Vietnam Journal of Community Medicine, Vol. 65, English version, 2024, 149-155

EFFECTIVENESS OF TELEHEALTH INTERVENTION ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AT LIEN CHIEU DISTRICT MEDICAL CENTER, DA NANG CITY IN 2023-2024: A NON-RANDOMIZED CONTROLLED INTERVENTION STUDY

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Received: 12/11/2024
Revised: 26/11/2024; Accepted: 06/12/2024

ABSTRACT

Objectives: Global health is witnessing a rapid growth in the number of type 2 diabetes mellitus (T2DM) patients, and a key factor in the prevention and treatment of T2DM is the patient's self-management and medication adherence. Telehealth is an innovative instrument to enhance the healthcare service. This study aims to examine the Telehealth's effect on patients with T2DM at Lien Chieu District Medical Center in Da Nang city.

Methods: A non-randomized controlled intervention study using telehealth to enhance outpatient treatment management of patients with T2DM was conducted. We used YouMed application as an telehealth application.

Results: The telehealth intervention at Lien Chieu District Medical Center in Da Nang city showed significant HbA1c decrease after 3 months and glucose decrease after 6 months, respectively dropping from 6.75% to 6.60% ($p = 0.037$) and from 8.31% to 7.61% ($p < 0.001$).

Conclusion: Telehealth has been shown to be effective in improving glycemic parameters, suggesting the potential for broader application of this intervention method in the care of type 2 diabetes patients. In addition, the integration of many patient support features promises to increase the effectiveness of telehealth.

Keywords: Telehealth, type 2 diabetes mellitus, glycemic control, Lien Chieu District Medical Center.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a rapidly growing global health crisis. In 2021, a staggering 537 million adults aged 20 to 79 were living with the condition. This number is projected to soar to 643 million by 2030, according to alarming data from the International Diabetes Federation [1]. A key component in the prevention and treatment of TD2M is the patient's self-management and adherence to treatment plans. In Vietnam, the management of patients with T2DM is still limited with consultation heavily focused on providing medication instructions, with little attention to helping patients adjust their lifestyle. Since T2DM is a lifestyle-related disease that requires strict routines, monitoring these patients who have this medical condition is therefore essential [2].

Telehealth provides health care, patient education, and self-care support through telecommunications and digital media. There is growing evidence that telehealth can significantly enhance the quality of health care in

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the future, in addition to traditional hospital visits[3]. Currently, the Vietnamese Government is promoting national digital transformation, including the application of information technology in medical examination and treatment facilities, organizing remote consultation and treatment. The 2023 Law on Medical Examination and Treatment allows remote examination and treatment, creating legal conditions for medical facilities to deploy remote medical examination and treatment[4].

After the legal legislations were passed, many health care centers in Vietnam started to implement telehealth care model into their existing infrastructure to improve their services for patients, most notably in Lien Chieu District Medical Center in Da Nang city (LC Center). The LC Center is a part of the primary health care system that plays an important role in screening and providing primary health care for patients. Currently, the Center conducts communication and education activities on diabetes and screening and evaluation of retinal complications [5]. However, the outpatient treatment management of patients with T2DM is limited to monitoring and providing regular medication, which leads to some limitations in patient medication compliance with the treatment plan. Therefore, providing telehealth services is an important addition to the outpatient treatment management of patients with T2DM.

A non-randomized controlled intervention study using telehealth to improve outpatient management of type 2 diabetes at the LC Center is currently being conducted. The study employs the YouMed application (www.youmed.vn), an online health consultation application developed by YouMed Vietnam Co., Ltd., Ho Chi Minh City, Vietnam (YouMed). Through this app, patients will receive regular reminders about medication use and will be continuously monitored for their health status. This paper includes an analysis of the effect of telehealth on glycemic control and hemoglobin A1c levels in patients with T2DM at the LC Center after six months of intervention.

2. SUBJECT AND METHODOLOGY

2.1. Subject

The study focused on Patients with T2DM who are examined and treated as outpatients at the LC Center. Patients were selected based on specific inclusion and exclusion criteria to ensure the study's reliability and relevance.

Inclusion criteria: patients aged 18 or older, diagnosed with T2DM for at least one year at the start of the study, came for examination and have glycemic test (HbA1c and blood glucose) at the time of the study.

Exclusion criteria: patients with severe or unstable co-morbidities that could interfere with study participation or outcomes (e.g., active cancer, myocardial infarction).

2.2. Research time

Patient data were started collecting from October 2023 at the outpatient medical examination registration room of the LC Center until the minimum sample size was reached in January 2024. The intervention phase lasted six months, allowing for a strong evaluation of outcomes related to glycemic control.

2.3. Study design

A non-randomized controlled intervention study was used to assess the outpatient telehealth care model in improving paraclinical indicators glycemic of patients with T2DM at the LC Center. Glycemic control was assessed through two primary parameters: blood glucose level (mmol/l) and HbA1c (%).

2.4. Sample size

The study chose HbA1c as the main criteria to evaluate the intervention results because this is the desired result to change to achieve the management and treatment goals. HbA1c <7% is considered good glycemic control, so the improvement in the proportion of patients with good glycemic control was used to calculate the sample size [1].

The sample size calculation formula in non-RCT design research with equivalent intervention and control groups is used as follows:

$$n = 2 \times \left\{ \frac{Z_{1-\alpha/2} + Z_{1-\beta}}{\sigma_0} \right\}^2 \times p(1 - p)$$

n: Sample size (number of patients in each group: intervention and control).

$Z_{1-\alpha/2}$=1.96 value from the normal distribution, calculated based on the probability of type 1 error (probability of type 1 error = 5% and 2-sided test).

$Z_{1-\beta}$: = 1.28: the value is calculated based on a statistical power of 90%.

p: response rate, expected p = 0.90.

σ: clinically acceptable margin with the expected difference between the two groups is 0.13. Expectations based on eligible clinical trials of the effectiveness of self-management education in T2DM patients ranged -0.63% – 3.17% for non-RCTs studies.

Substitute the numbers into the formula to get the minimum sample size of patients managed by telehealth n = 112. The control group and the intervention group were selected with a ratio of 1:1, which is 112 : 112. Thus, the required sample size is 224 patients. As a result, 230 patients participated in the study, the control group and the intervention group with a ratio of 1:1 as 115 : 115.

2.5. Sampling method

Patient recruitment began in October 2023 at the outpatient registration desk of the Lien Chieu Health Center and continued until the target sample size was achieved.

After patients are registered, doctors at the LC Center will cross-check with the sample selection criteria. The doctor will explain to patients about the study and invite them to participate. If the patient agrees to participate, he/she will sign the research consent form and draw one of 2 sealed envelopes (numbered 1 or 2). Patients drawn number 1 were selected to be in the intervention group, patients drawn number 2 were selected as the control group (not mentioned in this study).

2.6. Intervention activities

A plan was implemented at LC District Medical Center to strengthen outpatient management for T2DM patients, including establishing a Telehealth Consulting Room, promoting education, and training medical staff. Technical facilities and telehealth systems were provided by YouMed Vietnam (Business registration number 0315268642). The YouMed application offered features such as booking consultations, telemedicine, medication reminders, and health tips, enhancing patient care and supporting outpatient treatment management.

To guide the intervention effectively, a structured process was developed for managing T2DM via the YouMed app. Patients received consultations at least twice a month, with doctors maintaining regular communication through messages. The app sent reminders for medication schedules, supplementing treatment management without replacing Ministry of Health guidelines. Telehealth services were free and did not affect Health Insurance policies.

The process involved collaboration among the Telehealth Executive Board, doctors, and patients. The Board oversaw strategies, operations, and remote diabetes management procedures. Doctors participated in training, developed processes, managed treatments, and conducted surveys after consultations. Patients received telehealth training, participated actively in treatment management, and completed surveys as part of their care.

Eligible patients enrolled, downloaded the app, completed online forms, and submitted their blood sugar readings after monitoring. The app allowed patients to book consultations or contact doctors for immediate assistance. During scheduled consultations, doctors reviewed blood sugar results and recorded data for research.

Intervention activities included app installation, video call appointments, chat-based communication, medication reminders, and notifications for health tips and T2DM updates, enhancing remote management and patient support.

2.7. Data collection method

After 6 months of intervention, investigators conducted interviews using a predefined set of questions and extracted clinical data through the healthcare facility's management software.

2.8. Data analysis

The collected data was entered using Epidata software, and statistical analysis was performed using SPSS version 16.0. A 10% random sample of forms was checked for accuracy. Descriptive statistics included count, percentage, mean, median, Q1 - Q3. In terms of analytical statistics, we used a Chi-square test to compare the overall characteristics of the intervention and control groups. To analyze HbA1c and glucose levels at three different time points without assuming a normal distribution, we applied the Mann-Whitney U test to compare the two groups. For the changes in HbA1c and glucose levels before and after the intervention, we checked for normal distribution of the differences between baseline and 3-month, and baseline and 6-month follow-up. Since the differences were normally distributed, we used a paired t-test for analysis. Statistical significance was set at $p \leq 0.05$.

2.9. Outcome variables

HbA1c: This variable shows the average blood glucose level over the past three months. In our study, HbA1c values were evaluated at baseline, after 3 months, and after 6 months of intervention. This is considered as an important indicator to evaluate the effectiveness of diabetes management.

Blood glucose level: This variable measures the current blood glucose level. Blood glucose levels were monitored at baseline, after 3 months, and after 6 months. The comparisons between two groups help to evaluate short-term glycemic control and the overall impact of the intervention on the outcomes.

2.10. Research ethics

The research received ethical approval from the Ethics Committee of Biomedical Research, Hanoi University of Public Health, under approval document No. 415/2023/YTCC-HĐ3 dated September 28, 2023. All participants voluntarily joined the study after being fully informed about the study's objectives and procedures.

3. RESULTS

The subject distribution of patients based on intervention time is shown in Figure 1. After 3 months, there were more patients from the intervention group who lost followed-up. Meanwhile, the lost followed-up patients in the control group surpassed that in the other group after 6 months.

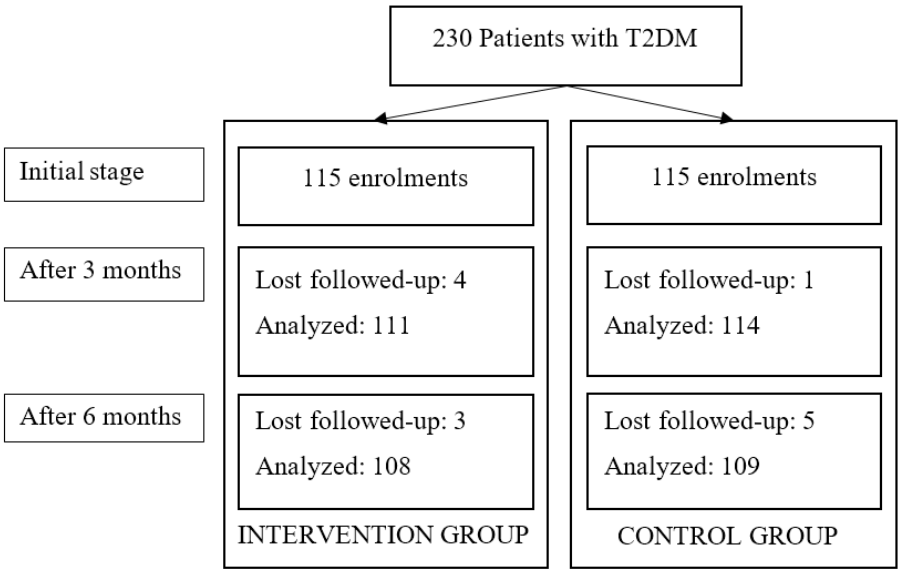

Figure 1. Distribution of subjects in study groups based on intervention time

The patients in this study were selected from the participants in our previous research, which was published in the Vietnam Journal of Preventive Medicine [6]. Of the 230 study participants, the response rate at 6 months was 94.3%. Demographic for the intervention group (n = 115) and the control group (n = 115) are given in Table 1. There was a higher number of patients under 60, and the total number of females was exceeding the male figure.

Table 1. General characteristics of the research subjects

	Intervention group (n = 115)		Control group (n = 115)		p
	n	%	n	%	
Age					
< 60	82	52.6	74	47.4	0.259*
≥ 60	33	44.6	41	55.4	
Gender					
Male	51	47.2	57	52.8	0.428*
Female	64	52.5	58	47.5	

*Note: *Chi-square test results*

There was similarity in age and gender characteristics in both intervention and control groups with p > 0.05.

In order to ensure the intervention was successful, two meetings as professional exchanges were held at the Medical Center with the participation of many doctors and healthcare staff. In addition, personnel and resources were invested to support patients with T2DM to install and use the application, as well as provide advice on medication use and health issues. A Telehealth Consultation Room was set up at the LC Center's non-communicable disease clinic, enabling patients to seek help. The program also provided 250 YouMed user guides for patients and 15 for healthcare workers, conducted multiple patient-doctor consultations via the app, and shared hundreds of notifications related to news and treatment reminders every week. In addition, more than 1,000 messages were exchanged between the intervention group and doctors. Additionally, all services that patients received were completely uncharged. There were only few errors caused by application that happened, which were related to the inaccurate information of patients and unable to login error.

Comparison of the differences in glucose and HbA1c between the intervention and control groups before and after the intervention based on time is presented in the following tables:

Table 2. Comparison of glucose in the intervention group and the control group

Glucose (mmol/L)	Intervention group	Control group	p
Baseline	7.7 (6.8 – 9.1)*	7.3 (6.3 – 9.1)*	0.312**
After 3 months	7.5 (6.45 – 8.8)*	7.9 (6.1 – 9.5)*	0.526**
After 6 months	7.5 (6.6 – 8.5)*	7.6 (6.6 – 9.0)*	0.404**

*Note: *Median (Q1-Q3), **Mann-Whitney U test results*

Table 2 shows that the glucose in the intervention group and the control group did not differ between the intervention group and the control group. After 6 months, the glucose after 6 months in the intervention group 7.5 (6.6 – 8.5) was lower than that in the control group 7.6 (6.6 – 9.0), but there was no statistical significance p > 0.05.

Table 3. Comparison of HbA1c in the intervention group and the control group

HbA1c (%)	Intervention group	Control group	p
Baseline	6.3 (5.4 – 7.45)*	6.5 (5.4 – 7.7)*	0.851**
After 3 months	6.35 (5.55 – 7.15)*	6.5 (5.6 – 7.8)*	0.431**
After 6 months	6.25 (6.0 – 7.2)*	6.9 (6.1 – 8.1)*	0.009**

*Note: *Median (Q1-Q3), **Mann-Whitney U test results*

Table 3 shows that the HbA1c in the intervention group 6.25 (6.0 – 7.2) was lower than that in the control group 6.9 (6.1 – 8.1) after 6 months, $p < 0.05$. There was no difference in the HbA1c between the intervention group and the control group after 3 months of intervention, $p > 0.05$.

The following tables present the changes in HbA1c and glucose in the intervention group after 3 months and 6 months:

Table 4. HbA1c and glucose before and after intervention in the intervention group after 3 months (n=111)

Baseline	After 3 months	Difference	95% CI	p
HbA1c (%)				
6.75±1.71*	6.60±1.32*	0.15±0.74*	0.01- 0.29	0.037**
Glucose				
8.31±2.25*	7.81±1.77*	0.51±2.10*	0.11 - 0.90	0.013**

*Note: *Mean ± standard deviation, **Paired t-test result from analysis the differences between baseline and 6-month follow-up*

Table 4 shows that HbA1c decreased by 0.15 ± 0.74% before and after intervention in the intervention group after 3 months, statistically significant $p = 0.037$. Similarly, glucose decreased by 0.51 ± 2.10 before and after intervention in the intervention group after 3 months, statistically significant $p = 0.013$.

Table 5. HbA1c, glucose before and after intervention in the intervention group after 6 months (n=108)

Baseline	After 6 months	Difference	95% CI	p
HbA1c (%)				
6.78±1.73*	6.65±1.03*	0.13±0.95*	-0.05-0.31	0.155**
Glucose				
8.31±2.27*	7.61±1.40*	0.70±1.90*	0.34 - 1.07	<0.001**

*Note: *Mean ± standard deviation, **Paired t-test result from analysis the differences between baseline and 6-month follow-up*

Table 5 shows that HbA1c decreased by 0.13 ± 0.95% before and after intervention in the intervention group after 6 months, but there was no statistical significance $p = 0.155$. Glucose index decreased by 0.70 ± 1.90 before and after intervention in the intervention group after 6 months, there was statistical significance $p < 0.001$.

4. DISCUSSION

Most individuals with high HbA1c and blood glucose levels initially showed improvement in subsequent measurements. These improvements were attributed to the effort of the Medical Center in timely diagnosis, treatment initiation, primary care measures, and patient adherence to medication. Some patients experienced significant fluctuations in blood glucose levels between measurements, potentially due to diagnostic errors, dietary changes, health incidents, lack of sleep, new treatments, or inconsistent testing times [7].

The novelty of our study is the use of a Telehealth application that integrates many functions to control, remind re-examination, and ex change disease information by texting or calling. Similarly to a study of Myers et al. (2021), which combined multiple features and devices for optimal intervention effectiveness [8]. They provided a Samsung tablet with 4G LTE connectivity and wireless Bluetooth devices, including a blood pressure monitor, scale, and pulse oximeter. Their research compared the effectiveness of managing patients via Telehealth versus phone, with both methods improving HbA1c (Telehealth: -2.07 ± 1.99; Telephone: -2.57 ± 2.44). Although the improvement via phone was higher, patients using Telehealth demonstrated greater initiative by updating their metrics at home with provided devices.

The telehealth intervention at the LC Center resulted in improvements in key outcomes such as HbA1c and blood sugar levels. HbA1c, an important indicator of diabetes management, decreased in the intervention group from 6.75 ± 1.71% to 6.60 ± 1.32% after 3 months, which was only recorded as statistically significant ($p = 0.037$) in the decrease of HbA1c. The non-statistical significant decrease after 6 months may be due to reaching a stable threshold, reduced compliance, or the influence of external factors, slowing down the initial improvement. In addition, the reason may be that telehealth did not have a significant additional impact after 3 months, which was similarly recorded in the study by Onyia et al. (2023) [9].

Meanwhile, glucose values in the intervention group improved remarkably, decreasing from 8.31 ± 2.27% to 7.80 ± 1.77% after 3 months ($p = 0.013$), and further to 7.61 ± 1.40% ($p < 0.001$), which is higher than the results of Sotomayor et al. (2024), where the control group received daily glucose monitoring devices and smart insulin pens but showed no significant glucose improvement [10]. Overall, it is evident that providing

patients with a multifaceted intervention has the potential to lead to better outcomes in blood glucose management, but the implementation of the intervention is extremely important, and the Center has done a good job in contributing to ensuring the effectiveness of telehealth.

The results show that telehealth has the potential to improve the quality of care and delivery. These interventions not only improve the quality of care but also improve patient satisfaction, increase accessibility and support healthcare professionals in monitoring and managing patients more effectively [9, 10]. Evidence suggests that there is an opportunity to expand telehealth models such as YouMed to more healthcare facilities. However, to ensure the effectiveness of telehealth, potential risks need to be considered [11]. One of the biggest risks is data security and safety, as personal health information is now at high risk of being leaked. Challenges related to technology infrastructure also need to be carefully considered, especially in rural or remote areas where Internet connections are unstable and there is a lack of suitable equipment. In addition, issues of healthcare staffing, skills, and affordability need to be considered. Addressing these risks requires coordinated efforts across multiple technology, policy, and resource areas to ensure effective and sustainable telehealth deployment.

This study's limitations include the inability to assess additional clinical indicators beyond those reported due to factors such as time and resource constraints. Furthermore, patient test results were inconsistent between measurements, partly due to significant variability in results for some patients and inconsistent time between measurements. Finally, the changes in HbA1c and glucose levels in this study were not very pronounced due to many related factors such as study design, initial HbA1c levels close to the acceptable range, compliance, and participant factors. These factors somewhat affect the accuracy and consistency of the research findings, limiting the generalizability of the conclusions drawn from the study.

5. CONCLUSION

This study has indicated the effectiveness of remote outpatient management for patients with T2DM through telehealth application, contributing to improved glycemic indices and increased treatment adherence. However, some limitations were noted, including the inability to assess additional clinical indicators and inconsistencies in measurement results across testing sessions. Despite these challenges, the positive outcomes demonstrate the significant potential of healthcare technology in supporting chronic disease management, especially in resource-limited settings.

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