

Clinical Impact of Personalized Physician Education and Remote Feedback via a Digital Platform on Glycemic Control in Diabetes : A Pilot Randomized Controlled Trial

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Abstract

Background: The Digital Education platform, Doctorvice? (iKooB Inc., Seoul, South Korea), offers both physicians' face-to-face education and remote glucose monitoring, which is expected to be effective for personalized diabetes care.

Objective: To evaluate the effectiveness of the digital education platform for diabetes care and compare cases where both face-to-face education and remote monitoring were provided with cases where only education was provided.

Methods: Sixty-six patients with type 2 diabetes mellitus who visited the Diabetes Center of Seoul St. Mary's Hospital were enrolled in this randomized clinical study. Participants were aged ≥ 19 years and had hemoglobin A1C (HbA1C) levels of 7.5–9.5%. Of the 66 participants, 26 in the intervention group and 30 in the control group were analyzed, excluding 10 who dropped out of the study. In the intervention group, physicians used the digital education platform to provide face-to-face education at enrollment and at the 3- and 6-month visits, along with remote monitoring during the first 3 months of the 6-month study period. The control group received conventional outpatient education. The primary endpoint was the change in the HbA1c levels.

Results: The baseline HbA1c levels were $8.3 \pm 0.6\%$ in the intervention group and $8.0 \pm 0.5\%$ in the control group. At the 3-month follow-up, HbA1c decreased by 0.5% to $7.8 \pm 0.9\%$ ($P = .010$) in the intervention group and by 0.2% to $7.8 \pm 0.7\%$ in the control group. HbA1c levels significantly improved during the first 3 months with both face-to-face education and remote glucose monitoring; however, HbA1c tended to increase without the remote monitoring service during the 3 to 6-month follow-up in the intervention group. Subgroup analysis indicated that the effect of reducing HbA1c was greater for patients with baseline HbA1c levels $\geq 8.0\%$, those aged ≥ 65 years, smokers, drinkers, and those with obesity in the intervention group.

Conclusions: The digital education platform for personalized diabetes management appears beneficial for glycemic control in type 2 diabetes mellitus. It was especially effective when physicians provided personalized face-to-face education and remote feedback together. Clinical Trial: KCT0007953

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Original Manuscript

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Clinical Impact of Personalized Physician's Education and Remote Feedback via a Digital Platform on Glycemic Control: A Pilot Randomized Controlled Trial

Abstract

Background: The Digital Education platform, Doctorvice® (iKooB Inc., Seoul, South Korea), offers face-to-face physician-patient education during outpatient clinic, remote glucose monitoring, and educational messages sent, which is expected to be effective for personalized diabetes care.

Objective: To evaluate the effectiveness of the digital education platform for diabetes care and compare cases where both face-to-face education and remote monitoring were provided with cases where only face-to-face education was provided.

Methods: This was a randomized clinical study (Trial registration : KCT0007953) conducted at the Diabetes Center of Seoul St. Mary's Hospital. Participants were aged ≥ 19 years and had hemoglobin A1C (HbA1C) levels of 7.5–9.5%. In the intervention group, physicians used the digital education platform to provide face-to-face education at enrollment and at the 3- and 6-month visits, along with remote monitoring during the first 3 months of the 6-month study period. The control group received conventional outpatient education. Both groups completed questionnaires (satisfaction with diabetes treatment, diabetes stress measurement, and adherence of diabetes medication) at the beginning and end of the study. The primary endpoint was the change in the HbA1c levels.

Results: Total 66 participants were enrolled between August 1, 2022 and August 31, 2023. Of the 66 participants, 26 in the intervention group and 30 in the control group were analyzed, excluding 10 who dropped out of the study.

The baseline HbA1c levels were $8.3 \pm 0.6\%$ in the intervention group and $8.0 \pm 0.5\%$ in the control group. At the 3-month follow-up, HbA1c decreased by 0.5% to $7.8 \pm 0.9\%$ ($P=.010$) in the intervention group and by 0.2% to $7.8 \pm 0.7\%$ in the control group. HbA1c levels significantly improved during the first 3 months with both face-to-face education and remote glucose monitoring; however, HbA1c tended to increase without the remote monitoring service during the 3 to 6-month follow-up in the intervention group.

The satisfaction with diabetes treatment significantly improved at the end of study compared to baseline in the intervention group (mean change: +3.6 points, $P=.006$). Medication adherence improved in both groups, with no significant difference at 6 months ($P=.59$), although the intervention group showed a greater increase from baseline.

Subgroup analysis indicated that the effect of reducing HbA1c was greater for patients with baseline HbA1c levels $\geq 8.0\%$, those aged ≥ 65 years, smokers, drinkers, and those with obesity in the intervention group.

Conclusions: The digital education platform for personalized diabetes management may be beneficial for glycemic control in type 2 diabetes mellitus. Its effectiveness seems to be enhanced when physicians provided personalized face-to-face education and remote feedback together.

Keywords: Diabetes Mellitus, Type 2; Digital Health; Education, Distance

Introduction

Diabetes is a global health challenge, with 540 million people affected worldwide as of 2021, a number projected to reach 783 million by 2045 [1]. In Korea, the prevalence of diabetes has steadily increased over the past 9 years, reaching 16.7% in 2020; however, only 25% of these individuals achieved an hemoglobin A1C (HbA1C) level of <6.5% [2].

Effective diabetes management is crucial, as patients with diabetes are required to make most of their own health decisions, including dietary choices, physical activity, blood glucose monitoring, carbohydrate counting, and insulin dosage adjustments [3]. Recognizing the complexity of diabetes management, the American Diabetes Association (ADA) guidelines emphasize 'diabetes self-management education and support' (DSMES) an essential component of comprehensive diabetes treatment [4]. Studies conducted in the United Kingdom, such as the X-PERT program and the 'Diabetes Education and Self-Management for Ongoing and Newly Diagnosed' (DESMOND) program [5,6], along with the 'Structured Intensive Diabetes Education Program' (SIDEPE) study in Korea [7], have demonstrated that DSMES significantly improves glycemic control. Additionally, DSMES reportedly reduces the HbA1c levels, enhances quality of life, and decreases hospitalizations and healthcare costs [3,8].

Patients with type 2 diabetes mellitus (T2DM) present with diverse characteristics, including age, sex, body mass index (BMI), and lifestyle habits. These differences, along with differences in insulin resistance and insulin secretion capacity, and the presence of comorbidities, contribute to the heterogeneity of diabetes and its related complications [9-12]. Therefore, it is crucial to provide individualized education tailored to patient-specific characteristics rather than relying solely on general education.

Given the chronic nature of diabetes, maintaining consistent blood glucose control over the long term is particularly challenging [13]. Therefore, in addition to engaging patients in self-monitoring, effective diabetes management requires medical professionals to provide continuous, appropriate, and patient-specific feedback through education. Considering patients' diverse characteristics and the need for continuous professional management, it is essential for physicians who best understand the patient to provide in-person education tailored to individual needs. Moreover, providing blood glucose monitoring to patients may enhance diabetes management.

Recent advancements in information technology have led to the development of various digital healthcare systems. In line with these advancements, the ADA now recommends that DSMES can be effectively delivered through telehealth and digital healthcare systems [4]. Studies exploring glucose control via applications, web-based platforms, and message-based diabetes education has been introduced [14-16]. However, these studies primarily focus on patients who measured their own blood glucose levels and received standardized feedback, falling short of achieving individualized treatment and management. More effective diabetes treatment and management can be achieved if patients monitor their blood glucose levels under physician guidance and receive immediate, appropriate feedback from their physicians.

In response to this need, a digital-based smart education platform for physicians and patients called Doctorvice® (iKooB Inc.) has been developed [17]. This system provides a comprehensive web interface, Doctorvice® Clinic, for physicians to access patients' clinical information at a glance and deliver education messages. Physicians can conduct face-to-face education by selecting appropriate content from a web-based library containing over 3,000 pages of educational materials or customize additional instructions on a canvas. The content used for education can be transmitted to the patient via short message service (SMS) or the Doctorvice® app, enabling patients to receive and review educational content repeatedly. Patients can upload self-measured blood glucose (SMBG) data through the app, which

physicians can access on the web at any time to send additional educational content such as healthy eating habits, physical activity, and diabetes self-care. This bidirectional communication enables education combining face-to-face sessions with continuous remote monitoring and feedback.

In this study, we aimed to evaluate the effectiveness of physician-led digital education platform on glycemic control in patients with type 2 diabetes mellitus (T2DM). Specifically, we hypothesized that physicians providing both face-to-face education and continuous remote monitoring and feedback would greater improvements in glycemic control compared to physician providing face-to-face education alone during outpatient visits without subsequent feedback.

Methods

Study aim

This study was a 6-month non-blinded randomized controlled trial (KCT0007953) involving patients with T2DM who visited the Diabetes Clinic of Seoul St. Mary's Hospital between August 1, 2022, and August 31, 2023. The study utilized a digital education platform to determine the effect on the diabetes care model where the physician provides individualized face-to-face education for each patient based on digital content; the patients uploaded their blood glucose levels and received feedback from the physician remotely. Moreover, we examined the difference between providing face-to-face education and continuous feedback remotely and providing only face-to-face education.

Study design

Participants

Patients with T2DM aged ≥ 19 years with an HbA1c level of 7.5–9.5% were enrolled. Patients with type 1 diabetes mellitus, latent autoimmune diabetes in adults, gestational diabetes, or those using insulin were excluded. Patients who required immediate treatment for acute diabetic complications, had serious medical conditions, had an infection, underwent surgery, or had a serious injury were also excluded. Additionally, individuals who had difficulty using a digital smart platform owing to cognitive decline, illiteracy, or without access to a smartphone could not participate in the study. People who had no history of accessing the app were classified as non-users and excluded.

Intervention and control groups

The participants were assigned to the intervention and control groups in a 1:1 ratio using a random allocation table created by the Clinical Trial Support Center. Both groups received basic education consisting SMBG, blood pressure (BP) measurement, and lifestyle modification regimens according to the clinical practice guidelines of the Korean Diabetes Association [2]. Outpatient visits were made at 3-month intervals over a period of 6 months, with questionnaires administered at the beginning and end of the study, and blood tests were performed at 0, 3, and 6 months. The blood tests included measurement of blood glucose, HbA1c, blood urea nitrogen, creatinine, liver function tests (aspartate aminotransferase and alanine aminotransferase), and lipid profiles (total cholesterol, triglyceride, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol levels). BP, weight, and height

were assessed during each outpatient visit.

Alcohol consumption was categorized into non-drinkers and alcohol-drinkers. Non-drinkers were defined as individuals who did not consume any alcohol, whereas alcohol-drinkers were those who consumed alcohol regardless of the amount. Obesity was classified into five stages according to the BMI value: underweight ($<18.5 \text{ kg/m}^2$), normal ($18.5\text{--}22.9 \text{ kg/m}^2$), overweight ($23.0\text{--}24.9 \text{ kg/m}^2$), obesity class I ($25.0\text{--}29.9 \text{ kg/m}^2$), and obesity class II ($\geq 30 \text{ kg/m}^2$).

Control group–Usual care group

The control group received standard face-to-face care at the office, with diabetes education provided at the time of registration, at the 3-month follow-up, and at the end of the study. The participants received training on SMBG levels at enrollment and were asked to record these levels in their own notebooks, and did not use the digital education platform, Doctorvice®. Therefore, the control group did not receive feedback from the physician.

Intervention group–The digital education-platform user group

In the intervention group, we aimed to assess the effects of a management model that includes digital content-based education delivered through a platform during face-to-face care at outpatient clinics, combined with remote monitoring and feedback provided by the physician at home. Therefore, digital content-based education was conducted at the time of patient's registration, and the educated content was provided through the patient's application (Doctorvice®) or via SMS. For the first 3 months, patients uploaded their SMBG via the application, and the physician regularly provided appropriate feedback, consisting of messages and contents, to the patients. Feedback was provided at 2–3-week intervals depending on the patient's SMBG levels. The feedback included newly created educational content tailored for each patient based on their physician's recommendations, covering topics, such as diet control, physical activity encouragement, and diabetes self-care.

The platform allowed physicians to view patients' basic information at a glance using the platform, including BMI, medical history, family history, and alcohol and smoking history, as well as SMBG data, which facilitated personalized education. From months 3 to 6 (end of the study), patients were asked to measure their own blood glucose levels and upload the values via the application; however, their physicians were not allowed to provide feedback during this period. Thus, only self-management was maintained from months 3 to 6 (Figure 1). By structuring the study in this manner, we can evaluate the effects of remote education.

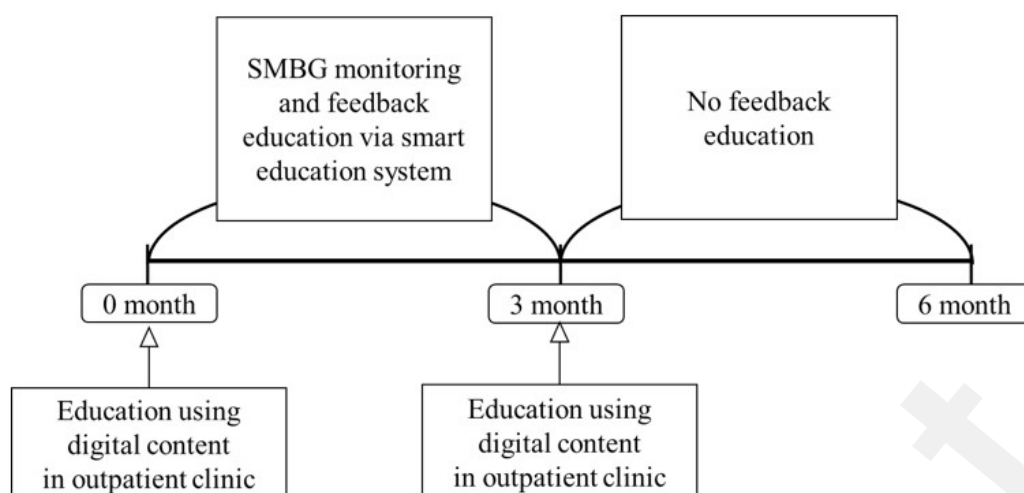


Figure 1 Study Design in intervention group

Digital education platform

The digital education platform (Doctorvice®) serves as a medical consulting and support system connecting physicians and patients. The platform includes Doctorvice® Clinic, accessible to physicians in web form during outpatient clinic visits, and the Doctorvice® App, which patients can use on their mobile devices. Physicians can utilize Doctorvice® Clinic to review the patient's clinical information (e.g., age, sex, past medical history, family history, and smoking and alcohol history) at a glance and monitor the blood glucose level and blood pressure data uploaded by the patient (Figure S1).

The platform includes a digital content library containing approximately 3,000 pieces with contents related to diabetes and hypertension education. The contents were categorized according to disease and symptoms, diagnosis, treatment, side effects, medications, complications, prevention, and management. Physicians can use these contents to conduct personalized education according to patients' characteristics. Moreover, they can use the web canvas for personalized education. Especially, they can select contents relevant to each patient's situation (e.g., food intake, exercise, moderation in alcohol consumption, smoking cessation, and medication adherence) and place them on the canvas. Physicians can edit the contents on the canvas by drawing pictures or writing text using editing tool (Figure S2). This enables the creation of new personalized educational content tailored to the patient, which can be sent to the patient via SMS or the Doctorvice® App. Patients can repeatedly access and learn from this educational content on their smartphones.

Patients can upload their SMBG or BP data through the Doctorvice® App (Figure S3). Physicians can monitor these uploaded data in real-time via Doctorvice® Clinic and send feedback in the form of messages and personalized contents at any time. This platform fosters a continuous connection between physicians and patients through shared content and data, facilitating both face-to-face and remote interactions as needed.

Questionnaires

This study chose three questionnaires to confirm the clinical impact of a smart education platform to strengthen diabetes self-management behavior, which can measure diabetes

patient management patterns. Three questionnaires were satisfaction with diabetes treatment, diabetes stress measurement, and adherence of diabetes medication (Tables S1–S3) [18–20]. Satisfaction with diabetes treatment was measured with a total of 8 questions, with a maximum score of 48 points, where higher scores indicate greater satisfaction. Diabetes stress was assessed with a total of 17 questions, with a maximum score of 85 points; higher scores signify higher stress levels. Adherence of diabetes medication was evaluated with 8 of questions, where a “No” answer received a score of 1 point. The final question “How often do you have difficulty remembering to take all your diabetes medications?” was scored from 4 (Never) to 0 points (Always), for a total possible score of 11 points. Higher scores indicated higher adherence. These three surveys were administered at the time of enrollment and at the end of the study (6 months later) by the same research nurse to minimize investigator bias.

Outcomes

The primary outcome measure was the difference in the HbA1c levels between the control and intervention groups. Changes in the HbA1c levels from baseline to 3 months and from 3 to 6 months were analyzed. Subgroup analyses were performed according to SMBG upload frequency, age, baseline HbA1c level, smoking status, alcohol consumption, and BMI. Also, the secondary outcome was the difference in questionnaire results before and after the study.

Statistical analysis

Statistical analyses were conducted using SPSS (version 27.0; IBM Corp., Armonk, NY, USA) and Rex-Pro v3.6.0. The Kolmogorov–Smirnov test or Q–Q plot was used to evaluate the normal distribution of data. Descriptive data are presented as means and standard deviations (SDs) for continuous variables and as frequencies with proportions for categorical variables. Two-tailed independent sample *t*-tests and ANOVA were used to assess the differences between groups for normally and non-normally distributed data, respectively. Paired *t*-tests and Wilcoxon tests evaluated pre- and post-intervention differences for normally and non-normally distributed data, respectively. Pearson’s correlation coefficient was used to assess relationships between the variables.

Ethical Considerations

This study was approved by the institutional review board at The Catholic University of Korea (approval number: KC19FESI0604) in September 2019. This study was conducted with the informed consent of the participants. To protect the privacy of the participants, an independent anonymization officer, who was not involved in the study intervention, was assigned to handle the anonymization process. No monetary compensation was provided to the participants.

Results

Baseline characteristics

A total of 66 participants were initially enrolled in the study. After excluding 10 individuals who did not attend the outpatient clinic at 3 or 6 months, the final analysis included 26 participants (46.4%) in the intervention group and 30 (53.6%) in the control group. Among these 56 participants, the mean age at baseline was 60.3 years, and 42 (75%) were male (Table 1). The mean HbA1c levels were $8.1 \pm 0.5\%$ overall, $8.3 \pm 0.6\%$ in the intervention group, and $8.0 \pm 0.5\%$ in the control group. The average BMI was 26.5 ± 4.6 kg/m² in the intervention group and

25.5±3.4 kg/m² in the control group. There were no significant differences in the proportions of non-smokers, ex-smokers, and current smokers. Also, there were no significant differences observed in alcohol consumption. The average number of diabetes medications was 2.9±0.7 in the intervention group and 2.8±0.8 in the control group. Of the 56 participants, 47 completed the surveys at the beginning and end of the study, including 20 from the intervention and 27 from control groups, respectively.

Table 1. Baseline clinical characteristics of the study participants.

	Total (N=56)	Intervention group (N=26)	Control group (N=30)	P-value
Age, years	60.3±9.1	59.0±10.8	61.3±7.3	.37
Male sex	42 (75.0%)	22 (84.6%)	20 (66.7%)	.22
Glucose, mg/dL	154±30	159±34	150±25	.26
HbA1c, %	8.1±0.5	8.3±0.6	8.0±0.5	.10
DM duration, years	12.4±7.0	12.4±7.5	12.5±6.6	.94
SBP, mmHg	124±13	126±7	123±16	.47
DBP, mmHg	73±11	76±10	70±12	.046
Urea Nitrogen, mg/dL	18.1±5.5	18.0±6.2	18.1±4.9	.95
Creatinine, mg/dL	0.89±0.27	0.95±0.30	0.84±0.25	.15
eGFR, mL/min/1.73m ²	87.6±18.7	86.1±20.7	88.8±16.4	.59
AST, U/L	27±13	30±14	24±11	.07
ALT, U/L	39±57	33±19	43±77	.48
GTP, U/L	56±110	62±88	51±129	.70
Total cholesterol, mg/dL	142±31	144±34	140±28	.62
Triglycerides, mg/dL	139±78	156±87	124±68	.15
HDL-cholesterol, mg/dL	45±11	46±12	45±10	.60
LDL-cholesterol, mg/dL	70±24	71±25	70±25	.88
Body weight, kg	72.1±14.5	74.5±17.3	70.1±11.5	.28
BMI, kg/m ²	26.0±4.0	26.5±4.6	25.5±3.4	.37
No. of OHA	2.8±0.7	2.9±0.7	2.8±0.8	.95
Smoking				.28
None	35 (44.6%)	9 (34.6%)	16 (53.3%)	
Ex	22 (39.3%)	13 (50.0%)	9 (30.0%)	
Current	9 (16.1%)	4 (15.4%)	5 (16.7%)	
Alcohol consumption	29 (51.8%)	16 (61.5%)	13 (43.3%)	.28
Total education time (min)		22.6±9.7		
No. of education session		4.4±1.1		
Education time per session (min)		5.2±2.1		
No. of education contents sent to patients		24.8±7.8		

Data are presented as means±standard deviations or n (%)

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index;

DBP, diastolic blood pressure; DM, diabetes mellitus; min, minute; No., number; OHA, oral hypoglycemic agents; SBP, systolic blood pressure

In the intervention group, the average duration of each educational session using the platform was 22.6 ± 9.7 minutes, with an average of 4.4 ± 1.1 sessions held over the first 3 months. Additionally, a total of 24.8 ± 7.8 pieces of educational content were sent to participants during this period. The average education time per participant was 5.2 minutes.

Although it was not possible to precisely measure the education time in the control group, considering the unique characteristics of the outpatient care environment in Korea—where the average consultation time per patient typically ranges from 3 to 5 minutes—it can be assumed that the education time in the control group was similar to this range.

Change in HbA1c

Changes in HbA1c over the first 3 months

In the first 3 months, the intervention group experienced a significant reduction in the HbA1c levels, decreasing from a baseline of $8.3 \pm 0.6\%$ to $7.8 \pm 0.9\%$, a change of -0.5% ($P=.01$) (Figure 2). In contrast, the control group presented a non-significant decrease in HbA1c from $8.0 \pm 0.5\%$ to $7.8 \pm 0.7\%$, a change of -0.2% ($P=.13$).

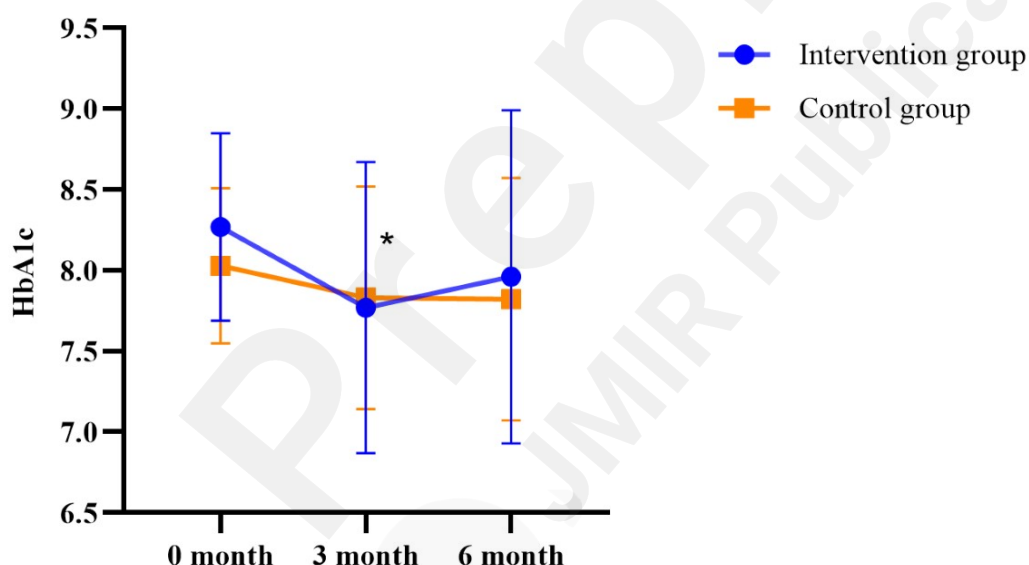


Figure 2 Changes in HbA1c after education using the digital platform

Changes in HbA1c between 3 to 6 months

In the intervention group, the HbA1c levels exhibited a tendency to increase by 0.2% (from $7.8 \pm 0.9\%$ at 3 months to $8.0 \pm 1.0\%$) at 6 months, though this change was not significant ($P=.28$). Conversely, in the control group, the HbA1c levels changed little, with no significant change from $7.8 \pm 0.7\%$ at 3 months to $7.8 \pm 0.8\%$ at 6 months ($P=.92$).

Changes in HbA1c over 6 months

At the 6-month follow-up, the HbA1c levels in the intervention group decreased by 0.3% (from baseline), while in the control group, they decreased by 0.2%. However, neither group exhibited a significant decrease compared to the baseline.

Analysis of questionnaires

Satisfaction with diabetes treatment

The baseline Cronbach's alpha for both the intervention and control groups was 0.8, indicating a high level of reliability. At the 6-month follow-up, the Cronbach's alpha decreased to 0.6 for both the intervention and control groups, yet still maintained a moderate level of reliability.

The baseline satisfaction score for diabetes treatment was 35.6 ± 6.4 points in the intervention group and 38.1 ± 6.8 points in the control group (Figure 3A). At 6 months, the score of the intervention group increased by 3.6 points to 39.2 ± 5.2 points, while in the control group, it decreased by 0.3 points to 37.8 ± 6.4 points. The individuals in the intervention group showed a significant increase in satisfaction with diabetes treatment (compared with the baseline) ($P=.006$).

Diabetes stress measurement

The baseline Cronbach's alpha was 0.7 for the intervention group and 0.9 for the control group, indicating a high level of reliability. At the 6-month follow-up, the Cronbach's alpha increased to 0.8 in the intervention group and remained at 0.9 in the control group, maintaining a high level of reliability.

The baseline diabetes stress score was 44.2 ± 8.5 points in the intervention group and 46.4 ± 11.3 points in the control group (Figure 3B). At 6 months, the score of the intervention group was 44.7 ± 10.4 points, while that of the control group was 42.2 ± 13.3 points. The change in stress scores was notably different; the intervention group showed an average change of 0.5 ± 9.7 , whereas the control group exhibited a decrease of -4.2 ± 6.8 . This indicates that stress levels improved more in the control group compared to those in the intervention group, with the difference approaching significance ($P=.06$).

Adherence of diabetes medication

The baseline Cronbach's alpha was 0.6 for the intervention group and 0.4 for the control group. At the 6-month follow-up, the Cronbach's alpha decreased to 0.4 in the intervention group and 0.3 in the control group.

The baseline adherence score was 9.0 ± 2.2 points in the intervention group and 9.8 ± 1.2 points in the control group, with no significant difference observed between the two groups ($P=0.11$). However, individuals in the control group demonstrated better adherence at the time of enrollment (Figure 3C). At 6 months, the score of the intervention group increased by 0.8 points to 9.8 ± 1.6 points, while that of the control group increased by 0.2 points to 10.0 ± 1.2 points. There was no significant difference in adherence scores between the two groups ($P=0.59$). Although adherence scores in the intervention group tended to improve more than the control group.

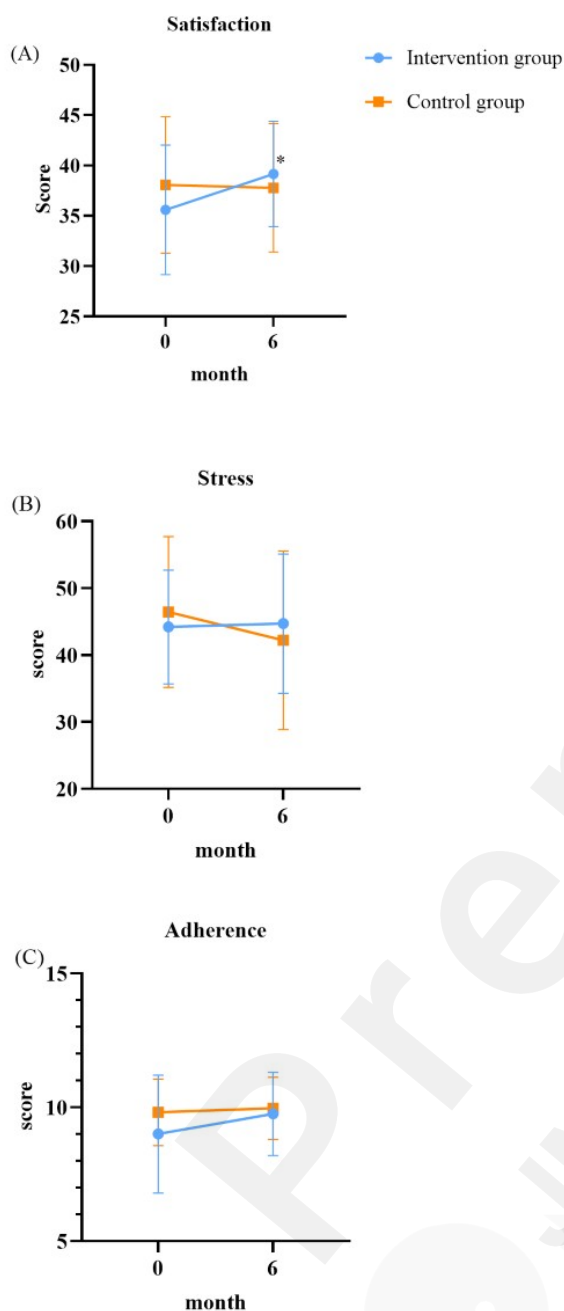


Figure 3 (A) Changes in satisfaction with diabetes treatment score. (B) Changes in diabetes stress measurement score. (C) Changes in adherence of diabetes medication score.

Correlation analysis between questionnaires' score and HbA1c

Correlation analysis was conducted to examine the relationship between changes in HbA1c levels and survey result scores over the study period.

In the intervention group, difference of HbA1c level during the first 3 months showed strong and significant inverse relationship with differenced of HbA1c level during the 3 to 6 months (-

0.7095), which means improvement in HbA1c level during the first 3 months was associated with aggravation in HbA1c level during 3 to 6 months (Table 2). The difference of stress score associated with difference of HbA1c level during first 3 months (-0.3339), whole 6 months study period (0.4372), and 3 to 6 months (0.6294). It is suggesting, during first 3 months, improvement of HbA1c level was moderately associated with reduced stress. However, improvement in HbA1c level during 6 months and 3 to 6 months was associated with worsened stress. Additionally, although the correlation between HbA1c improvement and adherence scores was not statistically significant, there was a tendency for improved adherence to be associated with better HbA1c levels in the intervention group during first 3 months and overall 6 months.

Table 2. Pearson's correlation in the intervention group.

	HbA1c 0-3	HbA1c 0-6	HbA1c 3-6	Satisfactio n 0-6	Stress 0-6	Adherence 0-6
HbA1c 0-3		0.2881 (.21)	-0.7095 (<.001)	-0.0097 (.97)	-0.3339 (.15)	-0.3160 (.17)
HbA1c 0-6	0.2881 (.22)		0.4704 (.04)	0.0051 (.98)	0.4372 (.05)	-0.3229 (.17)
HbA1c 3-6	-0.7095 (<.001)	0.4704 (.04)		0.0126 (.96)	0.6294 (.003)	0.0536 (.82)
Satisfaction 0-6	-0.0097 (.97)	0.0051 (.98)	0.0126 (.96)		-0.3945 (.09)	0.5198 (.02)
Stress 0-6	-0.3339 (.15)	0.4372 (.05)	0.6294 (.003)	-0.3945 (.09)		-0.3795 (.10)
Adherence 0-6	-0.3160 (.17)	-0.3229 (.17)	0.0536 (.82)	0.5198 (.02)	-0.3795 (.10)	

HbA1c 0-3, changes in HbA1c during the first 3 months; HbA1c 0-6, changes in HbA1c during the the first 6 months; HbA1c 3-6, changes in HbA1c during 3-6 months; satisfaction 0-6, changes in satisfaction on diabetes treatment over 6 months; stress 0-6, changes in diabetes stress measurement over 6 months; adherence 0-6, changes in adherence of diabetes medications over 6 months ; (P-value)

In the control group, Pearson's correlation between the degree of HbA1c improvement over the 6-month period and the degree of stress improvement was 0.4475 (Table 3).

Table 3. Pearson's correlation in the control group.

	HbA1c	HbA1c 0-6	HbA1c	Satisfactio n 0-6	Stress	Adherence 0-6
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	0-3	3-6	0-6		
HbA1c 0-3	0.7331 (<.001)	-0.1907 (.34)	0.0133 (.95)	0.3083 (.12)	0.0310 (.88)
HbA1c 0-6	0.7331 (<.001)	0.5278 (.005)	-0.1690 (.40)	0.4475 (.02)	0.0571 (.78)
HbA1c 3-6	-0.1907 (.34)	0.5278 (.005)	-0.2605 (.19)	0.2608 (.19)	0.0437 (.83)
Satisfaction 0-6	0.0133 (.95)	-0.1690 (.40)	-0.2605 (.19)	-0.1907 (.34)	0.1357 (.50)
Stress 0-6	0.3083 (.12)	0.4475 (.02)	0.2608 (.19)	-0.1907 (.34)	0.0051 (.98)
Adherence 0-6	0.0310 (.88)	0.0571 (.78)	0.0437 (.83)	0.1357 (.50)	0.0051 (.98)

HbA1c 0-3, changes in HbA1c during the first 3 months; HbA1c 0-6, changes in HbA1c during the the first 6 months; HbA1c 3-6, changes in HbA1c during 3-6 months; satisfaction 0-6, changes in satisfaction on diabetes treatment over 6 months; stress 0-6, changes in diabetes stress measurement over 6 months; adherence 0-6, changes in adherence of diabetes medications over 6 months ; (p-value)

Subgroup analysis

Change in HbA1c according to SMBG Upload Frequency

Participants who uploaded their blood glucose levels via the application more than once a week were classified as “High,” whereas those who uploaded less frequently were classified as “Low.” The intervention group was subdivided based on their upload frequency in the first and last 3 months: Group 1 consisted of those classified as “High” for both periods, Group 2 as “High” for the first 3 months and “Low” for the last 3 months, Group 3 as “Low” for the first 3 months and “High” for the last 3 months, and Group 4 as “Low” for both periods. In the intervention group, there were 4 patients in Group 1, 6 in Group 2, 4 in Group 3, and 12 in Group 4. Compared to baseline, the HbA1c levels improved by -1.3% in Group 1, -0.5% in Group 2, and -0.5% in Group 4 at 3 months, while HbA1c increased by 0.2% in Group 3. Notably, patients classified as “High” throughout the 6 months (Group 1) had a significantly greater reduction in HbA1c compared to those classified as “Low” for 6 months (Group 4) (post-hoc analysis $P=.02$) (Table 4, Figure 4). The control group could not be analyzed for this metric due to the absence of SMBG uploads via the application.

Table 4. Changes in HbA1c according to SMBG upload frequency.

	Baseline	3 months	P-value	Δ (baseline to 3 months)	6 months	P-value	Δ (3-6 months)
Group 1 (N=4)	8.4 $\pm$ 0.7	7.1 $\pm$ 0.9	.14	-1.3 $\pm$ 1.3	6.9 $\pm$ 0.8	.49	-0.2 $\pm$ 0.6
Group 2 (N=6)	8.4 $\pm$ 0.6	7.9 $\pm$ 1.3	.33	-0.5 $\pm$ 1.1	8.1 $\pm$ 1.2	.79	0.1 $\pm$ 1.0
Group 3 (N=4)	8.2 $\pm$ 0.4	8.3 $\pm$ 0.4	.64	0.2 $\pm$ 0.6	8.1 $\pm$ 0.5	.43	-0.3 $\pm$ 0.5
Group 4 (N=12)	8.2 $\pm$ 0.6	7.7 $\pm$ 0.7	.03	-0.5 $\pm$ 0.7	8.3 $\pm$ 1.0	.08	0.5 $\pm$ 0.9

Δ , difference in HbA1c

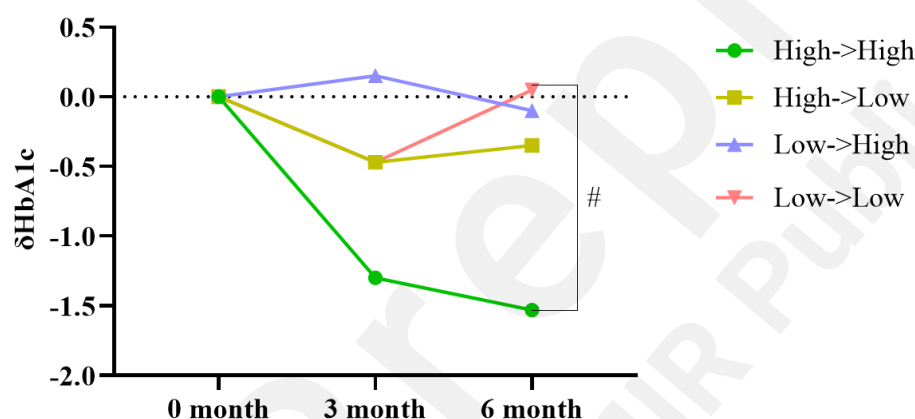


Figure 4 Changes in HbA1c according to SMBG upload frequency

Change in HbA1c according to age

The degree of improvement in the HbA1c levels was confirmed by classifying patients into those aged <65 years and $\geq$ 65 years. In the intervention group, there were 18 individuals aged <65 years, and the baseline HbA1c level was 8.1 $\pm$ 0.6% (Figure 5A-1). At 3 months, it improved by -0.4% to 7.7 $\pm$ 1.0% ($P=.10$). There were eight individuals aged $\geq$ 65 years, and the baseline HbA1c level was 8.6 $\pm$ 0.5%, improved by -0.7% to 7.9 $\pm$ 0.7% ($P=.03$) at 3 months. In the control group, there were 19 people aged <65 years, and the baseline HbA1c level was 8.0 $\pm$ 0.5%. Also, there were 11 individuals aged $\geq$ 65 years and the baseline HbA1c level was 8.0 $\pm$ 0.6%. There was no significant difference in the improvement of HbA1c in each age group (Figure 5A-2).

Change in HbA1c according to baseline HbA1c

In the intervention group, 16 participants had an HbA1c level $\geq 8.0\%$, while 10 participants had an HbA1c level $< 8.0\%$. At 3 months, the group with HbA1c $\geq 8.0\%$ improved HbA1c by -0.8% ($P=.006$) compared to baseline, and the group with HbA1c $< 8.0\%$ showed only a slight change ($P=.95$) compared to baseline, with a significant difference between the two groups ($P=.03$) (Figure 5B-1). In the control group, 13 patients had an HbA1c level $\geq 8.0\%$, while 17 patients had an HbA1c level $< 8.0\%$. There was no significant difference between two groups (Figure 5B-2).

Change in HbA1c according to the smoking status

In the intervention group, nine people were non-smokers, thirteen were ex-smokers, and four were current smokers. At 3 months, the degree of improvement in HbA1c compared to baseline was $-0.3 \pm 0.5\%$ in non-smokers, $-0.2 \pm 0.6\%$ in ex-smokers, and $-2.0 \pm 1.0\%$ in current smokers (Figure 5C-1). Post-hoc analysis revealed significant differences between current smokers and both non-smokers ($P<.001$) and ex-smokers ($P<.001$), but no significant difference between non-smokers and ex-smokers ($P=.98$).

In the control group, 16 participants were non-smokers, 9 were ex-smokers, and 5 were current smokers. Changes in HbA1c were not significantly different among the smoking status groups (Figure 5C-2).

Change in HbA1c according to alcohol consumption

In the intervention group, there were 10 non-drinkers and 16 alcohol-drinkers. At 3 months, the degree of improvement in HbA1c compared to baseline was -0.1% in non-drinkers and -0.8% in alcohol-drinkers ($P=.06$) (Figure 5D-1). The control group included 17 non-drinkers and 13 drinkers. There was no significant difference between the two groups (Figure 5D-2).

Change in HbA1c according to the baseline BMI level

Based on baseline BMI, participants were classified into four groups, i.e., Group 1 (normal weight), Group 2 (pre-obesity), Group 3 (obesity stage 1), and Group 4 (obesity stages 2 and 3), with no participants classified as underweight in either group. In the intervention group, there were 6 participants in Group 1, 5 in Group 2, 11 in Group 3, and 4 in Group 4. At 3 months, HbA1c improvement was more pronounced in Group 4 compared to the other groups, though this difference was not statistically significant (Figure 5E-1). In the control group, with seven participants in Group 1, 10 in Group 2, 10 in Group 3, and three in Group 4, no significant differences in HbA1c improvement were observed among the groups (Figure 5E-2).

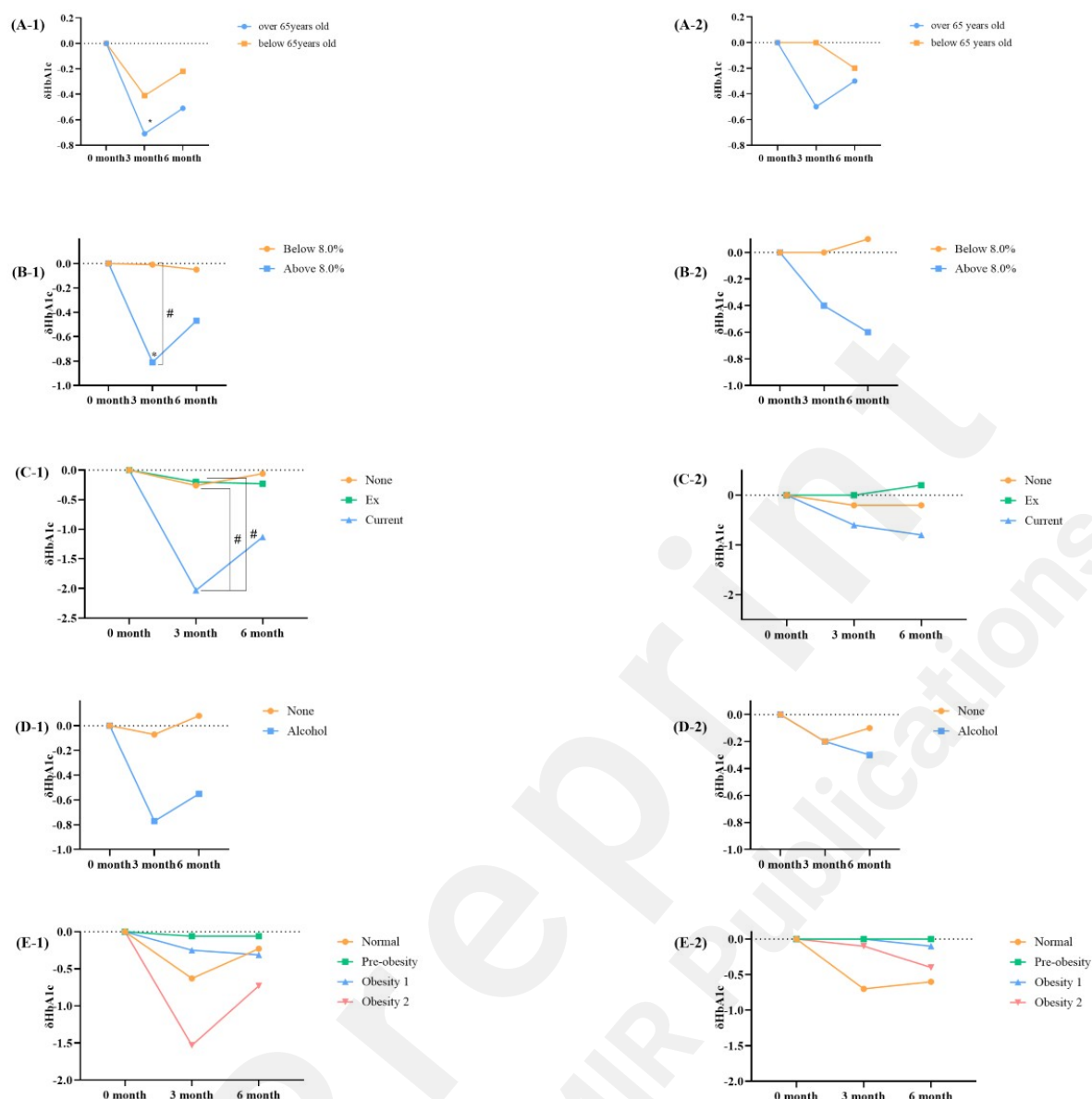


Figure 5 Changes in HbA1c according to variables

Discussion

In this pilot randomized controlled trial involving patients with type 2 diabetes mellitus, a digital education platform that combined face-to-face education with remote feedback over a 3-month period led to a significantly greater reduction in HbA1c (-0.5% , $P = .01$) compared to conventional education (-0.2%). However, HbA1c levels in the intervention group slightly increased after remote feedback ended. Treatment satisfaction improved significantly in the intervention group ($P = .006$), while stress decreased more in the control group ($P = .06$). Medication adherence improved modestly in both groups without significant between-group differences. Greater HbA1c improvement was associated with frequent SMBG uploads and was more pronounced in participants with higher baseline HbA1c, age ≥ 65 years, smoking, drinking, or obesity.

This study demonstrated that the digital education platform for personalized diabetes management was beneficial for glycemic control in T2DM, and it was fairly effective when

physicians provided both personalized face-to-face education and remote monitoring and feedback. A significant decrease in HbA1c was observed during the first 3 months when face-to-face education and remote monitoring and feedback were provided through this platform. However, during the 3–6-month period, when education was only face-to-face at the outpatient clinic without further feedback from physicians, HbA1c levels tended to increase slightly. Even in the control group, which only received regular face-to-face education at the outpatient clinic, HbA1c levels decreased over the first 3 months, suggesting that initial education might be effective in diabetes management. Nevertheless, the more significant reduction in HbA1c levels in the intervention group can be attributed to the additional effect of SMBG uploads and feedback from physicians. The effectiveness of education was enhanced by enabling more continuous learning for the intervention group, as they received digital education and educational materials via SMS or the Doctorvice[®] app, contributing to a more significant reduction in HbA1c levels. One study has noted that fostering user engagement is essential for diabetes self-management apps to effectively complement clinical care [21]. Another study emphasized that outcomes in diabetes management varied depending on the level of message-based interaction [22]. These findings align with the results of our study, underscoring the importance of patient-centered, personalized, and sustained interaction for optimal diabetes care. The slight increase in HbA1c levels after the discontinuation of remote feedback in our intervention group further reinforces the critical role of ongoing feedback in supporting long-term glycemic control.

In this study, at 3 months, the difference in the HbA1c levels between the two groups was approximately -0.3%, suggesting that additional education on diabetes management provided during the first 3 months showed similar results to those of other studies. In a systematic review and meta-analysis of diabetes management using mobile phone applications [23], the difference in HbA1c between the intervention and control groups ranged from -0.69% to -0.28%. Additionally, another meta-analysis indicated that the HbA1c levels improved only when clinical interventions, such as medication adjustments, were included [24]. Although no medication adjustments occurred during this study, the improvement in the HbA1c levels aligns with findings from other studies emphasizing the importance of physicians' interventions in diabetes management. In the intervention group, HbA1c levels tended to increase again during the 3- to 6-month period when remote feedback was no longer provided. This aligns with findings from other studies [25,26], which reported the greatest effects from short-term study period. Furthermore, these studies suggested that the most significant effects are observed at six months. The decline in educational effect observed after discontinuing the intervention highlights the importance of sustained support. These findings suggest that healthcare providers should be able to offer longer-term remote education to maintain and reinforce behavioral changes in diabetes care.

Survey results indicated that satisfaction with diabetes treatment and adherence of diabetes medications tended to improve in the intervention group compared to the control group. Non-face-to-face education outside of outpatient clinic is an additional treatment effect and is tailored to each patient, so both are expected to have increased. However, the reliability of the adherence of diabetes medications survey was low, which may be attributed to the small number of items. Additionally, the use of a dichotomous response format (Yes/No) may have also contributed to the lower reliability. In the diabetes stress measurement, the stress score significantly improved in the control group. Regarding Pearson's correlation, there was a negative correlation between changes in the HbA1c levels during the first 3 months and stress in the intervention group. The diabetes stress measurement included items on emotional burden, physician-related distress, regimen-related distress, and diabetes-related interpersonal

distress. While it would have been beneficial to analyze the changes in scores for each category, this was not conducted. In the intervention group, the increase in stress may have been influenced by the continuous contact, which could have heightened emotional burden and exacerbated regimen-related distress due to the discrepancy between personal lifestyle and educational content. In contrast, the control group may have perceived the overall experience more positively. Nevertheless, improvements in treatment satisfaction and adherence suggest that the digital intervention still provided meaningful benefits, consistent with previous studies reporting positive effects of digital health interventions on quality of life in patients with type 2 diabetes [27,28]. A detailed analysis of individual item scores could have provided a clearer explanation of these findings.

SMBG upload frequency, inferred from blood glucose level uploads via the application, indicated that participants who consistently uploaded their SMBG data over 6 months experienced better HbA1c improvement compared to those with poor upload frequency.

In addition, the effect of digital education platform on reducing HbA1c level was notably greater for individuals with HbA1c levels $\geq 8.0\%$ and those aged ≥ 65 years. However, some studies have suggested that the digital education effect is more pronounced in patients with higher baseline HbA1c levels, younger age, and shorter disease duration [29], while others indicate it is effective in the elderly regardless of the baseline HbA1c levels [30]. The optimal age group for the effect of digital education platform has not yet been clearly established. Our research suggests that simultaneous face-to-face education and remote feedback can enhance effectiveness, even in older adults. As widely recognized, higher baseline HbA1c levels are associated with greater educational effects. Similarly, our study demonstrated that the effectiveness of digital education platform was more pronounced in individuals with higher baseline HbA1c levels.

Interestingly, current smokers in the intervention group experienced a more significant reduction in the HbA1c levels compared to non-smokers and ex-smokers, and there was a trend toward decreased HbA1c in alcohol drinkers compared to non-drinkers. Furthermore, the intervention group's HbA1c reduction was more pronounced among those with a BMI ≥ 30 kg/m², suggesting that the digital education system may have been effective in encouraging lifestyle improvements through continuous education, especially for individuals with less healthy habits.

The strength of our study lies in the additional survey conducted in the outpatient clinic, which allowed us to confirm the use of the digital education system and assess patients' health status, behavior, and adherence in various ways. This comprehensive approach enables a thorough analysis of patient self-management. Unlike previous studies, which did not establish the effect of diabetes self-management through digital education on smoking or other lifestyle groups, our study conducted detailed subgroup analyses to identify specific groups where digital education would be effective. As the age group of smartphone users gradually expands, it is crucial for seniors to actively use digital healthcare. Notably, our study included participants aged ≥ 65 years, addressing a gap in the existing research. The main strength of this study is that it attempted to examine the effectiveness of the digital education system based on various factors such as baseline HbA1c, age, and lifestyle habits.

However, our study had limitations. The sample size was smaller than initially targeted, with <30 participants in each group after accounting for dropouts. This small sample size hindered more detailed subgroup analyses and limited the statistical power of our findings. Also, since the patient intervention period was 6 months, which is a short period to evaluate changes in lifestyle habits, only blood glucose control was evaluated in diabetes management. Additionally,

the exact number of SMBGs checked by the control group was unknown, complicating the analysis of blood glucose control improvements. Another limitation was the insufficient assessment of the digital education platform itself; feedback on satisfaction, needs, and educational content evaluation through surveys would have been beneficial for system development. Conducting a survey at the 3rd month would have allowed for a more accurate comparison of the platform's functions and survey results. Also, it would have been beneficial to include not only HbA1c and three survey results but also the lifestyle improvements. Further analysis of the changes in individual items for each questionnaire would have provided a more detailed understanding of the results. Moreover, analyzing the data according to category of educational contents would have strengthened the findings.

In conclusion, personalized diabetes management using a digital education system appears to be beneficial for glycemic control in patients with T2DM. Specifically, the system was more effective for individuals who did not achieve optimal glycemic control, were older, or had poorer lifestyle habits. Future research should focus on evaluating the efficacy of this digital education platform system in individuals with various clinical situations in T2DM and conduct more long-term follow-up studies involving larger participants.

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Conflicts of Interest

Jae-Hyoung Cho is the CEO of iKoob Inc.

Author contributions

Conceptualization: Jin Yu and Jae-Hyoung Cho conceived and designed the study.

Data collection: Jin Yu, Joonyub Lee, Yeoree Yang, Eun Young Lee, Seung-Hwan Lee, Jae-Hyoung Cho collected data.

Data curation: Jin Yu collected and prepared the data for analysis.

Formal analysis: Jin Yu and Jae-Hyoung Cho conducted the statistical analyses and interpreted the results.

Visualization: Jin Yu created the figures and visualizations used in the manuscript.

Writing – original draft: Jin Yu drafted the manuscript.

Writing – review & editing: Jin Yu and Jae-Hyoung Cho reviewed and edited the manuscript.

Abbreviations

ADA: The American Diabetes Association (ADA)

BMI: body mass index

BP: blood pressure

DSMES: diabetes self-management education and support

HbA1c: glycated hemoglobin

SD: standard deviation

SMBG: self-measured blood glucose levels

SMS: short message service

T2DM: type 2 diabetes mellitus

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Supplementary Files

Figures

S2. Doctor's canvas and digital contents.

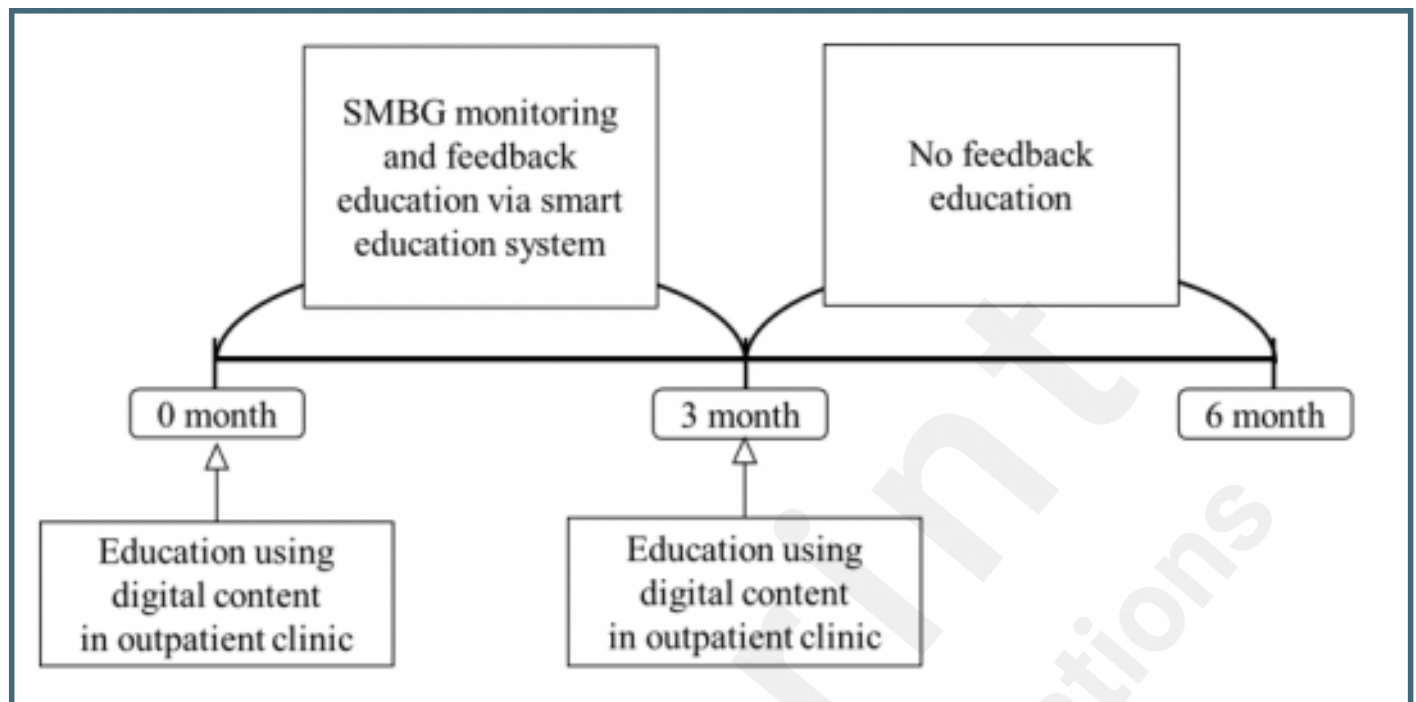


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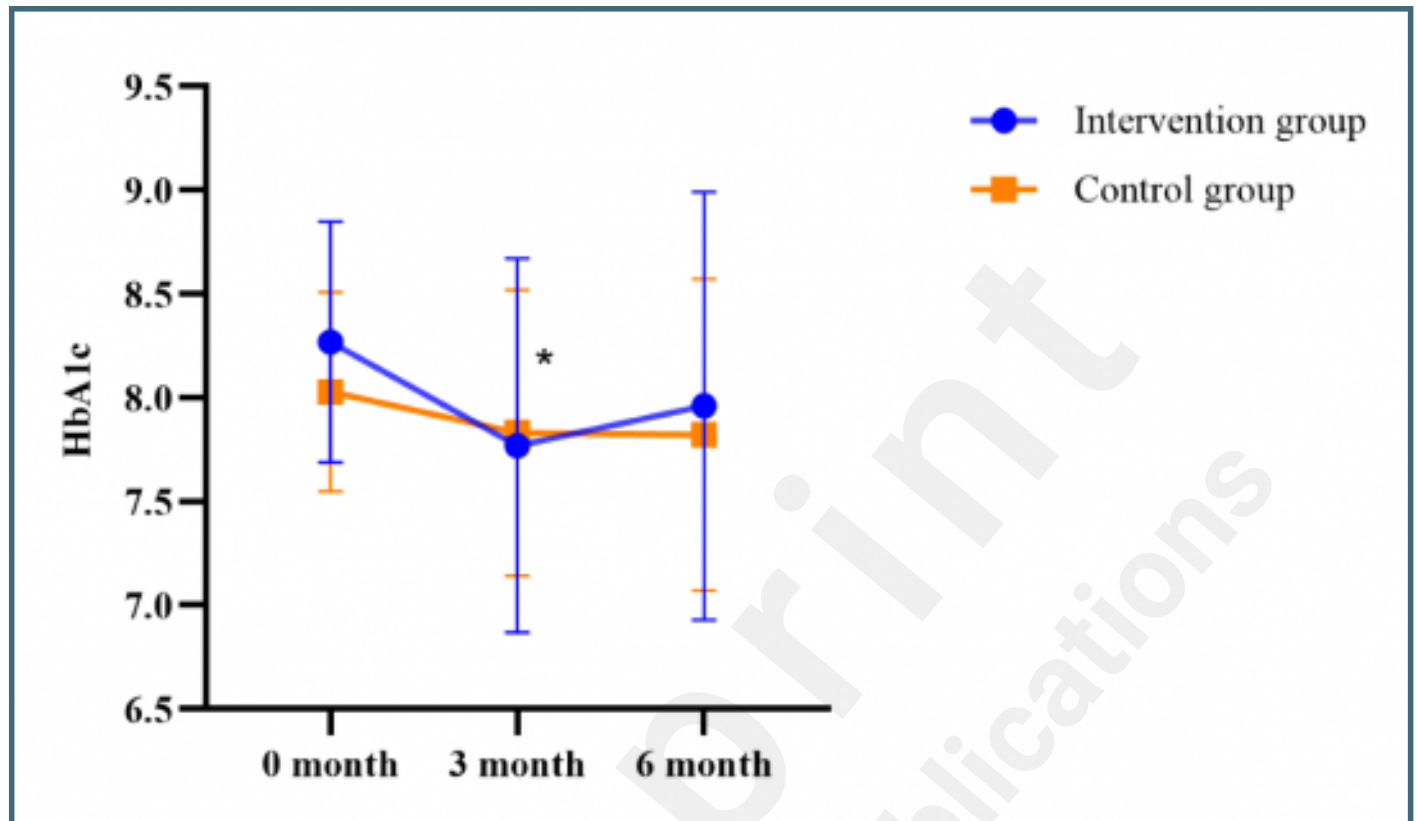
S3. Upload screen on application.



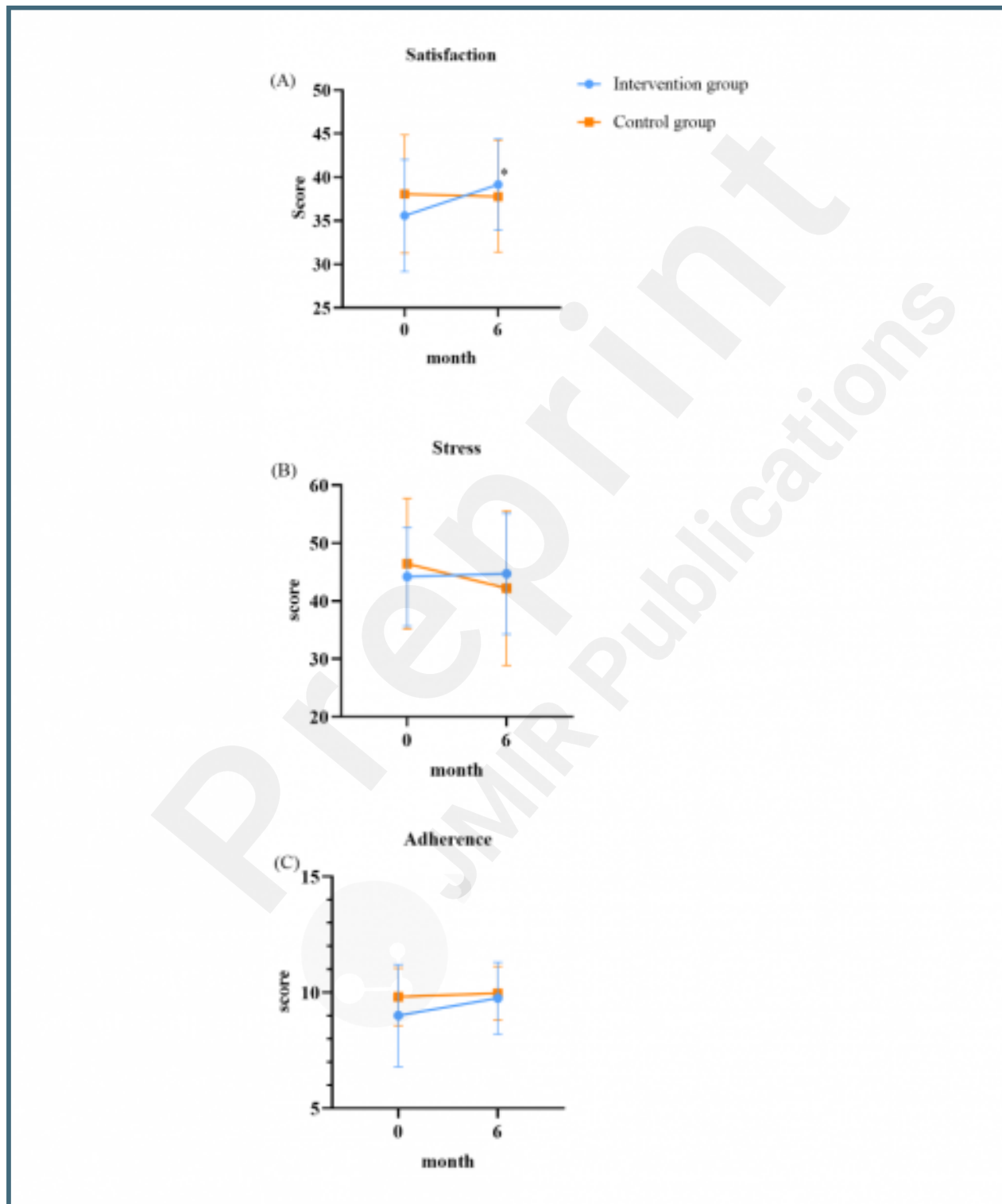
Study design in intervention group.



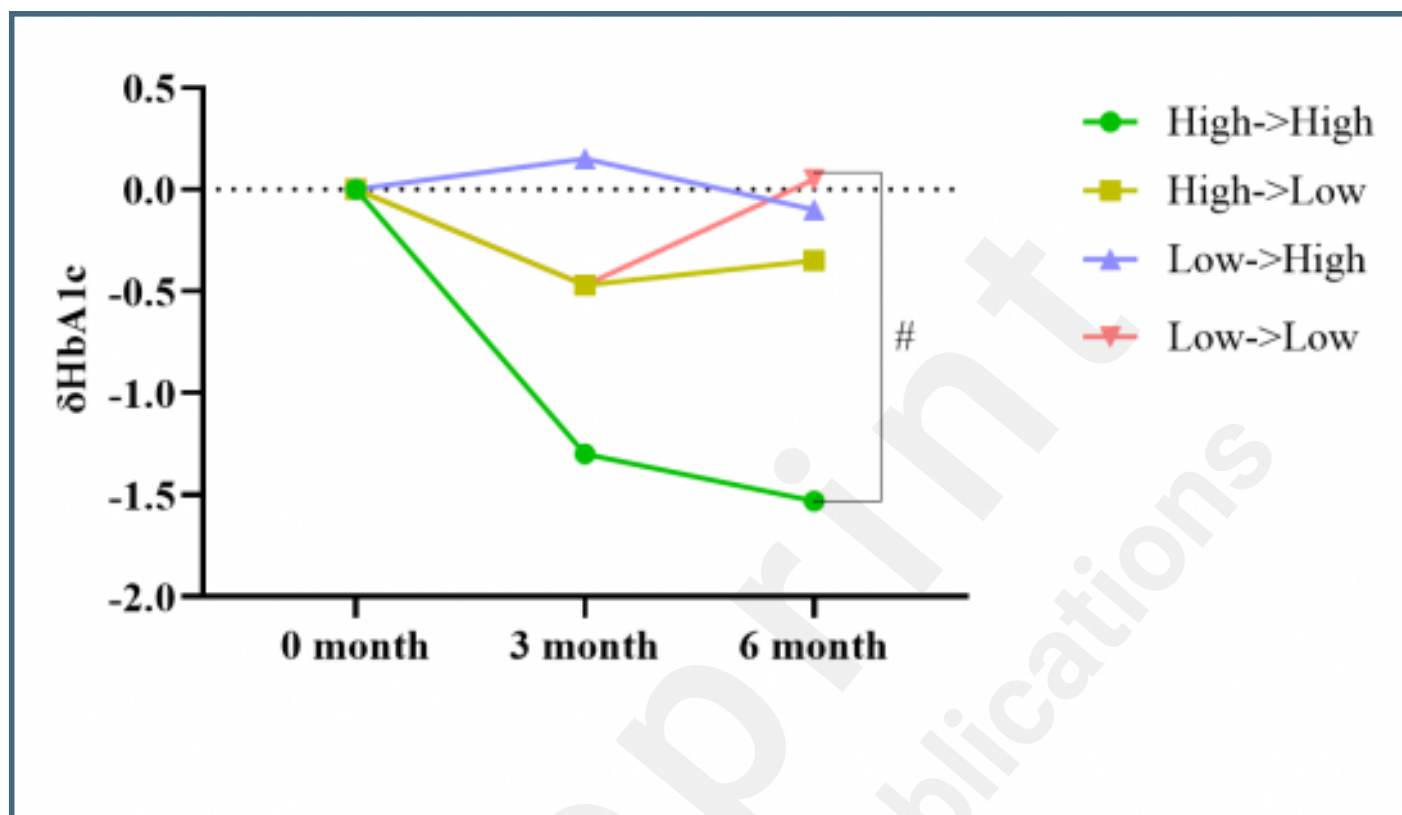
Changes in HbA1c after education using the digital platform. * means that HbA1c change from baseline to 3month was significant in the intervention group ($P=.010$).



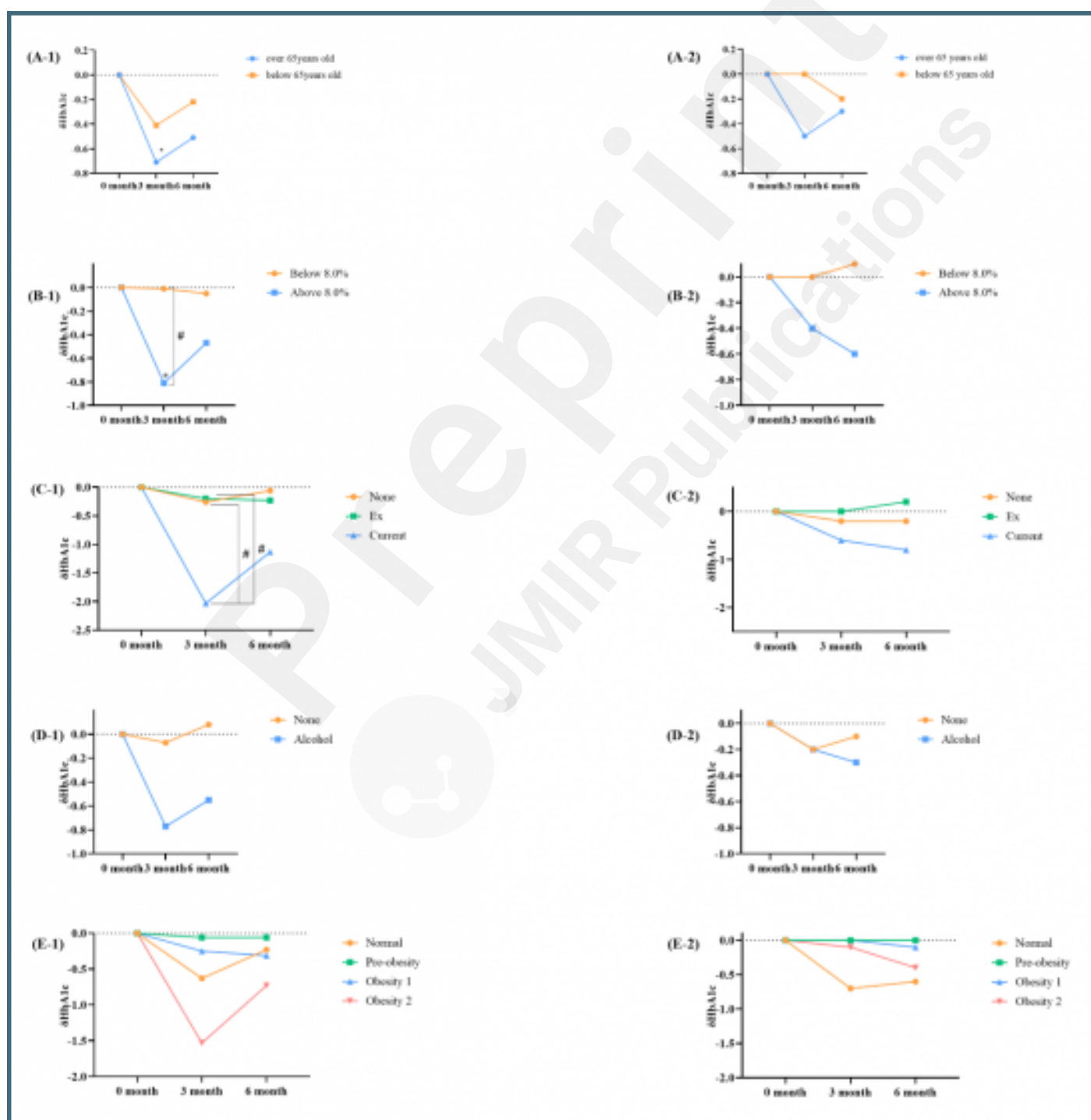
(A) Changes in 'satisfaction with diabetes treatment' score. (B) Changes in 'diabetes stress measurement' score. (C) Changes in 'adherence of diabetes medication' score. * means the satisfaction score change was significant in intervention group ($P=.006$). Vertical error bars indicate SD.



Changes in HbA1c according to SMBG Upload Frequency # means Group 1 had a significantly greater reduction in HbA1c compared to Group 4 (post-hoc analysis $P = .022$).



(A-1) Changes in HbA1c according to age (≥ 65 years vs. < 65 years) in the intervention group. (A-2) Changes in HbA1c according to age (≥ 65 years vs. < 65 years) in the control group. (B-1) Changes in HbA1c according to baseline HbA1c $\geq 8.0\%$ in the intervention group (B-2) Changes in HbA1c according to baseline HbA1c $\geq 8.0\%$ in the control group (C-1) according to smoking status in the intervention group. (C-2) Changes in HbA1c according to smoking status in the control group. (D-1) Changes in HbA1c according to drinking status in the intervention group. (D-2) Changes in HbA1c according to drinking status in the control group. (E-1) Changes in HbA1c according to BMI level in the intervention group. (E-2) Changes in HbA1c according to BMI level in the control group. * means that compared to baseline, 3months HbA1c change was significant in the intervention group. # means there was significant difference in degree of HbA1c change between two groups.



Multimedia Appendixes

Supplementary tables and figures.

URL: <http://asset.jmir.pub/assets/c3c224f3ba25bbaec1c2173e64f935f5.docx>



CONSORT (or other) checklists

URL: <http://asset.jmir.pub/assets/b48318d86f47c7b0a7b9f3fe7f0ba520.pdf>