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Effectiveness of self-management applications in improving clinical health outcomes and adherence among diabetic individuals in low and middle-income countries: a systematic review

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ABSTRACT

Introduction A variety of mobile health (mHealth) applications are available to monitor an individual's health or lifestyle to make it convenient to access healthcare facilities at home. The usability of mHealth applications in controlling HbA1c (estimated average blood glucose) levels is unclear despite their increasing use. 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 behaviour 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 and the Cochrane Central Register of Controlled Trials; 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 framework and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 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.

PROSPERO registration number CRD42021245517.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Effectiveness of using mobile health (mHealth) apps on HbA1c levels.
⇒ Adherence to mHealth applications and positive behavioural outcomes will be evaluated.
⇒ The exclusion of articles in languages other than English and articles behind a paywall.
⇒ The geographical area of the study will be limited to low and middle-income countries.

INTRODUCTION

'Diabetes' is a term used to describe a group of diseases characterised 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.[1] Various scientific studies have established that adequate blood glucose regulation minimises 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.[2] The use of mobile health (mHealth) tools to help people manage chronic diseases is on the rise, but evidence of their effectiveness is mixed.[3] An overview and a scoping review were conducted to understand the impact of mHealth interventions among patients with chronic diabetes and showed improving glycaemic control using diverse mHealth interventions.[4 5] Another trial proved to have improved behavioural outcomes among diabetic individuals.[6] People 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.

Type 2 diabetes in low and middle-income countries

A slew of issues plague the delivery of healthcare in low and middle-income 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.[7] In 57 developing countries, 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.[8] 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 communications technology for health

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

Mobile health

The Global Observatory for eHealth defined mHealth as medical and public health practice supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants and other wireless devices.[9]

An 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.[10] Evidence generated by another Indian study using an mHealth application 'DIAGURU' mainly focused on lifestyle modification and medication management over 6 months, suggesting technological approaches can be used as a public health measure to improve the quality of life of patients with T2DM.[11]

Non-Exercise Activity Thermogenesis, a smartphone intervention used to reduce the health consequences of sedentary behaviour, provided an opportunity to intervene and improve 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,[13] desired elements such as blood sugar monitoring, instructional content, personalised feedback, reminders and goal setting were thought to be beneficial.[14] 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.[15]

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. Optimising patient outcomes by combining medications with self-management of glycaemic control and other risk variables could be a better approach. To help people keep blood sugar within the normal range (ie, ≤5.7% of the haemoglobin A1c (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 glycaemic 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.[16] Along with dietary adherence, behavioural factors such as 'Self-efficacy' have proved to be the most significant predictive factor of HbA1c, physical activity for body mass index and glucose self-monitoring for fasting blood glucose (FBG) in leading a healthy lifestyle.[17] In recent years, there are an increasing number of smartphone applications that are meant to help patients with T2DM manage their condition, but only a few have been thoroughly evaluated among the general population globally.[2]

Review questions

1. Are mHealth applications effective in managing blood glucose levels among individuals with T2DM in LMICs?
2. What is the impact of using mHealth applications in managing T2DM concerning health-promoting behaviour 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 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement, an updated guideline for reporting systematic reviews,[18] will be used for reporting the review and the Population-Intervention-Comparison-Outcomes framework will be used for defining the methods of the review. (Refer to online supplemental file 1—PRISMA checklist.) The systematic review protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO; registration number: CRD42021245517).

Criteria for considering studies for this review

Types of studies

Study design

Randomised controlled trials (RCTs), non-RCTs (NRCTs) like the quasiexperimental 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 and diagnosed with T2DM based on any of the WHO 2020 criteria for diagnosis,[19] that is, HbA1c values ≥6.5% (48 mmol/mol), Fasting Blood Glucose (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 or 7.0 mmol/L), Random blood sugar (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 or 11.1 mmol/L), or Oral glucose tolerance test values (OGTT: A 2-hour test that checks your blood glucose levels before and 2 hours after you drink a special sweet drink. Diabetes is diagnosed at 2-hour blood glucose ≥200 mg/dL[20]).
[20]

Patient and public involvement

Patients and the public will not be involved in any way in this study.

Type of interventions

Digital health

Digital health is 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 technology for health and is inclusive of both mHealth and eHealth.[21] 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 outcome includes:

- *Clinical outcome* (HbA1c at 3-month interval): An HbA1c test measures the amount of blood sugar (glucose) attached to haemoglobin. An HbA1c test shows what the average amount of glucose attached to haemoglobin has been over the past 3 months. It is a 3-month average because that is typically how long a red blood cell lives.[22]

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.[23 24] 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 behaviour:* If the study participants during their follow-up period adapted a positive change in behaviour 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 is done in the studies.[25] Health-promoting behaviour 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 and the Cochrane Central Register of Controlled Trials; 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 online supplemental file 2—'Search strategies' for more search information.)

We will be using EndNote library V.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 flow chart (refer to online supplemental 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 standardised 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 online supplemental 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 2 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 tool version 2 will be used to evaluate RCTs,[26] and Risk of Bias in Non-randomized Studies of Interventions assessment tool for non-randomised studies.[27]

Data synthesis

First, 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. Second, 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 NRCTs (quasiexperimental and controlled before-after studies). The summary estimates will be expressed in mean difference, standardised mean difference for continuous outcomes and relative risk, and OR for categorical outcomes with 95% CIs. Forest plots, I^2 statistic, χ^2 test and tau^2 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 are obtained. An attempt will be made to contact the study authors if data are 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 V.5.3 and STATA V.16.

Description of primary and secondary outcomes, whether adherence to diabetic self-management applications and medication has improved or not and behaviour 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 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-month 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 United Nations.
- Gender.

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.

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