Original Article

Is Web-Based Program Effective on Self-Care Behaviors and Glycated Hemoglobin in Patients with Type 2 Diabetes: A Randomized Controlled Trial

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Abstract

Background: Diabetes Self-Management Education and Support (DSMES) as a framework focuses on seven self-care behaviors. Moreover, technology-assisted self-care education is increasingly suggested for patients with Type 2 Diabetes Mellitus (T2DM). Therefore, we examined the effect of a web-based program on self-care behaviors and glycated hemoglobin values in patients with diabetes mellitus. **Materials and Methods:** This randomized controlled clinical trial was conducted at Alzahra Hospital in Isfahan, Iran, between April and November 2020 and included 70 patients with T2DM. Data were collected using a questionnaire that included a demographic information section and a diabetes self-management section with 21 questions on a Likert scale. Fasting blood samples (2.50 ml) were collected before and after the interventions to measure HbA1c levels. The study intervention involved a web-based program that included multimedia educational content (such as videos, lectures, educational motion graphics, text files, posters, and podcasts) presented in seven sections based on DSMES over a 21-day period with monitoring by an instructor. **Results:** The mean scores for healthy eating ($F = 3.48$, $p = 0.034$) and medication adherence ($F = 6.70$, $p < 0.001$) significantly increased in the interventional group, while the mean scores for being active, monitoring, reducing risks, problem-solving, and healthy coping did not significantly change. Additionally, the mean differences in HbA1c values significantly improved in the interventional group compared to the control ($F = 5{,}1$, $p = 0.026$). **Conclusions:** A web-based program in accordance with DSMES improved HbA1c levels and increased scores for healthy eating and medication adherence in patients with T2DM. However, further research with larger sample sizes and qualitative interviews is needed.

Keywords: *Diabetes mellitus, education, glycated hemoglobin, self-care, type 2, web browser*

Introduction

Internationally, over six hundred million people aged 20–79 will be affected by Type 2 Diabetes Mellitus (T2DM) by 2045.[1] T2DM can significantly decrease both life expectancy and quality of life for diabetics while also causing economic and societal problems.[2] In response, Diabetes Self-Management Education and Support (DSMES) has emerged as a framework for improving patient outcomes. DSMES focuses on seven key self-care behaviors, including healthy coping, healthy eating, being active, medication adherence, monitoring, reducing risks, and problem solving. By providing ongoing training and support, DSMES helps patients improve their self-efficacy and ability to set and achieve personal self-management goals, leading to better health outcomes and reduced medical costs. Additionally, DSMES is a patient-centered approach that has been shown to improve treatment adherence in patients with T2DM.[3,4]

On the other hand, technology-assisted self-care education is increasingly being recommended for patients with long-term illnesses such as diabetes, but it remains unclear whether it leads to improved self-care compared to non-technology-based interventions.[5] A systematic review of technology-enabled diabetes self-management programs found that 18 of 25 reviews reported reduced levels of Glycated Hemoglobin (HbA1c), which is a sensitive and practical glycemic index for many non-pregnant adults with T2DM.[6,7] Another systematic review and meta-analysis concluded that digital-based

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DSMES can be influential in reducing HbA1c and improving knowledge in T2DM.[8] Moreover, studies have shown that providing DSMES through web-based programs may improve coverage and provide convenient treatment for patients, especially during the COVID-19 pandemic.[9,10] However, web-based programs are often underutilized in diabetes management, and previous studies have focused more on medication adherence than self-management education.[11-15] There are even fewer published studies covering the impact of mobile app-based trials, and most interventions have examined the effect of short messages on adherence to treatment in diabetic patients.[16] Additionally, none of the 25 interventions included in the previously mentioned systematic review reported a positive effect on all DSMES components (the seven self-care behaviors), and there was no significant change in health-related quality of life in another systematic review.[8] Therefore, this study aims to examine the effect of a web-based program on self-care behaviors and HbA1c in patients with type 2 diabetes during the COVID-19 pandemic.

Materials and Methods

This Randomized Controlled Trial (RCT) with registration number IRCT20190806044449N1 was conducted at Alzahra Hospital in Isfahan, Iran, between April and November 2020. Persian-speaking patients who had been under the supervision of a specialist physician for at least one year prior to admission were included, provided they were able to install the relevant program (Internet browser) on their smartphones and had a main caregiver.[17] Other criteria included attending the training program at least once per month, giving written consent, and being able to use a glucometer at home. Exclusion criteria comprised chronic complications of diabetes such as nephropathy, proliferative retinopathy, amputation, mental retardation, or psychological disorders. A disease duration of more than 30 years and a lack of caregivers were also exclusion criteria. Individuals who had not viewed the content within 21 days were to be replaced by another person. The duration of training was 3 months.[18] The main caregiver was included if their age range was 18–50 years and if they were literate, able to use a mobile phone, and able to care for the patient. Considering $Z\ 1\text{-}\alpha/2 = 1.96$, $Z\ 1\text{-}\beta = 0.84$, $d = S = 0.7$ (estimation of the average standard deviation of each of the variables in the two groups), the sample size was estimated to be at least 32 in each group. With an attrition rate of 10%, 35 patients were enrolled. D represented the minimum difference between the means of each variable in the two groups, indicating a significant difference.[19] The data collection tool was a questionnaire that included a researcher-made section with 15 questions related to demographic information, such as age, education, duration of disease, sex, marital status, occupation, economic status, family history of diabetes, type of medical strategy, and smoking. Another section was a diabetes self-management questionnaire, comprising 21 questions with a Likert scale (true for me, partially true for me, partially not true for me, and not true for me). The validity and reliability of the 21-item questionnaire had previously been determined by Torki *et al*.,[20] but we assessed its Cronbach's alpha again and found it to be 0.81, indicating adequate internal consistency. The face validity of the two questionnaire sections was approved by two nursing faculty specializing in psychiatric care, four nursing faculty specializing in diabetes care, two super-specialists in diabetes, and one diabetic education nurse. To increase clarity, unclear items and slight wording mistakes were modified.

Questions 2, 4, and 10 related to healthy eating; questions 7 and 13 focused on being active; questions 3, 6, and 15 pertained to medication adherence; questions 1, 9, 12, and 16 related to monitoring; question 18 assessed smoking habits; and questions 5, 8, 11, 14, 17, and 20 evaluated foot care practices. Additionally, question 19 was related to problem solving, while question 21 measured healthy coping. The minimum score on the questionnaire was 0, while the maximum score was 63.

In this study, fasting blood samples (2.5 ml) were collected before and after the interventions in the Alzahra clinical laboratory to measure glycosylated hemoglobin levels using high-performance liquid chromatography with the Sebia Capillarys 2 electrophoresis system. The patients with inclusion criteria were selected by a diabetic-trained nurse from the list of patients at Al-Zahra Hospital through a lottery method. The study goals were explained during a phone call to the patients, and those who expressed their willingness to participate were invited to the hospital, while unwilling patients were replaced with others. After the participants, along with their main caregiver, were present, they completed the written consent form and were randomly assigned to either the experimental or control group using random numbers. Each person was assigned a number and was randomly assigned to a group by taking numbers out of a bag by an unknown person. All participants completed the demographic and diabetes self-management questionnaires, and their HbA1c was measured.

In the intervention, the website password was set up on the patient's and the main caregiver's smartphones, and the researcher instructed them on how to use it effectively. The program was accessible through any browser on a tablet, computer, or phone, and participants agreed to watch videos and training contents within 21 days.[21] The researcher, a diabetic-trained nurse, also answered questions at specific times per day. The program's educational content was monitored regularly to ensure patients and caregivers viewed the files, and the researcher contacted patients every 3 days to remove any obstacles if the programs were not observed. The control group was given educational pamphlets and asked to return 3 weeks later. After 21 days to 3 months, the intervention group could use the program at any time and place.

Immediately after the educational intervention, the researcher asked all participants in both groups to complete a self-management questionnaire, and they were invited to the health education office on their next referral date (3 months later) to complete two more sections of the questionnaire and to have their HbA1c levels determined. Once logged in, the program provided permanent access for people to use and watch the program as many times as they wanted and to ask questions. The software was also designed to allow for questions and answers[22] [see Figure 1].

Web-based training: Through the website, multimedia educational content (including videos, lecturers' lectures, educational motion graphics, text files, educational posters, and podcasts) was provided in seven sections based on the seven main parts of DSMES[3] as well as input from the authors and the aforementioned specialists, taking into account cultural, religious, and moral considerations of the community. Patients were constantly monitored by educators as they followed the program through the website and were required to answer questions at the end of each program to continue to the next one. The maximum time allowed to view all the educational content was 21 days,[22] and if participants had not viewed the programs for more than 3 days, a reminder phone call was made to them [Figure 1].

Ethical considerations

The present study was approved by the ethics committee of Isfahan University of Medical Sciences with the code IR.MUI.RESEARCH.REC.1398.493. All participants provided written consent forms. Participants in the control group were provided with educational pamphlets, and at

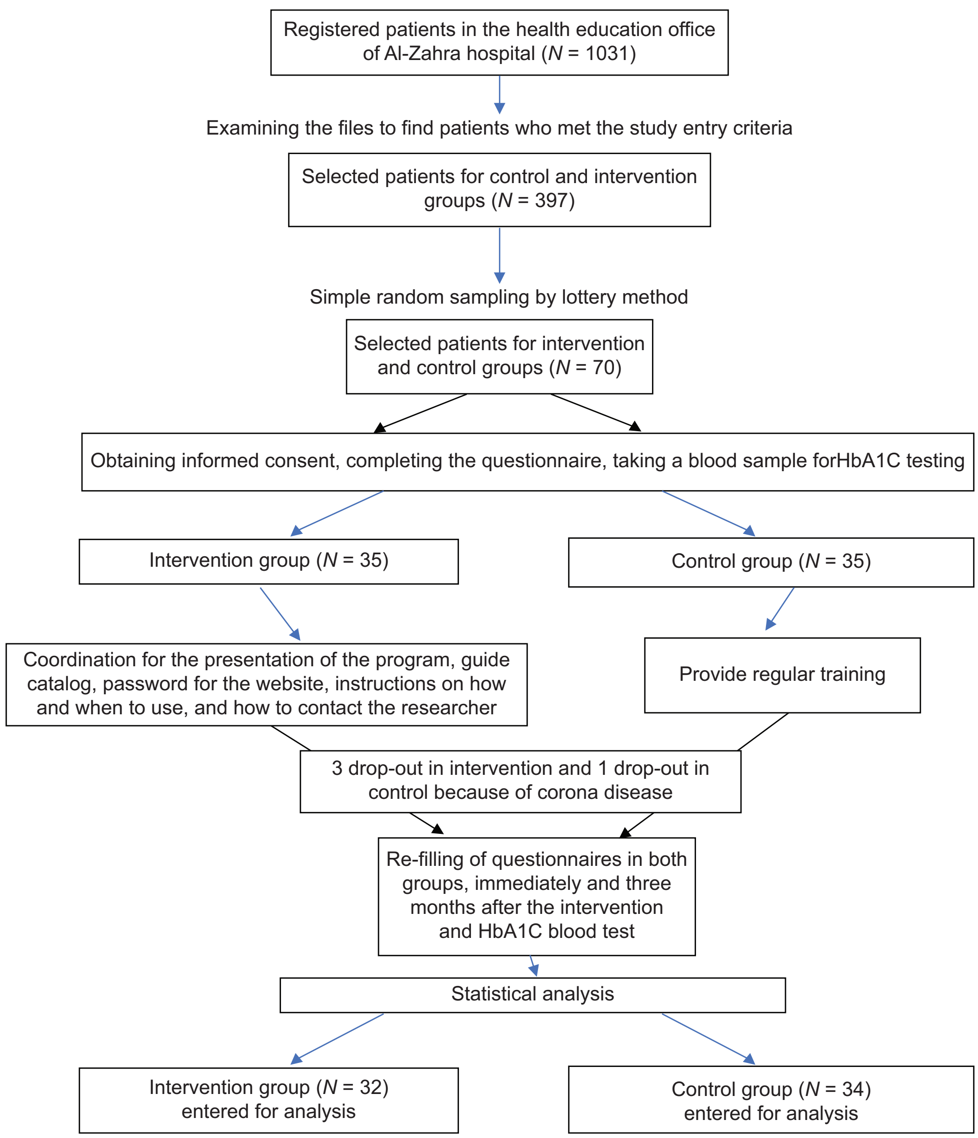

Figure 1: CONSORT trial flow diagram for patients who were recruited

the end of the intervention, the researcher gave them a password and a catalog for future use.

Results

The data were analyzed using SPSS 20 statistical software (IBM Corp., Armonk, NY, USA) by a statistician who was not involved in the study. Basal characteristics of the participants in the two groups were compared using independent t-tests and Chi-square tests to ensure homogeneity, which was not significantly different [Table 1]. The mean scores for healthy coping, healthy eating, physical activity, medication adherence, monitoring, risk reduction, and problem-solving were analyzed by analysis of variance with repeated measurements at three different time points (before, immediately after, and three months after the intervention). The mean differences in HbA1c values between the two groups were compared using an independent *t*-test [Table 2]. After the intervention, the mean scores for healthy eating and medication adherence significantly increased in the intervention group, while the mean scores for physical activity, monitoring, risk reduction, problem-solving, and healthy coping did not significantly differ after the intervention. Additionally, the mean differences in HbA1c values significantly decreased in the intervention group compared to the control group [Table 2].

Discussion

Our web-based program, in accordance with DSMES, proved effective in improving healthy eating and medication behaviors as well as reducing HbA1c levels in T2DM patients. Increasing medication adherence scores is in line with Chao *et al*.'s[23] and Vluggen *et al*.'s[24] trials that enhanced overall treatment obedience compared with control. Likewise, two other meta-analyses showed positive effects of short message services on medication adherence in T2DM.[8,25] However, another trial aimed at medication adherence observed no evidence of improvements.[26] Accurate and complete training of patients, telephone follow-up to accept the treatment, and full explanation and observation of the correct way of injecting the drug helped to eliminate the fears when using the computer program.

Also, this intervention promoted healthy eating, which is consistent with a study in China in which most participants

Table 1: Comparison of the participants' basal characteristics between the two groups

Participants' characteristics	Mean (SD)		df	*p**
	Intervention (*n*=32)	Control (*n*=32)		
Age (Years)	55.93 (10.97)	61.09 (9.37)	59	0.052
Education (Years)	8.73 (4.52)	7.77 (5.65)	51	0.502
Duration of illness (Years)	10.83 (7.34)	11.12 (7.21)	60	0.875
Sex (Female and Male)	1.60 (0.50)	1.53 (0.51)	60	0.593
Marital status (Single, Married, and Divorced)	2.00 (0.27)	2.06 (0.44)	59	0.507
Economic status (Poor, Medium, and Good)	2.63 (0.85)	2.84 (1.02)	60	0.383
Family history (Yes and No)	1.31 (0.47)	1.25 (0.44)	59	0.607
Medical strategy (Oral, Injection, and Both)	1.93 (0.98)	1.77 (0.76)	59	0.481
Smoking (Yes and No)	1.07 (0.25)	1.09 (0.30)	60	0.701

Table 2: Comparison of self-care behaviors and glycosylated hemoglobin

Self-care behaviors	Intervention (*n*=32)			Control (*n*=32)			Mean scores during three times		Mean scores between two groups	
	Before intervention Mean (SD)	After intervention Mean (SD)	3 months after the intervention Mean (SD)	Before intervention Mean (SD)	After Intervention Mean (SD)	3 months after the intervention Mean (SD)	*F*	*p*	*F*	*p*
Healthy coping	31.30 (1.43)	39.73 (1.29)	40.73 (1.36)	34.34 (1.38)	37.34 (1.25)	41.37 (1.32)	2.66	0.074	25.57	<0.001
Healthy eating	4.53 (0.36)	6.32 (0.32)	6.14 (0.31)	4.93 (0.35)	5.20 (0.31)	6.23 (0.30)	3.48	0.034	12.03	<0.001
Being active	2.62 (0.24)	3.34 (0.23)	2.96 (0.25)	2.80 (0.23)	2.77 (0.23)	3.00 (0.24)	2.07	0.135	1.26	0.292
Medication adherence	4.06 (0.33)	5.10 (0.34)	7.06 (0.34)	5.00 (0.33)	5.23 (0.34)	5.63 (0.34)	6.70	<0.001	15.72	<0.001
Glucose monitoring	6.20 (0.41)	6.55 (0.41)	7.55 (0.32)	5.96 (0.41)	6.13 (0.41)	6.89 (0.32)	0.34	0.709	11.98	<0.001
Reducing risks	11.57 (0.85)	15.50 (0.88)	16.42 (1.16)	12.92 (0.82)	14.50 (0.84)	17.75 (1.11)	2.06	0.138	22.66	<0.001
Problem-solving	1.23 (0.21)	1.40 (0.22)	1.20 (0.22)	1.34 (0.20)	1.34 (0.21)	1.4790.22)	0.12	0.891	0.44	0.645
Clinical outcome		**Intervention**			**Control**		**df**		**p**	
Glycated hemoglobin		-0.99 (1.01)			-0.26 (1.43)		57.86		0.026	

enhanced their attention to healthy eating after using a mobile app.[23] Similarly, a web-based, computer-tailored, multifaceted intervention increased healthy eating behaviors and subsequently decreased caloric intake from unhealthy snacks.[24] It seems that the novelty of the educational content, the accurate assessment of health-threatening risks, and personal feedback are the reasons for achieving success in this dimension of DSMES.

The mean differences in HbA1c values were significantly lower after intervention, which is consistent with a meta-analysis of 39 studies involving 6861 participants, which concluded that digital health-led DSMES are effective in improving HbA1c, especially when patients use mobile apps or portals. It seems that glucose monitoring and dose management have played a more important role in improving HbA1c than other factors.[8] In our study, both healthy eating and medication adherence scores increased significantly, and it is likely that both of these factors have contributed to the improvement in HbA1c levels.

There were no significant differences in scores of other behaviors (being active, monitoring, reducing risks, and problem-solving) between the two groups. It is common to observe no significant effects on physical activity scores after digital-based interventions.[27] This could be due to unreliable estimations of physical activity levels. However, the use of modern technology, such as accelerometers, may help overcome this barrier in the future.[28] Low levels of self-efficacy, improper goal setting, lack or inadequacy of facilities, inadequacy of family/social support, and insufficient attention to the details of cultural characteristics are other reasons. Additionally, the living environment, such as buildings, safe places to walk, and green spaces, also plays a crucial role in determining the ability and enthusiasm to be regularly active.[29]

The mean scores of behaviors, including healthy coping, monitoring, reducing risks, and problem-solving, were not significantly different between the two groups. In our opinion, the lack of a significant difference in these behaviors after the intervention is due to the fact that the control group also improved their behaviors after becoming familiar with DSMES items through the questionnaire [Table 2]. Additionally, Ye *et al*.[30] concluded that few apps presented aspects related to problem-solving. Fitzpatrick *et al*.[31] showed 36% of interventions performed in adults indicated significant improvement in HbA1c, and future problem-solving interventions should have enough strength and intensity to bring about the necessary changes in the factors that determine the treatment.

Problem-solving has been described as an educational topic, a therapeutic method, or a process that requires a support group. Therefore, designing problem-solving trials is an important contradiction that is difficult to resolve.[31] Our obtained result about reducing risks and healthy coping behavior is consistent with Ye *et al*.[30] and Alaofè *et al*.'s[32] studies. These two behaviors are often modified by direct interaction with diabetes instructors instead of web-based communication,[33] as confirmed by our educator.

It is hard to include qualitative information into web-based programs, as these programs have been designed for quantitative data such as insulin doses and plasma glucose values.[30] Additionally, managing emotional needs and human interactions through technology-based education might be difficult, and face-to-face interaction or group support may be more practical and effective methods to cope with stress compared to a mobile app.[34] For instance, a conversation between a patient and a physician is needed for the physician to present a professional solution for the patient to quit smoking.[35] Furthermore, patients with diabetes may prefer other effective and more convenient ways, such as searching on Google, instead of using web-based training for problem-solving, reducing risks, and healthy coping.[30]

This trial presents a practical strategy for promoting self-management behaviors in patients with T2DM and was conducted during the Corona pandemic. Additionally, our educational intervention can be used by software designers to develop a mobile app for self-care for diabetics. However, the sample size was small, and further work is needed to explore how physical activity levels could be improved or sustained through web-based interventions. Also, more research is needed to determine why web-based interventions have such a limited effect on behaviors such as reducing risks, problem-solving, and healthy coping scores. For example, qualitative interviews seem necessary to investigate the reasons for failure in depth. The reasons mentioned in the discussion section can be used for specific and effective practical plans.

Conclusion

The web-based program, in accordance with DSMES, improved HbA1c levels in patients with T2DM and also led to significant improvements in healthy eating and medication adherence scores. However, further research with larger sample sizes and qualitative interviews is needed to investigate the reasons behind the lack of significant improvements in other self-care behaviors.

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Conflicts of interest

Nothing to declare.

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