

Acknowledgments: Not applicable.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sector

**Conflicts of interest:** There is no conflict of interest in this project.

Supplemental material: Supplementary materials are enclosed as 1, 2 and 3

Patient and public involvement: patients and the public were not involved in any way in this study ele.

# **References:**

- 1. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes care. 2013 Jan;36(Suppl 1):S67.
- 2. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw J, Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-management of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealth and uHealth. 2019 Jan 10;7(1):e10321.
- 3. Dugas M, Crowley K, Gao GG, Xu T, Agarwal R, Kruglanski AW, et al. Individual differences in regulatory mode moderate the effectiveness of a pilot mHealth trial for diabetes management among older veterans. PLoS One. 2018; 13(3):e0192807.
- 4. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR

Mhealth Uhealth. 2018 Jan 17;6(1):e23. doi: 10.2196/mhealth.8873. PMID: 29343463; PMCID: PMC5792697.

- Eberle C, Löhnert M, Stichling S. Effectiveness of Disease-Specific mHealth Apps in Patients With Diabetes Mellitus: Scoping Review. JMIR Mhealth Uhealth. 2021 Feb 15;9(2):e23477. doi: 10.2196/23477. PMID: 33587045; PMCID: PMC7920757.
- Boels AM, Rutten G, Zuithoff N, de Wit A, Vos R. Effectiveness of diabetes selfmanagement education via a smartphone application in insulin treated type 2 diabetes patients - design of a randomised controlled trial ('TRIGGER study'). BMC Endocr Disord. 2018 Oct 22;18(1):74. doi: 10.1186/s12902-018-0304-9. PMID: 30348142; PMCID: PMC6196442.
- Dunachie S, Chamnan P. The double burden of diabetes and global infection in low and middle-income countries. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2019 Feb 1;113(2):56-64.
- Mahmud N, Rodriguez J, Nesbit J. A text message-based intervention to bridge the healthcare communication gap in the rural developing world. Technology and Health Care. 2010 Jan 1;18(2):137-44.
- 9. World Health Organization. mHealth: new horizons for health through mobile technologies. mHealth: new horizons for health through mobile technologies.. 2011.
- 10. Kleinman NJ, Shah A, Shah S, Phatak S, Viswanathan V. Improved medication adherence and frequency of blood glucose self-testing using an m-Health platform versus usual care in a multisite randomized clinical trial among people with type 2 diabetes in India. Telemedicine and e-Health. 2017 Sep 1;23(9):733-40.
- Kumar DS, Prakash B, Chandra BS, Kadkol PS, Arun V, Thomas JJ. An android smartphone-based randomized intervention improves the quality of life in patients with type 2 diabetes in Mysore, Karnataka, India. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2020 Sep 1;14(5):1327-32.
- Pellegrini CA, Hoffman SA, Daly ER, Murillo M, Iakovlev G, Spring B. Acceptability of smartphone technology to interrupt sedentary time in adults with diabetes. Translational behavioral medicine. 2015 Sep 1;5(3):307-14.

# BMJ Open

Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.	MJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de l
---	--

13. Alvarado MM, Kum HC, Coronado KG, Foster MJ, Ortega P, Lawley MA. Barriers to
remote health interventions for type 2 diabetes: a systematic review and proposed
classification scheme. Journal of medical Internet research. 2017 Feb 13;19(2):e6382.
14. Peng W, Yuan S, Holtz BE. Exploring the challenges and opportunities of health mobile
apps for individuals with type 2 diabetes living in rural communities. Telemedicine and
e-Health. 2016 Sep 1;22(9):733-8.
15. Azelton KR, Crowley AP, Vence N, Underwood K, Morris G, Kelly J, Landry MJ. Digita
health coaching for type 2 diabetes: randomized controlled trial of healthy at home
Frontiers in Digital Health. 2021;3.
16. West M. Controlling type 2 diabetes: With and without medication [Internet]
Medicalnewstoday.com. 2021. Available from
https://www.medicalnewstoday.com/articles/how-to-control-type-2-diabetes
17. Brown SA, García AA, Brown A, Becker BJ, Conn VS, Ramírez G, Winter MA, Sumlin LL
Garcia TJ, Cuevas HE. Biobehavioral determinants of glycemic control in type 2
diabetes: a systematic review and meta-analysis. Patient education and counseling
2016 Oct 1;99(10):1558-67.
18. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, Shaw J
Bouck Z, Jamieson T, Onabajo N, Cooper M. Mobile app for improved self-management
of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR mHealth
and uHealth. 2019 Jan 10;7(1):e10321.
19. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, Shamseer L
Tetzlaff JM, Akl EA, Brennan SE, Chou R. The PRISMA 2020 statement: an updated
guideline for reporting systematic reviews. Systematic reviews. 2021 Dec;10(1):1-1.
20. World Health Organization. Diagnosis and management of type 2 diabetes (HEARTS-
D). World Health Organization: Geneva, Switzerland. 2020.
21. Diagnosis   ADA. Diabetes.org. 2022. Available from
https://www.diabetes.org/diabetes/a1c/diagnosis
14
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

- 22. World Health Organization. Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment.
  - 23. Centers for Disease Control and Prevention, https://www.cdc.gov/learnmorefeelbetter/programs/diabetes.htm
  - Bandura A. Self-efficacy. The Corsini encyclopedia of psychology. John Wiley & Sons, 24. Inc. doi. 2010;10(9780470479216):1-3.
- 25. Bandura A, Watts RE. Self-efficacy in changing societies. Cambridge University Press; 1997.
- 26. Behaviour Change Models and Strategies [Internet]. Eufic.org. 2014. Available from: https://www.eufic.org/en/healthy-living/article/motivating-behaviour-change
- 27. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. bmj. 2016 Oct 12;355.
- 28. Higgins JP, Savović J, Page MJ, Sterne JA. on behalf of the RoB2 Development Group. Revised Cochrane risk-of-bias tool for randomized trials (RoB 2). 2019 Jul.

iez oni

SUPPLEMENTARY F	ILE: 1			
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	ltem No	Checklist item		
ADMINISTRATIVE I	NFORM	IATION		
Title:	C	6		
Identification	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		
Update	1b	N/A		
Registration	2	The study has been registered in PROSPERO and the Registration II is CRD42021245517.		
Authors:				
Contact	3a	<ul> <li>Sherize Merlin Dsouza<sup>1, 6</sup>, Sahana Shetty<sup>2</sup>, Julien Venne<sup>3</sup>, Prachi Pundir<sup>4</sup>, Priyobrat Rajkhowa<sup>1, 6</sup>, Melissa Glenda Lewis<sup>5</sup> and Helmut Brand<sup>1, 6</sup></li> <li>Department of Health Policy, Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Department of Endocrinology, Kasturba Medical College Hospital MAHE, Manipal, India.</li> <li>Coordinator, Dept. of Digital Health and wellbeing, PSPH, MAHE, Manipal, India</li> <li>Public Health Evidence South Asia (PHESA), Prasanna School of Public Health, Manipal Academy of Higher Education.</li> <li>Indian Institute of Public Health Shillong, Lawmali, Pasteur Hill, Shillong, Meghalaya.</li> <li>Department of International Health, Care and Public Health Research Institute – CAPHRI, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, The Netherlands.</li> </ul>		

2	
2	
5	
4	
5	
6	
7	
8	
9	
10	
10	
11	
12	
13	
14	
15	
16	
17	
17	
18	
19	
20	
21	
22	
23	
23	
24	
25	
26	
27	
28	
29	
30	
21	
21	
32	
33	
34	
35	
36	
37	
20	
20	
39	
40	
41	
42	
43	
44	
15	
C+	
46	
47	
48	
49	
50	
51	
51	
52	
53	
54	
55	
56	
57	
52	
50	
59	
60	

		BMJ Open
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	6	<b>Rationale:</b> 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	<ol> <li>To identify the effectiveness of mHealth applications in managing blood glucose levels of individuals with T2DM and</li> <li>To assess the impact of using mHealth applications in managing T2DM concerning health-promoting behavior among the LMICs in the context of India</li> </ol>

		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 diagnosis <sup>12</sup> 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	11a	The search results collected from the electronic databases will be

		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 or 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	13	A detailed summary of all the included studies will include
nrioritization		information on authors, study objectives. Inclusion criteria

Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.	Enseignement Superieur (ABES) .	MJ Open: first published as 10.1136/bmjopen-2021-060108 on 15 November 2022. Downloaded from http://bmjopen.bmj.com/ on June 12, 2025 at Agence Bibliographique de
--	---------------------------------	--

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 meta- analysis 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.
14 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 Non- randomized Studies of Interventions assessment tool (ROBINS-I) for Non-Randomised studies.
<ul> <li>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 &amp; odds ratio for categorical outcomes with 95% confidence intervals. Forest plots, I<sup>2</sup> statistic, Chi<sup>2</sup> test, and Tau<sup>2</sup> will be used to measure and assess heterogeneity among the included studies in each analysis. Meta-regression will be used to investigate beterogeneity if appropriate data is obtained. An</li> </ul>

		BMJ Open	
		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		
Meta-hias(es)	150	Not applicable	
Confidence in	10	Not applicable.	
cumulative		Ó	
evidence			
	For peer revie	ew only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Database	Search strategy	Hits
1 PubMed	Search: (("diabetes mellitus, type 2"[MeSH Terms] OR "self- management/education"[MeSH Major Topic]) AND "Mobile	<u>68</u>
	Applications"[MeSH Major Topic] AND "english"[Language] AND	
	"english"[Language]) AND ((fha[Filter]) AND (clinicaltrial[Filter] OR randomized controlled trial[Filter] OR review[Filter]) AND	
	(humans[Filter]) AND (english[Filter]))	
2	Search: ("Afghanistan"[All Fields] OR "Albania"[All Fields] OR	<u>5,860,98</u>
World Bank	"Algeria"[All Fields] OR "American"[All Fields] OR "Samoa"[All	
list of low	Fields] OR "Angola"[All Fields] OR "Argentina"[All Fields] OR	
and	"Armenia"[All Fields] OR "Azerbaijan"[All Fields] OR	
middleincom	"Bangladesh"[All Fields] OR "Belarus"[All Fields] OR "Belize"[All	
e countries	Fields] OR "Benin"[All Fields] OR "Bhutan"[All Fields] OR	
included in	"Bolivia"[All Fields] OR "Bosnia"[All Fields] OR "Herzegovina"[All	
the study	Fields] OR "Botswana"[All Fields] OR "Brazil"[All Fields] OR	
	"Bulgaria"[All Fields] OR "Burkina"[All Fields] OR "Faso"[All	
	Fields] OR "Burundi"[All Fields] OR "Cabo"[All Fields] OR	
	"Verde"[All Fields] OR "Cambodia"[All Fields] OR "Cameroon"[All	
	Fields] OR "Central"[All Fields] OR "African"[All Fields] OR	
	"Republic" [All Fields] OR "Chad" [All Fields] OR "China" [All Fields]	
	OR "Colombia" [All Fields] OR "Comoros" [All Fields] OR	
	"Congo" [All Fields] OR "dem" [All Fields] OR "rep" [All Fields] OR	
	Congo [All Fields] OR rep [All Fields] OR Costa [All Fields] OR	
	Rica [All Fields] OR Cole [All Fields] OR divolre [All Fields] OR	
	Cuba [All Fields] OK Djibouti [All Fields] OK Dominica [All Fields] OB "Dominican"[All Fields] OB "Bopublic"[All Fields] OB	
	"Feudor"[All Fields] OR "Empt"[All Fields] OR "Arab"[All Fields]	
	OR "rep"[All Fields] OR "El"[All Fields] OR "Salvador"[All Fields]	
	OR "Equatorial"[All Fields]	
1 & 2	Search: ((("diabetes mellitus, type 2"[MeSH Terms] OR "self-	15
(2016-2022)	management/education"[MeSH Major Topic]) AND "Mobile	<u> </u>
	Applications"[MeSH Major Topic] AND "english"[Language] AND	
	"english"[Language]) AND ((fha[Filter]) AND (clinicaltrial[Filter]	
	OR randomized controlled trial[Filter] OR review[Filter]) AND	
	(humans[Filter]) AND (english[Filter]))) AND (("Afghanistan"[All	
	Fields] OR "Albania"[All Fields] OR "Algeria"[All Fields] OR	
	"American"[All Fields] OR "Samoa"[All Fields] OR "Angola"[All	
Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies

2
3
1
4 5
5
6
/
8
9
10
11
12
13
14
15
16
10
17
18
19
20
21
22
23
24
25
26
20
27
20
29
30
31
32
33
34
35
36
37
38
30
40
40
41
42
43
44
45
46
47
48
49
50
51
52
52 52
22
54 55
55
56
57
58

59

60

1

Fields] OR "Argentina" [All Fields] OR "Armenia" [All Fields] OR "Azerbaijan" [All Fields] OR "Bangladesh" [All Fields] OR "Belarus"[All Fields] OR "Belize"[All Fields] OR "Benin"[All Fields] OR "Bhutan" [All Fields] OR "Bolivia" [All Fields] OR "Bosnia" [All Fields] OR "Herzegovina" [All Fields] OR "Botswana" [All Fields] OR "Brazil" [All Fields] OR "Bulgaria" [All Fields] OR "Burkina" [All Fields] OR "Faso" [All Fields] OR "Burundi" [All Fields] OR "Cabo" [All Fields] OR "Verde" [All Fields] OR "Cambodia" [All Fields] OR "Cameroon" [All Fields] OR "Central" [All Fields] OR "African"[All Fields] OR "Republic"[All Fields] OR "Chad"[All Fields] OR "China" [All Fields] OR "Colombia" [All Fields] OR "Comoros" [All Fields] OR "Congo" [All Fields] OR "dem" [All Fields] OR "rep" [All Fields] OR "Congo" [All Fields] OR "rep" [All Fields] OR "Costa" [All Fields] OR "Rica" [All Fields] OR "Cote" [All Fields] OR "d'Ivoire" [All Fields] OR "Cuba" [All Fields] OR "Djibouti" [All Fields] OR "Dominica" [All Fields] OR "Dominican" [All Fields] OR "Republic"[All Fields] OR "Ecuador"[All Fields] OR "Egypt"[All Fields] OR "Arab" [All Fields] OR "rep" [All Fields] OR "El" [All Fields] OR "Salvador" [All Fields] OR "Equatorial" [All Fields]) Filters: Abstract, Clinical Trial, Randomized Controlled Trial, Review Liezoni

## Supplementary file: 3

## III. Data extraction from

Title of the study	
Authors	
The Year of the study conducted	
Year of publication	
Doi & Journal	
Objectives of the study	
Participant characteristics	Number of participants
	Age
	Gender
	Ethnicity
	Socioeconomic group
	Educational status
	Duration of T2DM
Total number of participants	
Setting/ context/ country	Low-income country
	Lower Middle-income country
	Upper Middle-income country
World Bank Region	South Asia
	Sub-Saharan Africa
	East Asia and the Pacific
	Europe and Central Asia
	Latin America and the Caribbean
	The Middle East and North Africa
	North America
Description of intervention for type 2	M health application
diabetes	Infographics
	Video clips
	Text messages
	Others – to be specified
Search details	Year
Source	IndMED
	Medline Plus
	OpenMED

Page	26 of 25 <b>P</b>
	1J Ope
	en: fin
	st puk
	olishe
	d as 1
	0.1136 Prote
	ò/bmjc ¢cted I
	open-2 oy cop
	021-0 9yrigh
	60108 t, incl
	on 15 uding
	Nove for us
	imber Inseig ies rel
	2022. neme ated t
	Down nt Sup o text
	iloade perieu and c
	id fron r (ABE lata m
	n http ≘S) . ining,
	://bmj Al tra
	open.l iining,
	and s
	om/ oi simila
	n June r techi
	∍ 12, 2 nologi
	025 at les.
	Agen
	ce Bil
	bliogr
	aphiq
	ue de l

	Ovid Medline
	PubMed / MEDLINE
	Scopus
	Web of Science
	Other Bibliographical Databases
The range of years included	No limit
No of included studies	
Type of studies included	RCT
	Quasi-experimental study
	Case-control
	Cohort
	Controlled trial
Comparator	Duration of the intervention
	Across the regions (LMICs)
	Age groups
	Gender
Analysis	
Method of analysis	
follow up sessions	
Outcome assessed	Primary
	secondary
Results/ findings	
Significance	4
Heterogeneity if done	
Study Limitations	