ORIGINAL RESEARCH ARTICLE

Effectiveness of Digital Health Interventions in Managing Glycated Haemoglobin: A Randomized Controlled Trial

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ABSTRACT

Background: Digital health interventions, such as mobile apps and wearable devices, have emerged as potential tools to help individuals manage glycemic control. By comparing the outcomes of participants using digital health tools with those following traditional methods of diabetes management. The study aimed to evaluate the impact of digital interventions on Managing Glycated Haemoglobin control.

Methodology: A randomized, controlled trial was conducted at the Babylon Diabetes and Endocrinology Center/ Iraq. Participants were selected based on established inclusion and exclusion criteria and were assigned to either the intervention or control groups through randomization. The intervention group received a medication management app specifically designed for smartphones. Data were collected over six months through three tests and analyzed using SPSS-20.

Results: The study found no significant difference in HbA1c levels between the intervention and control groups during the pre-test period. However, significant differences emerged at both post-test I (after 3 months) and post-test II (after 6 months), with the intervention group showing a significant decrease in HbA1c levels from pre-test to both post-test I and post-test II.

Conclusions: The study underscores the need to use digital health interventions in diabetes management to improve the quality of patient care. Decision-makers can improve the quality of blood sugar control and overall health by keeping up with such smart applications.

Keywords: Digital Health Interventions, Glycated Haemoglobin Control, Mobile health, Digital tools in diabetes management

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INTRODUCTION

T2DM is one of the biggest management challenges in health systems worldwide because of the long-term nature of the condition and the complications that may arise from this.[1] Hemoglobin A1c (HbA1c) is a key indicator of the overall glycemic status of a diabetic patient with a long-time horizon.[2] Maintenance of HbA1c at optimal levels is vital in the control of T2DM complications such as cardiovascular diseases, neuropathy, and nephropathy.[3] However, to achieve the desired glycemic control, patients have to follow their prescribed medication, meal plans, and exercise regimes very closely.[4] Non-adherence to these regimens is not uncommon, and results in comparatively inferior clinical results and higher healthcare costs.[5]

Mobile health applications have been identified as potential methods for improving compliance with treatment among T2DM patients. These interventions include mobile health applications, telemedicine applications, wearable technology applications, and online education applications. The application of digital health tools is based on the ability to offer constant support, feedback, and even the opportunity to communicate with the patient's physician. This may in turn result in enhanced self-management behaviors and thus better glycaemic control.[6] For example, mHealth applications can provide alerts on when a patient should take his/her medicine, monitor the amount of exercise he/she has taken, and the kind of food he/she has been taking, and even knowledge-based content that is personalized to a specific patient.[7,8]

Several systematic reviews and meta-analyses have also indicated the usefulness of mHealth and eHealth for enhancing HbA1c among T2DM populations. A systematic review and meta-analysis conducted on the effects of digital health interventions showed that it had a positive effect on HbA1c levels compared to conventional care. This is because, through the use of digital tools, patient involvement is enhanced and there is the promotion of responsibility to ensure that they strictly follow the prescribed regimen.[9] Another systematic review found that there was a better outcome of treatment and clinical results in T2DM patients with the use of digital interventions that included behavior change theories aspect.[10]

However, several challenges may affect the use of digital health interventions when adopted in real-world settings. These involve matters concerning the use of these technologies, privacy concerns, and the way they can fit into the current healthcare systems.[5] However, there is a lack of long-term RCTs with ''hard'' outcomes and more research is needed to determine the long-term effects of these interventions on medication adherence and HbA1c. However, it has become increasingly apparent that digital health interventions offer a promising approach to tackling the adherence issues of T2DM patients and helping to improve public health.

The aim of this study is to evaluate the effectiveness of digital health interventions in managing glycated hemoglobin (HbA1c) levels among individuals with diabetes through a randomized controlled trial. By comparing HbA1c levels of contributors using digital health tools with those receiving traditional care, the study seeks to determine whether those technological interventions can significantly improve blood glucose management. This research aims to provide insight into the benefits of being able to integrate digital health answers into diabetes management, contributing in the long term to increased physical health consequences and a more beneficial life expectancy for people with this chronic condition.

METHODOLOGY

Study design, sampling and data collection: A randomized controlled pilot study was conducted from December 2023 to May 2024. The research population consisted of type 2 diabetes patients who attended the Babylon Diabetes and Endocrinology Center, in Iraq. This hospital is a prominent diabetes health center and has specialized clinics and services in endocrine diseases. This specialized center welcomes clients for routine and periodic health checkups based on their health needs and doctor's request on all days of the week.

The inclusion criteria were patients with T2DM, with duration of diagnosis being at least one year. Adults aged 18-75 years. The basal HbA1c concentrations are in the region of 7.0% and 10.0% Currently using oral hypoglycemic medications or insulin for diabetes. Having a smartphone or other electronic device that can support the digital health intervention application. Good communication in terms of being able to comprehend and read the language that the intervention is delivered in. Demonstration of willingness to give informed consent and adherence to the study procedures.

Exclusion criteria were the patient's age of over 75 years, and severe diabetes-related complications such as end-stage renal disease, severe neuropathy, or proliferative retinopathy. The other potentially excluding comorbid conditions affecting the participant's ability to engage in study activities (e.g., terminal cancer, severe congestive heart failure). Suffers from a severe psychiatric disorder or has a cognitive impairment that would hinder her ability to adhere to the intervention. Another clinical trial could influence adherence or HbA1c levels in the same manner. History of non-compliance with medical treatment or study protocols as evidenced in documented reports. The participant also reported that they were unable to use the digital health interventions due to technical issues (e. g., the inability to read due to poor vision and therefore not to use the app, or never learned to use such a device as a smartphone or similar.

For instance, in a study aimed at determining the effect of an intervention that could potentially reduce poor adherence by 20%, with a 95% confidence interval and a power of 80%, 86 participants per group were required.[11] This calculation was based on an estimated attrition rate of 10%, which means that 96 participants per group were required.

Hemoglobin A1c (also known as glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c) is a useful test to determine a person's status of glucose control. The test is based on the average of blood sugar within the last 90 days and is in percentage. The test can also be used in diagnosing diabetes.[12]

In this case, recruitment was done among the inpatient and outpatient clients who were being referred to the specialty center. The investigators were positioned at the reception of the center to screen diabetic patients who were qualified according to inclusion and exclusion criteria. From this pool, simple random sampling was applied to select two hundred and nine diabetic patients who meet the inclusion criteria. Finally, 192 patients with diabetes, who provided their informed consent, were then allocated to the intervention or control groups using a random block size of two (Figure 1).

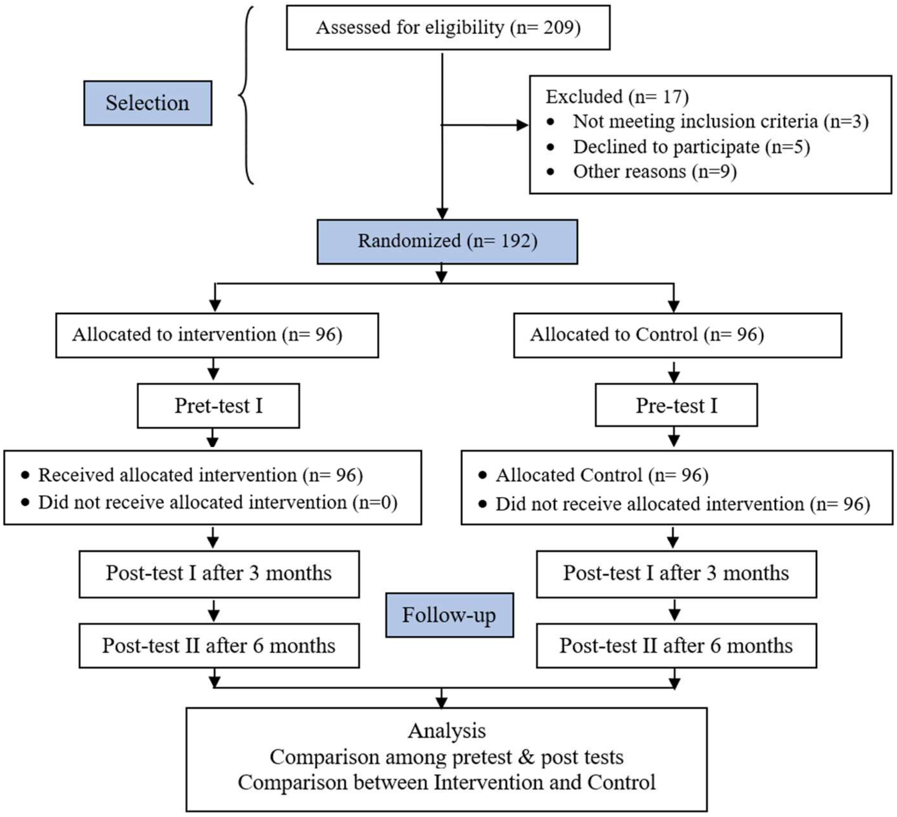

Figure 1: CONSORT 2010 Flow Diagram

The preliminary cumulative blood sugar levels were determined by three tests- pre-intervention, post-intervention by 3 months, and post-intervention by 6 months while patients were under a digital application. The instruments used for data collection were a demographic questionnaire and cumulative blood sugar level, which was measured in the laboratories of the Babylon Diabetic and Endocrinology Centre. The demographic questionnaire included questions related to gender, age, educational level, and income sufficiency, the list and number of medications that the participants were taking (to confirm polypharmacy), and the source of information about the medications that they were using. The control group only took prescribed medicine. In the first assessment, after offering the intervention group the given app, the researchers made sure that patients had enough pills until the next visit in both groups.

Intervention: In this study, an existing medication reminder application in Arabic was reviewed to understand its drawbacks and then these problems were avoided in the new design of the application. A medication management app with an Android operating system that has features like; Being easy to use, the user can change the font and text size, the appropriate color of the background and application element, pronounce the name of the medicine, display the image when the medicine reminder is due and use phrases such as "Dear patient! For your recovery," "It's time to take your medicine. It has been introduced into Iraq for the first time for Iraqis with diabetes when the reminder alarm is set, the name and image of the medication are captured. All contents of this application are linked to education and have been approved by three diabetes and endocrinology specialists.

To maintain the privacy and security of the application users, the latest software codes were used to develop the application as a pilot test, to identify any defects, and to test the proper functioning of the application on the patients' mobile phones. The application was installed on the mobile phones of ten diabetic patients and they were asked to report any inconvenience they faced and their suggestions regarding... By modifying the application and its easy-to-use interface. This field and diabetes patients are in the design stage. Comments from commitment medicine experts were used. Final correct operation confirmation and informed consent were obtained from study participants and the application was installed on their mobile phones in the intervention group. Each participant was trained on how to use the app through 1-hour face-to-face sessions, and medication use alarms were set.

During the intervention, app users were called or contacted in routine visits to the specialized center to ask and confirm whether there was any difficulty in using the app to determine the effectiveness of the intervention. Participants can also contact the researchers using their assigned phone number to ask questions. The total number of medications and distribution of medications across different therapeutic groups did not differ significantly between the control and intervention groups. The control group received only standard care from the health center and had occasional follow-ups to evaluate the treatment process and necessary care.

Statistical Analysis: The IBM SPSS 20.0 software package was used to conduct the statistical analysis. Numbers and percentages were used to rank the variables, while mean and standard deviation were used to statistically characterize the continuous variables. Additionally, to find significant differences between the two groups, the independent samples t-test was used (between the two groups), and for each group, a Post Hoc Testes test was used (between each group). A significance threshold of 0.05 was applied to the statistical interpretations that were employed.

RESULTS

The findings indicate a predominance of male patients in both groups, with 82.3% in the intervention group and 77.1% in the control group. The average age of participants in the intervention group ranged from 29 to 68 years, with a mean age of 52.06 ± 12.32 years. In the control group, the age ranged from 32 to 63 years, with a mean age of 50.64 ± 11.75 years. Regarding education level, the majority of participants in both groups were college graduates, comprising 65.6% of the intervention group and 70.8% of the control group. Employment status showed that 72.9% of participants in the intervention group were employed, compared to 80.2% in the control group. Monthly income ranged from 200 USD to 1000 USD in both groups, with an average income of 50.550 ± 7.288 in the intervention group and 56.850 ± 7.487 in the control group. The duration of diabetes mellitus ranged from 10 to 18 years in the intervention group, with an average duration of 14.52 ± 6.13 years.

In the control group, the duration ranged from 9 to 21 years, with an average of 14.95 ± 5.80 years. The average number of medications used ranged from 1 to 4 in both groups, with a mean of 1.98 ± 0.85 in the intervention group and 1.95 ± 0.79 in the control group. Physicians were the primary source of information about consumed medications in both groups, with 83.3% in the intervention group and 74.0% in the control group. All demographic characteristics are comparable between the two groups because there are no statistically significant differences between them p> 0.05 (Table 1).

Table 1: Sociodemographic Characteristics of Studied Sample

Sociodemographic Characteristics	Interventional Group (N= 96) (%)	Control Group (N= 96) (%)	p-value
Sex			
Male	79 (82.3)	74 (77.1)	0.192
Female	17 (17.7)	22 (22.9)	
Education level			
Primary school	15 (15.6)	13 (13.5)	0.351
Secondary school	18 (18.8)	15 (15.6)	
College	63 (65.6)	68 (70.8)	
Occupation			
Employed	70 (72.9)	77 (80.2)	0.275
Unemployed	26 (27.1)	19 (19.8)	
Information of consumed medications			
Family	11 (11.5)	17 (17.7)	0.178
Nurses	5 (5.2)	8 (8.3)	
Physician	80 (83.3)	71 (74)	
Age			
Min - Max	29-68	32-63	0.592
M ± SD	52.06 ± 12.32	50.64 ± 11.75	
Income in USD/ month			
Min - Max	200-1000	200-1000	0.351
M ± SD	50.55±7.288	56.85 ± 7.487	
Duration of DM			
Min - Max	10-18	9-21	0.431
M ± SD	14.52±6.131	14.95 ± 5.801	
Number of medications uses			
Min - Max	1-4	1-4	0.476
M ± SD	1.98±0.845	1.95±0.786	

Table 2: Comparison of HbA1c between Intervention and Control Groups

Periods	Mean ± SD	P value (t test)
Pre-test		
Intervention	8.22±0.785	0.850
Control	8.201±0.818	
Post-test I		
Intervention	5.98±0.480	0.001
Control	8.19±0.821	
Post-test II		
Intervention	5.93±0.575	0.001
Control	8.15±0.911	

Table 3: Multiple Comparison of HbA1c between Interventions and Control Groups within Periods of Measurement

Groups	(I) Period	(J) Period	Mean Difference (I-J)	Std. Error	Sig.
Intervention	Pre-test	Post-test I	2.23948*	.09043	.000
		Post-test II	2.29365*	.09043	.000
	Post-test I	Pre-test	-2.23948*	.09043	.000
		Post-test II	.05417	.09043	.550
	Post-test II	Pre-test	-2.29365*	.09043	.000
		Post-test I	-.05417	.09043	.550
Control	Pre-test	Post-test I	.00854	.12295	.945
		Post-test II	.04708	.12295	.702
	Post-test I	Pre-test	-.00854	.12295	.945
		Post-test II	.03854	.12295	.754
	Post-test II	Pre-test	-.04708	.12295	.702
		Post-test I	-.03854	.12295	.754

*The mean difference is significant at the 0.05 level.

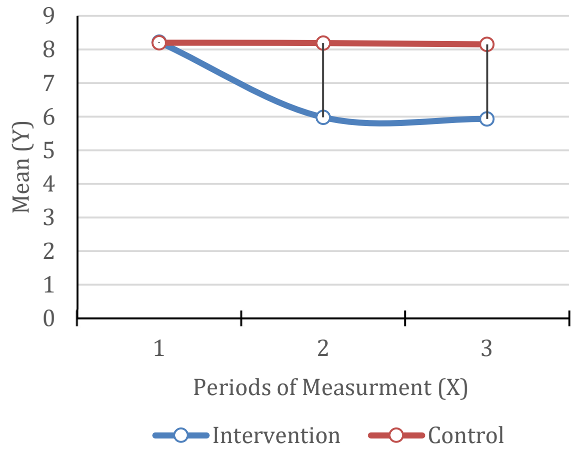

Figure 2: Comparison of HbA1c between Intervention and Control Groups within Three Periods of Measurement

Findings in Table 2 indicate there were no statistically significant differences in HbA1c between intervention and control groups in the pre-test periods (t=0.189; p=0.850). While there were statistically significant differences in HbA1c between the intervention and control groups at the post-test I periods (t=22.746; p=0.001) and post-test II periods (t=20.217; p=0.001) (Fig. 1).

The findings in Table 3 indicate that there were significant differences in HbA1c in the intervention group specifically between pre-test and post-test I (p= 0.000) and post-test II (p= 0.000). Such HbA1c in post-test I differ from those who are pre-test (p=0.000) and no differs from post-test II (p= 0.550). Such HbA1c in post-test II differs from those who are pre-test (p=0.000) and no differs from post-test I (p= 0.550). The findings indicate that there were no significant differences in HbA1c in the control group specifically between pre-test and post-test I (p= 0.945) and post-test II (p= 0.702). Such HbA1c in post-test I do not differ from those who are pre-test (p=0.945) and post-test II (p= 0.754). Such HbA1c in post-test II do not differs from those who are in pre-test (p=0.702) and post-test I (p= 0.754).

Discussion

HbA1c is a glycoprotein composed of hemoglobin and glucose, which can be used as a marker to regulate blood glucose levels in diabetic patients. It measures the average blood glucose concentration over the past 2-3 months, making it an important landmark for diabetes management and prevention of complications.[13] Therapeutic adherence, or the degree to which patients adhere to the prescribed treatment plan, is critical to reducing HbA1c levels. Adherence to medications, diet, and lifestyle changes also play a large role in improving blood sugar control. As for reminders, it can be said that they have an effective role in ensuring that the patient adheres to the prescribed treatment regimen; They help the patient remember to take his medications.[5] These reminders have been enhanced by digital health technologies such as mobile apps and wearable devices, as they provide timely notifications, monitor adherence, and provide feedback, contributing to lower HbA1c and improved overall diabetes management.[14]

The findings of the study have shown that DHIs are useful in the reduction of glycated hemoglobin (HbA1c) among patients with diabetes. To begin with, there were no differences in the mean HbA1c levels of the two groups during the pre-test phase, implying that the two groups had similar HbA1c levels at the start of the study (t=0. 189; p=0. 850). The fact that there was no significant difference between the two groups before the intervention means that any changes observed later could be attributed to the intervention rather than differences in the groups.

Nonetheless, the study revealed that the use of DHIs led to a considerable enhancement of the following. During the post-test I period, which occurred three months after the initial test, the participants in the intervention group had a lower HbA1c level than the control group (t=22. 746; p=0. 001). This indicates that DHIs can be useful in improving glycemic control within a short period, due to the increased self-management practices, constant feedback, and monitoring.

The trend was also observed during the post-test II which was administered six months after the intervention; the intervention group recorded lower HbA1c scores than the control group to a statistically significant level (t=20. 217; p=0. 001). This sustained improvement suggests that DHIs have the potential to be useful tools for managing diabetes in the long term. The long-term positive effects could have been due to constant interaction and the feedback that was availed by the digital tools, underlining the importance of such tools in developing long-term behavioral changes & overall health improvement.[15,16]

These results align with other studies showing that telehealth and other digital health interventions can produce substantial improvements in glycemic control. For example, a meta-analysis of telehealth interventions established that remote patient monitoring was effective in reducing the HbA1c level, proving the efficiency of such technologies in the short and long term for diabetes management.[17] Likewise, research has demonstrated that digital solutions that include behavioral economics interventions can result in considerable changes in HbA1c levels through improving self-management and offering rewards and reminders.[18,19] The findings of the study indicate that the implementation of DHIs is beneficial for managing diabetes in the short and long run as it enhances glycaemic control and assists patients in maintaining their regimens.

The results of the differences in HbA1c levels between the two groups are summarized in this study, and the p-values of the results are reported with 0. 000 for the post-test I and post-test II. This statistical significance supports the reliability of the changes that have been observed and enhances the credibility of the conclusion that has been made in this study.[20] Similarly, the post-test I and post-test II results of the intervention group regarding HbA1c levels reveal no statistically significant differences (p=0. 550), which, again, indicates a plateau effect in the effectiveness of the intervention after the first three months of implementation in reducing HbA1c levels.[21]

Likewise, the lack of drastic differences in the outcomes of the control group in terms of HbA1c levels can be explained by the p-values stated in the literature (p<0.001). The results of post-test I showed that the mean score was 945; for post-test II, the mean score was 0. The pre-test and post-test measurements are not statistically significantly different from 702 for post-test II). These statistical results contribute to the overall understanding of the effectiveness of digital health interventions to lower the HbA1c levels, specifically, the differences between the results obtained in the intervention group and the control group.

The reliance on statistical analysis also gives the study credibility and the observed effects of digital health interventions on glycemic control. Thus, the analysis of HbA1c levels at different time points in the study and comparison of these values between the intervention and control groups allows us to fill the gaps in knowledge about the temporal characteristics of changes in HbA1c in response to the use of digital health interventions, which can be useful for the further development of this approach.[22,23]

The results of the study, based on the statistically valid analysis, reveal the efficacy of digital health interventions in enhancing glycemic control, as reflected by a decrease in patients' HbA1c levels in the intervention group compared to the control group. These findings have significant implications for the understanding of the current state of diabetes and the long-term health of the affected individuals to design and implement effective interventions.[24]

Conclusion

Study results showed that HbA1c levels decreased in participants who received digital health interventions for HbA1c, with differences between the intervention and control groups emerging. As for the HbA1c level, there were no statistically significant differences between the two groups in the pre-test phase, but in the first post-test phase (after 3 months) and the second post-test (after 6 months) the discrepancy was clear, which indicates the efficiency of the interventions. At different points in time. In particular, the intervention group reported a significant reduction in HbA1c levels compared to baseline, which confirmed the effectiveness of digital health interventions in enhancing glycemic control. However, the control group had a relatively small variation in HbA1c levels over the entire trial period. This study highlights the need to integrate mHealth solutions into diabetes treatment to improve the quality of care. For future research, it is suggested to study the long-term effects and feasibility of these interventions. Furthermore, there is a need to integrate and personalize digital health interventions to get the best results in blood sugar control and other health outcomes for patients with diabetes.

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