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Review Article: Systematic Review

MOBILE SMARTPHONE INTERVENTION FOR MANAGING GLYCAEMIA CONTROL IN THE PATIENTS WITH DIABETES MELLITUS: A SYSTEMATIC REVIEW

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Abstract

Background: Diabetes mellitus (DM) is a chronic disease that is a global public health problem that has a social impact, economic impact, and quality of life for patients, which leads to increased morbidity and mortality. Uncontrolled blood sugar levels and long-term DM, affecting the pathophysiology of disorders including diabetic retinopathy, heart disease, kidney failure, hyperglycemia and hypoglycemia are needed interventions that can help regulate glycemic (blood sugar levels and HbA1c) (Sami & Ansari, 2015).
Objective: This study aimed to identify efficacy mobile smartphone application for managing glycaemia control in the patients with diabetes mellitus.
Design: This study design is a systematic review to search and review article from database and the theory underlying this study or guidance in this systematic literature review using *Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA).*
Data Sources: Database search for article are from Scopus, Proquest, Pubmed, Science Direct, and Springer Link is limited to the publication of the last five years from 2015 to 2020 and full text article in English.
Review Methods: This review methods in a systematic review based on *Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA)*.
Results: In this review literature, thirteen articles were found that fit the specified inclusion and exclusion criteria. The results of this review literature found that mobile smartphone impelmentation led to a decrease in HbA1c and fasting blood glucose in the patients with diabetes mellitus.
Conclusion: The findings from this study help validate the efficacy of the mobile diabetes intervention for managing glycaemia control in the patients with diabetes mellitus.

Keywords: *Diabetes Mellitus, Glycaemia Control, Health Education, M-Health*.

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INTRODUCTION

Diabetes mellitus (DM) is a chronic condition that occurs when there is an increase in glucose levels in the blood, the body cannot produce anything from the amount of the hormone insulin or the function of insulin cannot work properly (Edwina & Manaf, 2015) The number of people with DM in the world in 2011 reached 336 million people and is predicted to continue to grow to 350 million by 2020. Diabetes can make many complications for people living with DM such as kidney failure, blindness or retnopati diabetic, heart attack stroke, numb in lower extrimity, ulkus diabetic until finished with amputation. Estimated 1.5 million deaths were directly caused by DM and other 2.2 million deaths caused by high blood glucose and increased risk of macrovascular and microvascular complications, as well as early mortality(Metwally & Soliman, 2019)

Almost half of all deaths cases associated with high blood glucose and cardiovascular problem (heart attack) occur before 60 years old. WHO projects that diabetes will be the 7th leading cause of death in 2030 (World Health Organization, 2016). Self-management includes checking, measuring and recording blood glucose (fasting and post-prandial), exercise or physical activity, adherence of diabetes diet and taking of medication. Many studies have indicated that improvement in dietary and physical activity habits can prolong life expectancy in patients with T2DM because the process can increase knowledge, ability and skill for doing daily diabetes self care (Powers & Bardsley, 2017)

In the past self-management's data must written in the medical record manually by health workers and then they must input the data from each patient into computer. It was need long time and data will only be updated if patients come for control to the health service, so maybe it doesn;s very update. Many recent studies, have shown use mobile phone interventions for diabetes self-management have been able to significantly reduce HbA1c levels and blood glucoce level. This is maybe associated to fast feedback, interaction between patients and providers, synchronized system and automatically patient's can update data in the implementation process as well as the advantages of mobile phones such as adherence, intensity of the interventions and the behavior-change techniques used by the interventions (Pal & Eastwood, 2014)

The function and features of these apps can modified suitable for patients condition, but mainly at monitoring clinical sign such as blood pressure, blood glucose, body weight, daily activity and diet prorgam can uploaded by users in the application. As a new type of management media for diabetes intervention, mobile phone interventions offer T2DM patients away to overcome the short coming of traditional health tracking methods by providing convenience and medical care in daily life and minimizing the distance, time, and cost. However, more evidence is still needed regarding the effectiveness of these apps.

The aim of this study was to conduct a systematic review of randomized controlled trials (RCT) articles for assessing the impact of mobile phone on the glycaemic control of adult patients with T2DM. The design of this study uses a randomized controlled trial (RCT) design, which is the most powerful design to evaluate interventions that are used to show that interventions are used is really feasible for experimental. In addition, this RCT research model compares the control group and the intervention group in actual reality. Values outcome of interest included changes in HbA1c and blood glucose.

METHODS

Design

This study is a systematic review based on *Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA)*. PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized

trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. Authors must us PRISMA as a guideline and theory underlying aims to help authors improve the reporting of systematic reviews and meta-analyses (PRISMA Statement, 2015).

Search Methods

Database search for article are from five database such as Scopus, Proquest and Pubmed, Science Direct and Springer Link is limited to the publication of the last five years from 2015 to 2020 and full text article in English. Keywords used in the article search are "*diabetes mellitus*" AND "*glycaemic control*" AND "*health education*" AND "*m-health*". The next step after the articles that meet the criteria are collected is to analyze and form the articles according to the specified inclusion and exclusion criteria. Inclusion criteria for this systematic review are (1) adult-elderly patients (45-60 years), (2) uncomplicated or non comorbid diabetes mellitus patients, and (3) patients who are conscious and cooperative (4) study design that include in this review is randomized control trials (RCT). Exclusion criteria in this systematic review are (1) patients experiencing complications (stroke, heart, kidney), and (2) patients who have dementia and aphasia.The article search process was carried out in July 2020. The article search uses keywords that have been determined by the researchers and limits the inclusion and exclusion criteria. The data obtained are then selected one by one by the researchers to determine the suitability of the articles desired by the rvesearchers and delete the same articles or those that do not fit the criteria. After getting the articles according to the researchers, the articles are analyzed one by one and grouped to get the results. The next step is to discuss based on the points obtained from the selection results.

Search Outcome

From five database literature search resulted total 310 articles are (Scopus=80), (Proquest=20), (Pubmed=98), (Science Direct =45), and (Springer Link=67) . After reviewing the abstract for relevance and matching to inclusion criteria, 50 articles were selected for full text review. There are 25 full text articles excluded for several reasons, namely the suitability of the sample, the type of research and the health conditions. Article excluded (n = 25) with reason:

1. Children as sample (n = 5)
2. Inappropriate study design such as qualitative, cohort, case study (n = 8)
3. Samples has comorbidities (n = 9)
4. The sample has decreased hearing and communication (n =3)

We exclude inappropriate study design such as qualitative, cohort, case study because want to focus on inclusion criteria of study use Randomized Control Trials (RCT) that consist of intervention, divided into control and intervention group and RCT study is the most powerful design to evaluate interventions that are used to show that interventions are used is really feasible for experimental include in systematic literature review.

The final selection of 13 articles was choosen for sytematic review, has showed in Figure 1.

Main outcomes in the study is that mobile phone app strategies were associated with a significant reduction in HbA1c and blood glucose level in patient with diabetes.

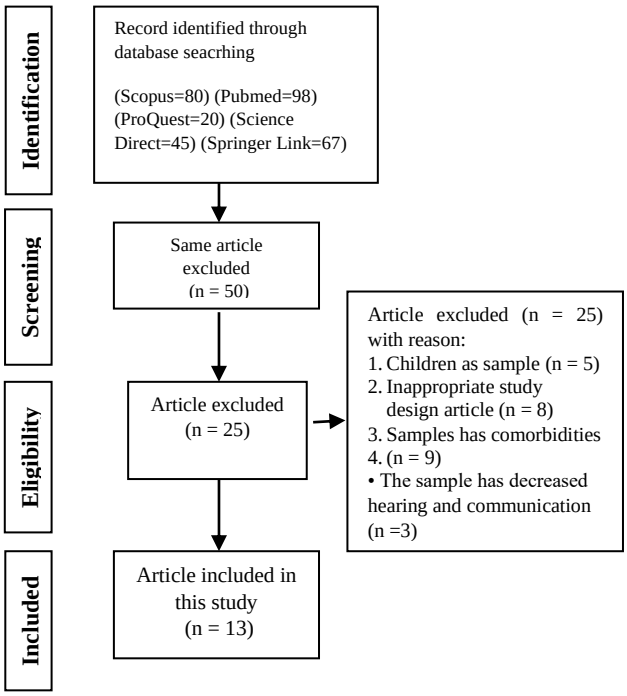

Figure 1. The PRISMA flow diagram is depicting the flow of information through the different phases of the systematic review

Quality Appraisal.

Title, abstract and the article were reviewed independently according to inclusion and exclusion criteria. The information that should be considered each study that the full text study consists of authors, date and year of study, population, exercise type, outcome measures, study design, duration of the intervention and its intensity. Quality appraisal assessment for each selected study was conducted using the *Preferred Reporting Items for Systematic Reviews and Meta-Analyzes* (PRISMA) method and risk of bias assesment study was conducted using *The Joanna Briggs Institute* (JBI) checklist specially for RCT with 13 question and the final result 13 articles showed more than 80%(JBI, 2017).

Data Abstraction

Two authors independently reviewed the abstracts of studies retrieved from the database. Search and read the fulltext of potentially relevant articles. For studies that met the inclusion criteria, data extraction was independently conducted by two investigators using standard data extraction templates. Disagreements in data extraction were solved by a third investigator.

Data Analysis/ Synthesis

Thirteen studies were selected for the systematic review,of which eleven with both primary and secondary outcomes containing 650 patients were included for the systematic review. The sample size, the mean change of HbA1c or the mean± standard deviation (SD) value of HbA1c and bloog glucose at baseline and the end point were extracted. The other one studies had several data points unavailable; for example ,theme an changes in interval of HbA1c were missing or had only descriptive results reflecting changes in blood glucose,life-style behaviors,and adherence of medicine after using the apps. Extracted data of thirteen studies are presented in Table1.

RESULTS

Descriptions of Studies

From five database literature search resulted total 310 articles are (Scopus=80), (Proquest=20), (Pubmed=98), (Science Direct =45), and (Springer Link=67). Only 13 articles fulfilled our selection criteria. Fig 1.shows the flow diagram of article selection from three databases. Additional information, include the author name, year of published, number of subject, study design, country (setting), types of apps, summary of result and duration (time) is shown in Table 1. All study participants had diabetes. The duration of the intervention was less than 6 months in 4 studies and more than 6 months is 2 studies and 6 months is 5 studies. The number of subject in each study ranged from 20 to 484. Four studies took place in China, 2 in USA, 2 in Kingdom Saudi Arabia, 2 in Korea, 1 in Malaysia, 1 in Netherland and 1 in Sri Lanka.

Study Outcomes

Main outcomes. We found that mobile phone app and online application strategies implementation were associated with a significant reduction in HbA1c in standarized

mean differences (SMD) when compared to standart diabetes care. However,one studies no significant decrease of HbA1c in patients with diabetes.

Twelve studies assesed the effect of mobile smartphone application on Hba1c reduction in the intervention group was significantly decreased HbA1c and blood glucose (fasting and postprandial) and one study by (Cheng & Sit, 2018) between two grooup (intervention and control) was not significantly different (P=.037). One studies from was significantly decreased HbA1c and fasting plasma glucose P=.005) than those in the control group (Yang & Lee, 2020)

According to the American Diabetes Association (ADA) ,there are multiple factors that dictate the target HbA1c for individuals living with diabetes mellitus ;for patients with more severe disease, control of diabetes to achieve an HbA1c of 8% (64.0mmol/mol) is recommended (ADA, 2018).

According to (Yu & Yan, 2019) study in outpatient department of Shanghai East Hospital with 185 participant showed that The Diabetes-Carer application, a mobile phone-based diabetes management platform, which can be used by both patients and clinicians. Diabetes-Carer for patients consists of four main parts: diabetic education, self management, patient community, and real-time communication between patients and clinicians and HbA1c levels in patients of all groups decreased significantly from baseline. There were significant differences in the proportions of patients that achieved HbA1c<7% between groups, especially in intervention group after six months intervention. Next study from(Zhou & Chen, 2016) about Welltang is a smart phone-based diabetes management application, which can be used by both patientsand clinicians. Welltang for clinicians is associated with patients' data. Welltang for patients consists of three main parts: knowledge, self-management, and communication between patients and clinicians showed that The average decrease in HbA1c was 1.95% (21 mmol/mol) in the intervention group and 0.79% (8 mmol/mol) in the control group (P< 0.001) after 3 months intervention.

In the other hand, the study from (Osborn & Van Ginkel, 2017) also showed significant result a significant 1.36% or 14.9 mmol/mol HbA1c reduction (F=62.60, P<.001) from the first (8.72%, 71.8 mmol/mol) to second HbA1c (7.36%, 56.9 mmol/mol) measurement. about The One Drop Mobile app is free One Drop users the Bluetooth-enabled One Drop | Chrome blood glucose meter) store and track blood glucose readings, medication doses, physical activity , and carbohydrates consumed. A built-in food library expedites carbohydrate tracking after 12 months intervention.

The study from Cho & Kim (2017), in Outpatient clinics of the Diabetes Center of Seoul St. Mary's Hospital, the Seoul Asan Hospital's Diabetes Center, and Kangbook Samsung Hospital's Diabetes Center. The new device, a health gateway (HiCare, HX-461,Insung, South Korea) with Internet-based communication, to which a glucose meter and electronic manometer could be mechanically linked and data automatically transferred, was implemented within one week after randomization. Participants could upload the glucose and blood pressure data automatically to the online server through the device. After 6 months intervention the result is Upon six-month follow-up, HbA1c levels were significantly decreased from 7.86 0.69% to 7.55 0.86% within the intervention group (p<0.001) compared to 7.81 0.66% to 7.70 0.88% within the control group.

Also recently study from (Alanzi & Alanazi, 2018) in a clinic in Saudi Arabia-Dammam SANAD system (Saudi Arabia Networking for Aiding Diabetes) to support Saudi type 2 diabetes adult patients has result nineteen patients completed the study. Mean baseline HbA1c (%) was 8.14 (SD 1.20) and decreased to 7.54 (SD 0.96) after the SANAD intervention process [mean (SEM) decrease 0.600 (0.102)] after six months intervention.

However, overall there were all of significant differences in HbA1c and fasting blood glucose with respect to main outcomes between the groups. These results indicate relevant about the potential effect of mobile smartphone intervention tools for self-monitoring , self-care by patients and the role of remote access to health care professionals where there appears to be similar effectiveness with conventional access to diabetes patients.

DISCUSSION

Newly study evidence suggest that mobile smartphone application may be utilized to help deliver health services to patients and can be used as self-management tools (Izahar & Lean, 2017). In this study, we showed diabetes self management apps, either in iOS or Android, with the goal of manage self management diabetes and glycaemic control in pastient with diabetes mellitus. We found that the mobile apps varied in their features and usability and also has a significant effect to decrease HbA1c and blood glucose in patient with DM.

Mobile-phone/smartphone-based self management apps appear to have moderate benefits on glycemic control with a pooled effecton HbA1c reductionof -0.50%(-5.47mmol/mol), indicating that them smartphone health app intervention could improve diabetes patients'glycemic conditions. Glycated haemoglobin (HBA1C) is an indicator that reflects the average plasma glucose level over the past 2 to 3 months. The HBA1C test is relatively stable and has less variability(Cui & Wu, 2016)(Quinn & Butler, 2018).

The Diabetes-Carer application, a mobile phone-based diabetes management platform, which can be used by both patients and clinicians. Diabetes-Carer for patients consists of four main parts: diabetic education, self management,patient community, and real-time communication between patients and clinicians and the result HbA1c levels in patients of all groups decreased significantly from baseline. There were significant differences in the proportions of patients that achieved HbA1c<7% between groups, especially in intervention group for six months duration of study in Shanghai (Yu & Yan, 2019). Welltang is a smart phone-based diabetes management application, which can be used by both patientsand clinicians. Welltang for clinicians is associated with patients' data. Welltang for patients consists of three main parts: knowledge, self-management, and communication between patients and clinicians and the result showed that the average decrease in HbA1c was 1.95% (21 mmol/mol) in the intervention group and 0.79% (8 mmol/mol) in the control group (P< 0.001) after 3 months study in China (Zhou & Chen, 2016). Both of study showed that it important that the mobile application features is including the interaction and communcation between clinician or helath worker with the patients. This study have a limitations because we just focus on one main outcomes, in the future research we perharps to add another outcomes for mobile smartphone application.

Table 1. Summary of included article management of mobile phone for glycemic regulation (blood sugar levels and HbA1c) in Diabetes Patients.

Author, year	Number of subject	Study design	Country (setting)	Types of apps	Summary of result	Duration (Time)
Cheng & Sit (2018)	276	RCT	Outpatient clinic Shanghai Jiao Tao Hospital	Smartphone apps was used by both patients and clinicians. For patients, mainly comprises 4 parts: education, self-management (including records of SMBG, diet, exercise, medication, body weight, and other diabetes data), patient community , and communication between patients and clinicians.	At months 3 and 6, all 3 groups showed significant decreases in HbA1c levels (all P<.05). Patients in the app interactive management group had a significantly lower HbA 1c level than those in the app self-management group at 6 months (P=.04).	6 months
Yu & Yan (2019)	185	RCT	Outpatient department of Shanghai East Hospital	The Diabetes-Carer application, a mobile phone-based diabetes management platform, which can be used by both patients and clinicians. Diabetes-Carer for patients consists of four main parts: diabetic education, self management, patient community, and real-time communication between patients and clinicians	HbA1c levels in patients of all groups decreased significantly from baseline. There were significant differences in the proportions of patients that achieved HbA1c<7% between groups, especially in intervention group.	6 months
Zhou & Chen (2016)	100	RCT	Outpatient Department of Endocrin ology	Welltang is a smart phone-based diabetes management application, which can be used by both patientsand clinicians. Welltang for clinicians is associated with patients' data. Welltang for patients consists of three main parts: knowledge, self-management, and communication between patients and clinicians.	The average decrease in HbA1c was 1.95% (21 mmol/mol) in the intervention group and 0.79% (8 mmol/mol) in the control group (P< 0.001)	3 months
Gunawardena & Jackson (2019)	67	RCT	Sri Lanka	Smart Glucose Manager (SGM) Mobile Apps The SGM is an android-based mobile application that includes unique features to remind patients to check their blood glucose, take medication on time, eat on time, and exercise at user-defined times	At the 6-month follow up, the SGM group had significant lower A1c levels than the control group (7.2% vs 8.17%, P <.0001).	6 months
Osborn & Van Ginkel (2017)	256	RCT	USA	The One Drop | Mobile app is free One Drop users the Bluetooth-enabled One Drop | Chrome blood glucose meter) store and track blood glucose readings, medication doses, physical activity , and carbohydrates consumed. A built-in food library expedites carbohydrate tracking	There was a significant 1.36% or 14.9 mmol/mol HbA1c reduction (F=62.60, P<.001) from the first (8.72%, 71.8 mmol/mol) to second HbA 1c (7.36%, 56.9 mmol/mol) measurement.	12 months
Yang & Lee (2020)	150	RCT	13 primary care clinics in Seoul and other large cities in South Korea were voluntarily recruited	Mobile phone app (Hicare smart K, Insunginformation). Then, the physicians of the primary care clinic educated participants on the individual management targets (glycemic, blood pressure [BP], lipid profile, and body weight) on the basis of the medical guidelines of the Korean Diabetes Association	participants in the intervention group showed significantly more improvement in HbA1c P=.003) and fasting plasma glucose P=.005) than those in the control group	3 months
Cho & Kim (2017)	484	RCT	Outpatient clinics of the Diabetes Center of Seoul St. Mary's Hospital, the Seoul Asan Hospital's Diabetes Center, and	The new device, a health gateway (HiCare, HX-461, Insung, South Korea) with Internet-based communication, to which a glucose meter and electronic manometer could be mechanically linked and data automatically transferred, was implemented within one week after randomization. Participants could upload the glucose and blood pressure data automatically to the	Upon six-month follow-up, HbA1c levels were significantly decreased from 7.86 0.69% to 7.55 0.86% within the intervention group (p<0.001) compared to 7.81 0.66% to 7.70 0.88% within the control group.	6 months

Author, year	Number of subject	Study design	Country (setting)	Types of apps	Summary of result	Duration (Time)
			Kangbook Samsung Hospital's Diabetes Center	online server through the device.		
Kumar & Moseson (2018)	146	RCT	Online recruitment in USA	The mobile app's coaching program is the only digitally delivered diabetes education program recognized by the American Diabetes Association. The program was designed in accordance with the National Standards for Diabetes Self-Management Education and Support.	HbA1c levels were significantly decreased from baseline Hba1c in intervention group.	3 months
Alanzi & Alanazi (2018)	20	RCT	a clinic in Saudi Arabia-Dammam	SANAD system (Saudi Arabia Networking for Aiding Diabetes) to support Saudi type 2 diabetes adult patients.	Nineteen patients completed the study. Mean baseline HbA1c (%) was 8.14 (SD 1.20) and decreased to 7.54 (SD 0.96) after the SANAD intervention process [mean (SEM) decrease 0.600 (0.102)].	6 months
Alotaibi & Istepanian (2016)	20	RCT	Kingdom of Saudi Arabia (KSA)	SAED consists of a smart mobile phone and a blood glucose measuring device enabled with Bluetooth. In this unit, the patient provides the measurements of his/her medical readings (e.g., by measuring the blood glucose level twice daily) as prescribed by the clinician. This data is transferred via a 3.5G/4G/LTE network to the SAED cloud server.	The mean baseline HbA1c for the intervention group was seen to be 8.76% (0.76% tolerance) and 8.61% for the control group. It is important to note that the mean baseline of the intervention group decreased to 7.85% from 8.76% at the end of the 6-month period.	6 months
Drion & Pameijer (2015)	63	RCT	Isala hospital in Zwolle, the Netherlands	Diabetes Under Control (DBEES) mobile phone application	The mean baseline HbA1c for the intervention group was seen dercreased	6 months
Lee & Chan (2020)	240	RCT	Primary healthcare centers in the Klang Valley, in Malaysia,	Home gluco-telemonitors and transmitted glucose data to a care team who could adjust therapy accordingly	At the end of the study at week 52, a total of 23 (19.2%) participants in the TG group achieved HbA1c levels of < 7% compared with 21 (17.5%) participants in the UC group.	12 months
Cheng & Sit (2018)	242	RCT	two tertiary hospitals in Xi'an city, China	Six phone-based telephone follow-upcounselling session	Empowerment-based self-management intervention did not induce a significant HbA1c reduction (p= 0.37)	3 months

CONCLUSION

This systematic review has shown that self-management in diabetes that deliver by with smartphone health application as a media, may help to manage to decrease glyacaemic control (HbA1c and blood glucose level) in patinet with diabetes in long term management. More applicable, features, content and free acces smartphone health application should be impove, new designed, and more rigorous studies are needed to further explore aspects of diabetes self-management that can be lauched into clinical practice and helpfull for health worker.

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DECLARATION OF CONFLICTING INTEREST

No conflict of interest in this study.

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AUTHOR CONTRIBUTION

Tifanny Gita Sesaria: Contribution in design, perform collecting article and analyze the literature.

Kusnanto Kusnanto: Contribution for involved in planning and supervised the work of systematic literature review.

Abu Bakar: Contribution for discussed the results and contributed to the final manuscript.

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