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The Use of Digital Telehealth for the Self-Management of Type 2 Diabetes Patients in Hinds County, Mississippi: A Pilot Study

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Abstract

Self-management is crucial for the management of type 2 diabetes. Remote patient monitoring via telehealth may enhance self-management and control of diabetes. A three-arm randomized controlled trial involving 90 participants randomized into two intervention groups and one control group was conducted. The purpose of this study is to test whether the use of a mobile phone-based app, with or without telehealth counseling, could improve HbA1c level, self-management, and health-related quality of life compared with usual care. The two intervention groups received a mobile phone with a self-management app. One intervention group additionally received telehealth counseling delivered by a diabetes specialist nurse for 6 months. All three groups continued to receive the usual care from their provider. The primary outcome is a reduction in HbA1c level. Secondary outcomes are self-management, health-related quality of life, depressive symptoms, and lifestyle changes. Data were analyzed using univariate and multivariate (descriptive, *t*-test, MANOVA) methods. There was a significant reduction in the HbA1c levels of participants after 3 and 6 months. There was also a significant difference in HbA1c levels between the control and two intervention groups. Pre- and posteducation surveys for intervention group 2 showed an improvement in the understanding of type 2 diabetes risk factors, diabetes, and self-management. Digital telehealth demonstrated considerable potential for reducing blood sugar levels, enhancing self-management, and improving the quality of life of type 2 diabetic patients. The addition of telehealth education and counseling further improved the positive outcomes.

Keywords

telehealth, mHealth, type 2 diabetes, diabetes self-management, telehealth counseling, HbA1c

Introduction

Type 2 diabetes is a complex disease[1] with an increasing prevalence worldwide.[2] It is among the top 10 leading causes of death in the United States with 103,294 deaths in 2021.[3] Among U.S. adults aged 18 years or older with diagnosed diabetes between 2013 and 2016, 50% had an A1C value of 7.0% or higher.[4] As stated in treatment guidelines, multifactorial treatment is necessary to improve long-term outcomes.[1,5] However, many do not meet the recommended goals for diabetes care.[6,7] New treatments are evolving rapidly, and self-management has been shown to be crucial in daily disease management and in preventing macro and microvascular complications.[8,9]

The field of technology-supported health care is growing and offers new ways of self-management education and support. Mobile phones are essential in people's lives today and may serve as a platform for various self-management tools, such as apps. However, the current reviews are inconclusive, and the effects of mobile health (mHealth) remain unclear.[10–12] The studies included in these reviews are heterogeneous. They have used different mobile phone-based interventions and lengths of follow-up, and people with type 1 and type 2 diabetes are often included in the same studies. In most interventions, patients are monitored by healthcare personnel in contrast to interventions in which self-management is based on self-monitoring and self-care.[11,13] Despite this, mHealth is recognized as a potential

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addition to usual care because some studies have found positive short-term effects on glycemic control. However, the effects of the intervention decreased with time.[12] mHealth apps have also been effective without healthcare personnel's support, which may reduce healthcare costs.[11]

Apps for mHealth interventions are often combined with health counseling, but the research related to these complex interventions is inconclusive because of heterogeneity in the types of studies.[13,14] Earlier research has shown that phone counseling is feasible, convenient, low cost, and may be an alternative to frequent visits.[13,14] In states such as Mississippi, people in rural areas may have less access to specialized health care. A recent coordination reform has reorganized health care delivery, with more responsibility transferred from specialist health care to primary health care services and with more emphasis on self-management. The application of innovative technologies may supplement this reform.[15]

Few studies have used the combination of a mobile phone app for self-management supported by health counseling via telephone. Studies often include monitoring with real-time feedback from healthcare personnel, which may lead to investigating dimensions other than self-management. However, an intervention based on the patient's initiative to self-manage at a frequency that does not interfere with daily life should be feasible in modern society.[16]

Earlier reviews noted the lack of integration of behavior change theory into mHealth research and recommended that interventions be theory-based.[10,13] Motivational interviewing is a technique in health counseling [17] and a well-known clinical method recommended for use in the American Diabetes Association guidelines for persons with diabetes.[3] Research has also indicated an effect of motivational interviewing on persons with type 2 diabetes trying to attain behavior change in lifestyle-related issues.[18,19] Further, some studies have tailored health counseling to the patient's stage of readiness to change according to the trans-theoretical model of stages of change [20] and have demonstrated effects for persons with type 2 diabetes using this model.[21,22] In the present study, both techniques were used in health counseling.

This study aims to determine if using a mobile phone-based self-management system, with or without telephone health counseling by a diabetes specialist nurse for 6 months, could improve HbA1c level, self-management, and health-related quality of life compared with usual care. The primary outcome is glycemic control, as assessed by the HbA1c level. Secondary outcomes are self-management and health-related quality of life, depressive symptoms, and lifestyle changes (dietary habits and physical activity).

Methodology

Study Design

This is a three-armed prospective randomized controlled trial with a 1:1:1 allocation ratio using block randomization to 1 of 2 intervention groups or control.

Participants. The study was conducted in Hinds County, Mississippi. All the participants were recruited from one health facility in Hinds County in collaboration with their GPs at this health facility. All participants lived in their homes and received the usual care which included taking their regular medications and three-monthly visits with their general practitioner (GP). The participants were eligible if they were aged ≥18 years, had an HbA_{1c} level ≥8% (≥64.1 mmol/mol), was diagnosed for at least 1 year, and could complete questionnaires in the English language. They also must be cognitively able to participate and use the system and devices provided, although familiarity with mobile phones is not necessary. The HbA_{1c} level will be set to $HbA_{1c} \geq 8\%$ (≥64.1 mmol/mol), that is, above the treatment target according to the American Diabetes Association "Standards of Medical Care in Diabetes.[5] Written informed consent was obtained from participants after the research team provided detailed information about the project during the start-up meetings. Data were collected through self-reported questionnaires, medical app monitoring, and from medical records at the GPs' offices. Three assessment points were established: baseline (during randomization), at 3 months, and 6 months after randomization.

Sample Size: Because this is a pilot study, thirty participants will be randomly assigned to each of the three groups. Therefore, the sample was 90 participants for the three groups.

Blinding: The study will not be blinded to the participants or GPs and health providers because of the nature of the intervention, which requires overt participation.[23] The research team participated in assessing eligibility, data collection, training patients to use the devices, and follow-up. Thus, those who delivered technical support will know which group the participants were allocated to.

Control Group. The control group received the usual care according to the standard clinical guidelines. Patients with type 2 diabetes are recommended to consult their GP every 2–6 months and to have a more thorough consultation once a year with measurements of their blood pressure, serum lipids, glucose, HbA1c, weight, body mass index (BMI), etc.

Intervention Groups I and II. In addition to the usual care provided by their GPs, the participants randomized to the intervention group I—Medical App (MA) group received a phone with the Diabetes-M app only while the intervention group II—Medical App + Health Counseling (MA-HC) group received the phone with the Diabetes-M app and telehealth education and counseling by a trained Diabetes nurse educationist. The Diabetes M is a mobile phone-based app that can be used for the daily collection of data on glucose levels, diet, physical activity, and other self-management goals. The phone-based app transmits the data wirelessly to a cloud-based monitor accessible to the care team and enables real-time monitoring and collection of

data. All participants continued to receive their usual care for the duration of the study which includes clinic visits every 3 months and taking their recommended medications.

Training

Intervention groups MA and (MA-HC) group were trained to use the mobile phone-based system at the start-up meetings, which included a demonstration of the diabetes diary. They were also provided with a printed sheet that contained instructions on the use of the smartphone. A telephone support service was available to answer questions and to help the participants with technical aspects during regular business hours on weekdays from 9:00 to 15:00. The participants in (MA-HC) group with health counseling were given additional training on how to send and receive secure messages to App monitor linked to the diabetes specialist nurse.

Ethics and Safety

The Jackson State University Institutional Review Board approved the study. All participants gave their written informed consent before the study started. The ethical guidelines and rules were followed with the intention of doing well and preventing harm or risks. The participants' entries in the Diabetes-M diabetes diary app were recorded continuously and transferred to a secure server. A comprehensive risk analysis of the technology was performed before the start of the study to ensure that privacy and security issues were addressed appropriately. Through the informed consent form, participants were made aware of the possibility of hypoglycemia-related to behavioral change. They were informed to contact their GP according to their instructions.

Data Collection

1. Demographic information was retrieved from the EHR at baseline and included HbA1c, age, gender, weight, calculated BMI, and Blood Pressure.
2. Daily data on glucose level, diet, and exercise were collected via the app monitor.
3. Data on diabetes self-care, behavior, confidence, and diet and exercise stages of change were collected through self-reported questionnaires at the beginning and end of the study.

Out of the sample population of 90, 76 participants completed the study resulting in a 26.6% attrition rate.

Statistical Analysis

Baseline differences between groups were assessed with one-way analysis of variance (ANOVA; continuous measurements) and chi-square tests (categorical data). Within-group changes were analyzed using Tukey and Scheffe. The differences in mean change from baseline to 6-month follow-up between the groups were analyzed using one-way ANOVA for the primary outcome (HbA1c) and the secondary outcomes. For baseline measurements, all three groups were compared using Kruskal–Walli's test. Also, the percentage decrease in HbA1c levels was determined after categorizing it into three HbA1c groups.

Unavailable data were considered missing, and the results were based on the intention-to-treat approach. All tests were two-sided. P values $< .05$ were considered significant. All analyses were performed using SPSS version 28.0.1.1 (IBM Corp, Armonk, NY, USA).

Results

Baseline Descriptive

The baseline sociodemographic, clinical, treatment variables, and lifestyle characteristics were expressed as counts with percentages for categorical variables or means and standard deviations for continuous variables. There were more females (68%) than males (32%) in the sample population who were predominantly African Americans (97%). The mean age of the participants was 55 years with a range of 21 to 75 years. The participants had a mean HbA1c level of 10.2% with no significant difference between the group means (control group—10.1, intervention 1 group—10.4, intervention 2 group—10.2). majority of the participants were overweight or obese based on the calculated BMI. Analysis of variance in means at baseline between Control, Intervention 1, and Intervention 2 showed no significant difference in Age, DBP, SBP, and BMI at a 95%confidence interval.

Overall Comparison of Primary Outcome:

Baseline and 3-month ANOVA measurements of HbA1c were insignificant between Control, Intervention 1, and Intervention 2 groups. During the 6 months, ANOVA measurements between the control, Intervention 1, and Intervention 2 groups were significant ($P < .001$).

Between Groups Comparison:

There was no significant difference in HbA1c levels between the groups (10.1, 10.4, and 10.2) at baseline Table 1. After 3 months, there was a mean difference of 8% in HbA1c levels between the control group and intervention

Table 1. Impact of Intervention on HbA1c.

Group	N	Baseline Mean HbA1c	3 Months Mean HbA1c	6 Months Mean HbA1c
Control	30	10.1	9.2	9.1
Intervention 1 (MA)	23	10.4	8.5	7.2
Intervention 2 (MA-HC)	23	10.2	7.8	7.6

Abbreviations: MA = Mobile App group; MA-HE = Mobile App + Health Education/counseling.

group 1 (MA) and 16% between the control group and intervention group 2 (MA-HC). After 6 months, the mean difference in HbA1c levels was 21% between the control group and intervention 1 group and 16.5% between the control group and intervention group 2.

The 6 months comparison of mean differences in HbA1c levels between the groups is shown in Table 2. During the 6 months, Scheffe and Tukey HSD showed differences between control and intervention 1 ($P = .001$, $P < .001$, respectively). In addition, Scheffe and Tukey HSD showed differences between control and intervention 2 ($P = .006$, $P = .008$, respectively). No significant differences were found between intervention 1 and intervention 2 groups.

Within Groups Analysis

Table 3 shows a comparison of differences in mean HbA1c levels within the groups at baseline, 3 months, and 6 months. There was no difference in the mean HbA1c level of participants in the control group at baseline, 3 months, and 6 months.

Intervention Group 1: Comparisons within intervention group 1 at baseline, 3 months, and 6 months showed significant changes ($P < .001$). Tukey HSD test showed substantial differences between baseline and 3 months ($P = .012$) and baseline and 6 months ($P < .001$, $P < .001$ respectively).

Intervention Group 2: Comparisons within intervention 2 between baseline, 3 months, and 6 months showed significant changes ($P < .001$). Tukey HSD test showed substantial differences between baseline and 3 months ($P < .001$) and between baseline and 6 months ($P < .001$).

Stages of Change Analysis

Chi-square analysis of diet and exercise stages of change between intervention groups 1 and 2 using both Pearson Chi-square and Fisher exact showed no significant difference in any of the questions asked.

Diabetes Self-Management

Diabetes self-management parameters between intervention groups 1 and 2 were compared using Chi-square and Fischer analysis. The results presented significant findings, as shown in Table 4. Pearson Chi-square analysis of diabetes self-management between Intervention 1 and Intervention 2 using both Chi-square and Fisher presented significant findings in the following questions. The responses ranged from "not confident at all" to "very confident" on a scale of 1 to 5.

Discussion

Data from this study show that there were more female participants (68.42%) than males (31.58%). This is skewed compared to the gender proportion in Jackson City, which is 53.8% females to 46.2% males.[24] However, statistics show that males have a higher proportion of undiagnosed diabetes than females in the United States.[25] The participants comprised 97.37% Black or African Americans, 1.32% Whites,

Table 2. Comparison of Differences in Mean HbA1c Levels Between Groups.

				95% Confidence interval	
	Difference of groups	Difference of means	*P*-value	Lower limit	Upper limit
Turkey HSD	Control–Intervention 1	1.8478*	<0.001	0.696	2.999
	Control–Intervention 2	1.4885*	0.006	0.379	2.594
	Intervention 1–Intervention 2	−0.3613	0.749	−2.99	0.696
Scheffe	Control–Intervention 1	1.8478*	0.001	0.645	3.051
	Control–Intervention 2	1.4885*	0.008	0.329	2.643
	Intervention 1–Intervention 2	−0.3613	0.769	−1.608	0.885

*The mean difference is significant at a 0.05 level of significance.

Table 3. Comparison of Differences HbA1c Levels Within Groups (Baseline, 3-Months, and 6-Months).

				95% Confidence interval	
	Difference of levels	Difference of means	*P*-value	Lower limit	Upper limit
Intervention 1 group (MA)	Baseline–3-months	1.9235*	0.012	0.367	3.400
	Baseline–6-months	3.2135*	<0.001	1.657	4.770
	3-Months–6-months	1.2900	0.140	−0.320	2.900
Intervention 2 group (MA-HC)	Baseline–3-months	2.4087*	<0.001	1.067	3.751
	Baseline–6-months	2.6217*	<0.001	1.280	3.964
	3-Months–6-months	0.2130	0.923	−1.129	1.555

*The mean difference is significant at a 0.05 level of significance.

Table 4. Comparison of Diabetes Self-Management Between Intervention Groups 1 and 2.

#	Question	*P*-value
Q2	How confident are you that you can do the things that are important to manage your diabetes?	0.001
Q3	How important is it to you to manage your diabetes?	0.021
Q23	Helped to plan so I could take care of my condition even in hard times.	0.011
Q26	Referred to another health care professional (my doctor, another member of the health team, etc.).	0.001
Q27	Told how my visits with other types of professionals helped my treatment.	0.008
Q28	Asked how my visits with other professionals were going.	0.023

and 1.32% declined to specify. The ANOVA in means between control, Intervention 1, and Intervention 2 showed no significant difference between the Age, DBP, SBP, and BMI groups at the 0.05 level. Some studies found that the incidence of diabetes increased proportionally with BMI and age [26,27] and another suggests a two-way relationship between diabetes and blood pressure.[28]

While the control group remained unchanged during the 6-month procedure, the mean HbA1c level of Intervention 1 and Intervention 2 groups differed significantly during the 3-month and 6-month periods. It was also observed that the standard deviation of Intervention 2 was much smaller than the standard deviation of Intervention 1. The analysis of the difference in means of HbA1c between the three groups suggests that the educational intervention was effective in reducing the HbA1c levels for up to 3 months but no additional benefit after 3 months. Other studies also found that telehealth education and counseling could enhance glycemic control.[29,30]

The within-group comparison showed that the mean HbA1c levels for intervention group 1, dropped by 18% (from 10.4 to 8.5) after 3 months of using the mobile phone-based app and by 31% after 6 months. There was also a significant reduction in the mean HbA1c levels for intervention group 2 (mobile phone-based app plus telehealth education and counseling) at 3 months by 24% (from 10.2 to 7.8) but a marginal drop from 7.8 to 7.6 at 6 months. This again suggests that the telehealth educational intervention did not have a significant additional impact after 3 months. A recent study comparing telehealth education with in-person education did not find any significant impact on participants' fasting blood sugar and HbA1c levels.[31] Other studies provide evidence that telehealth or mHealth can enhance patient-centered care and self-management of type 2 diabetes.[32,33] Participants with HbA1c levels between 10 and 11.9 experienced the most significant reduction in glucose levels (38.4% and 40.6% reductions after 3 and 6 months, respectively).

A comparison of self-management parameters between Intervention 1 and Intervention 2 showed a modest improvement with the addition of telehealth education and counseling, but many of the more specific questions were not significant. This suggests that the addition of the education consular was not a decisive factor in motivating self-management. Poor self-management and self-efficacy have been shown to have a negative effect on glycemic control.[34] Participants who gained more knowledge of carbohydrate management and glucose monitoring through the Telehealth intervention had better glycemic control and reduced HbA1c levels. This is in line with other studies that found that telehealth educational intervention helped to improve glycemic control, improve self-management, and reduce risk factors.[29,30]

Conclusion

The use of the mobile application did provide a change in the medical habits of the patients in intervention groups 1 and 2 compared to the control group. Participants with Hba1c between 10 and 12 had the highest impact of the intervention, while those between 8 and 10 had the least. This information could be valuable in the future design of targeted interventions.

Declaration of Conflicting Interests

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IRB Approval/Ethics and Safety

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Limitation

This pilot study was limited by its small sample size and gender imbalance.

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