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ORIGINAL ARTICLE

Effects of a smartphone-based nursing counseling and feedback system for women with gestational diabetes on compliance, glycemic control, and satisfaction: a randomized controlled study

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Abstract

Background Gestational diabetes mellitus (GDM) is a health problem that threatens maternal and infant health with increasing prevalence in the world. Patient education is very effective in managing the disease.
Aim In this study, we aimed to investigate the effect of a smartphone-based nursing counseling and feedback system on physical activity, glycemic control, and patient satisfaction among women with GDM.
Design This was a single-center, randomized controlled study. Women with GDM were randomized to the intervention and control groups. The groups received (1) routine biweekly prenatal care (control group) or (2) counseling and feedback from the nurse via a platform installed on their smartphone (smartphone group) in addition to routine clinical care.
Results A total of 45 GDM patients were randomly assigned to either the control ($n = 22$) or intervention groups ($n = 23$). Women in the intervention group received a mobile and web-based counseling program in addition to standard care. GDM knowledge, physical activity, and adherence to diet were higher in the intervention group compared to the control group ($p < .05$). There was no difference between the groups in terms of glucose level ($p > .05$). This study concluded that the mobile and web-based nursing counseling program increased patient satisfaction.
Conclusion Nursing counseling and feedback provided via smartphone is important as a factor in the individualization of care. It increased the physical activity status of women, facilitated their adherence to diet, increased patient satisfaction, and reduced the rate of insulin therapy. No effect was found on blood glucose values.

Keywords Smartphone-based · Gestational diabetes mellitus · Nursing · Self-care

Introduction

GDM is one of the most common medical problems of pregnancy [1]. The prevalence is reported to be 5.4% in Europe [2] while this rate is estimated to be between 6.5–15.7% in the east and southeast Asia [3]. GDM is associated with several long- and short-term adverse outcomes for the mother and child [4], including an elevated risk of premature birth and cesarean section, shoulder dystocia or birth injury, preeclampsia, neonatal hypoglycemia [5] premature rupture of membranes, congenital anomalies, fetal macrosomia, and later development of type 2 diabetes [6]. In Turkey, according to the clinical protocol, GDM testing should be performed at 24–28 weeks of gestation using a 50 g, 1-h glucose challenge test. If the blood glucose level is higher than 140 mg/dL, women undergo a 100-g, 3-h oral glucose tolerance test (OGTT). GDM is diagnosed in women who have ≥ 2 abnormal values for the 3-h OGTT (fasting ≥ 95 mg/dL, 1 h ≥ 180 mg/dL, 2 h ≥ 155 mg/dL, 3 h ≥ 140 mg/dL). Diagnosis criteria of American Diabetes Association (ADA) Diagnosis and classification of diabetes mellitus are used in Turkey. Dietary and lifestyle modification advice is generally recommended as the primary treatment strategy for women with GDM [7]. Medical treatment is started when blood sugar levels cannot be controlled by lifestyle changes [8]. GDM treatment usually begins with

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education that includes medical nutrition therapy, physical activity, weight management, and self-monitoring of blood glucose [9]. GDM training given by health personnel may be insufficient due to limited clinic visiting hours, crowded clinical environments, and insufficient number of nurses [10]. New ways are needed to train and equip women to manage their GDM.

Mobile health (mHealth) interventions are rapidly gaining popularity due to their low cost, ease of use, and sustainable features [11]. Smartphones are technological advances that can be easily integrated into educational interventions and used to improve the health of vulnerable groups in a community [12]. Smartphone applications can be considered as a support for health programs because they can be used by anyone individually [13]. It was stated that mobile applications personalize health services, improve patient care, and increase patient compliance [14]. The limited number of studies in the literature are generally planned as feasibility studies. However, to the best of our knowledge, no study was found in Turkey and in the recent literature on the use of smartphone-based nurse counseling for women with GDM. The present randomized, controlled study aimed to analyze the effects of a smartphone-based counseling system for women with gestational diabetes on compliance, glycemic control, and satisfaction. The following hypotheses were tested in this study:

H1. There are differences between intervention and the control group women's GDM knowledge.
H2. There are differences between intervention and the control group women's blood glucose levels.
H3. There are differences between intervention and the control group women's compliance diet and physical activity.
H4. There are differences between intervention and the control group women's satisfaction

Materials and methods

Study design

The study was a randomized controlled trial including women diagnosed with GDM at 24–28 weeks of gestation. Newly diagnosed GDM women were randomly allocated to the intervention or control groups. Group (1) (control) received prenatal clinic care. Group (2) (intervention) additionally used a smartphone-based counseling system. Results for pre- and post-intervention were compared.

Study sample

As no similar study was found in the literature, a priori sample size calculation would not be possible at first. So, the power of the study was calculated based on the completed data set covering all groups in the current study. G*Power 3.1. the software was used to calculate the sample size of the study. As GDM knowledge score was the main outcome, the power of the study was calculated based on the mean differences in total GDM Knowledge test scores from the baseline to the week 14. The sample size was determined with a power of 86% and an α-value of 0.05; the power analysis was conducted using the G*Power program, version 3.1.7.

Randomization

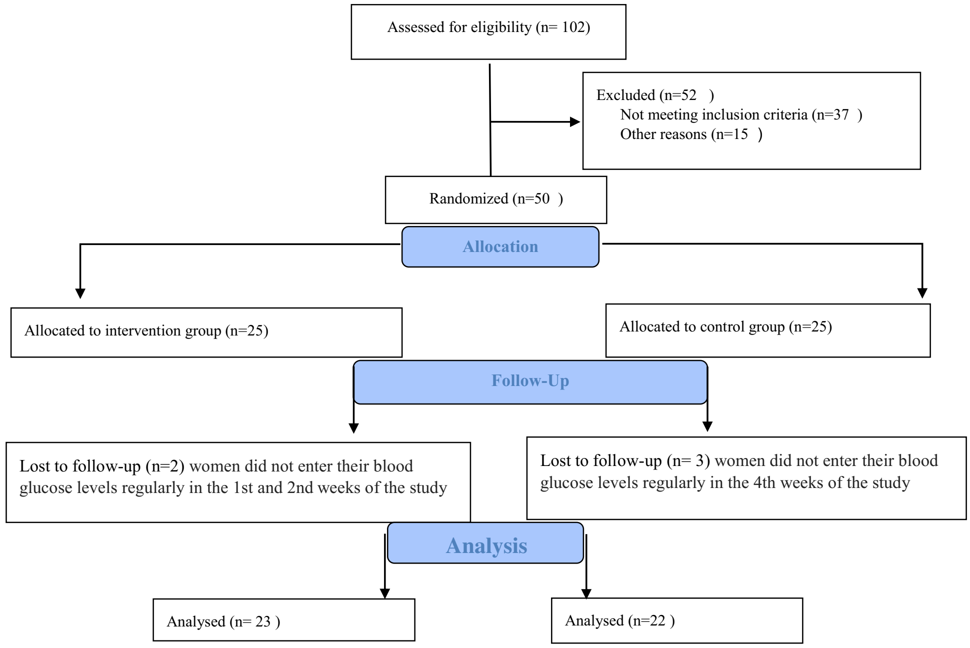
The list of potential participants was reported to the researchers by a nurse who was working at a perinatology outpatient clinic every week. The principal investigator (PI) evaluated the participants based on eligibility criteria and defined the study protocol to the selected patients. The study sample consisted of 50 women with GDM, who met the eligibility criteria and agreed to participate in the study. Of the 50 patients included in the study, 2 women from the intervention and 3 women from the control group were excluded because they did not enter their blood glucose levels regularly (Fig. 1). To ensure homogeneity between the intervention and control groups, the women were stratified according to age (18–34; 35–45), number of births (nullipara-primiparous) and body mass index (BMI) (below 18.5 kg/m2; 18.5–24.9 kg/m2; 25–29.9 kg/m2). To accomplish allocation, alternating assignment was used. Accordingly, the first patient was assigned to the control group, and the next was assigned to the intervention group by the independent nurse, as long as they were in the same strata in terms of conditioning regimen as the patient in the control group. If the next patient was not in the same strata as the patient in the control group, the patient was assigned to the control group. There were no differences between the two groups in terms of the conditions ($p > 0.05$). The inclusion criteria were as follows: uncomplicated pregnancies, at least primary school graduate, internet access, and able to use computer or smartphone. The exclusion criteria were as follows: co-morbid neurological or psychological disease, pregnancy loss, not following blood glucose levels regularly, and wanting to quit the study.

Instruments

Data were gathered using a patient information form (PIF) GDM knowledge test (GDMKT), physical activity diary (PAD), food diary form (FDF), and satisfaction form (SF) prepared by the researchers based on previous literature.

The patient information form was developed by the researchers after reviewing the related literature [15, 16] and included questions about the women's sociodemographic characteristics, general health status, previous pregnancies, current pregnancy, and GDM.

Fig. 1 Participant flow diagram



The physical activity diary was developed by the researcher to determine the type of physical activity, frequency of physical activity, and duration of physical activity of women and the reasons for not doing physical activity daily by researching the related literature [17]. The participants filled in the form daily themselves.

The food diary form was developed by the researcher based on the relevant literature [17, 18]. The form consisted of a total of six questions to determine the number of daily meals, the status of diet and reasons for noncompliance, blood glucose values, insulin initiation status, weight gain during pregnancy, and average daily water consumption. The participants filled in the form themselves daily.

The GDM information test was developed for this study after reviewing the related literature [17–19] and included 16 multiple-choice questions. The opinions of three experts were considered for content validity, necessary adjustments were made. GDM knowledge test scores vary between 0 and 16 points. On the GDM knowledge test, 0–7 points indicate low knowledge level, and 8–16 points indicate high knowledge level. The Cronbach's alpha coefficient was 0.55 for the pre-test and 0.88 for the post-test.

The satisfaction form was created by the researcher in line with the relevant literature (8,21, 22) to evaluate the satisfaction of women with health services. It consists of three open and closed-ended questions. The first question was prepared to determine the satisfaction levels of women, the second question was prepared to determine their opinions about satisfaction, and the third question was prepared to determine their suggestions. The satisfaction form was finalized by taking the opinion of experts in the field of women's health nursing.

The inventories were presented to both groups using the following schedule: the PIF during the first interview, the GDM knowledge test during the first interview and at 14 weeks, and PAD and FDF during the first interview and every day for 14 weeks. The SF form was filled out by the intervention group at the end of 14 weeks. The intervention group completed all the inventories online through the application.

Statistical analysis

The data were analyzed using IBM SPSS Statistics software (version 23.0, IBM Corporation, Armonk, NY, USA). The relationship between two independent categorical variables was analyzed using the chi-square test. Variables were compared with the McNamar and Friedman tests. Women's open-ended expressions were grouped and coded by the researcher and the frequency distributions are given as number and percentage. The alpha level used to define significance was 0.05.

Interventions

The intervention group received smartphone-based counseling accompanied by education with a nurse following the women's health status with individual and group counseling for 14 weeks. The control group received standard care and was evaluated with the data collection tools only.

Smartphone-based counseling system

Women assigned to the smartphone group installed an app on their smartphones in addition to standard care. The application (https://www.gdmgebe.com) is web-based, freely available, and simple to use, and was available only to women in the intervention group with a username and password during the study. A 15-min hands-on training about the use of the application was given to all women by one of the researchers in the pregnant training room of the hospital. A pilot test was employed with a small sample of women with GDM unrelated to the study to test the application. The application consists of a digital education booklet about GDM (in different versions with audio, visual, and video), diet compliance tracking (weight gain, number of meals, blood glucose levels, status of initiation of insulin therapy, and their insulin doses), and physical activity monitoring (type, intensity, and duration of their physical activity), a platform to ask questions and receive immediate answers regarding any aspect of GDM management and synchronized and asynchronous nursing counseling. Each patient documented each of their blood glucose measurements, diet status, and physical activity status using the application, which generated a daily report transmitted by an admin page every day from our computerized research database. The patient received short message service (SMS) messages to remind her about the lack of data transmission. According to clinical protocol, women who had high blood sugar levels for 3 days and did not do physical activity 3 days a week or had problems in following their diet were sent a warning message by the system and women received individualized feedback from the nurse. In addition, the patients were given synchronized individual and group counseling by the nurse, and the problems they experienced in managing the disease were discussed, therapeutic recommendations were given, and the patients were motivated. Online group counseling was given to the women by the researcher from the links section of the application once a week at a time that was appropriate for most of the women. Group counseling was done 7 times in total. The counseling time which the women communicated with other women and their questions were answered by the researcher, lasted about half an hour. Medical treatment could only be initiated by clinical appointment and not via the application.

Standard care

Pregnant women diagnosed with GDM are followed by a perinatology specialist once every 2 weeks until the 35th gestational week and once a week from the 35th gestational week until delivery. At the first visit, women with GDM are directed to the diabetes nurse by the perinatologist to teach them the correct use of the glucometer, the use of insulin if they receive medical treatment, and to inform them about the disease. Then they are directed to a dietitian for proper nutrition principles and dietary counseling in GDM. Patients are told to monitor blood glucose levels 4 times a day and manually record the measurements in a diary for review with their physician at each visit. Women in the control group received only standard care and filled out the PIF and GDM knowledge pretest in the first interview and the GDM knowledge posttest at 14 weeks. PAD and FDF were given during the first interview and recorded every day for 14 weeks and handed to the researcher at each perinatal visit. Reminder messages were sent to women's phones to complete these diaries.

Results

Women in the intervention and control groups were similar in terms of sociodemographic and obstetric characteristics (Table 1; $p > 0,05$). Most of the women in the intervention and control groups were between the ages of 18 and 34 years (I: 65.2%, C: 77.3%) and mass index between 18.5 and 24.9 (I: 69.6%, C (81.8%) More than half of the women were primipara (I:52.2%, C:63.6%) and high school graduates (I: 56.5%; C: 81.8%) and almost all of them were non-smokers (I: 95.7%, C 81.8%). Most of the women in both groups did not experience curettage or abortion (I: 78.3%; C: 86.4%) and had no history of large infants (I: 85.7%; C: 60.0%) and did not have a history of GDM in their previous pregnancy (I: 95.7%; C: 86.4%). More than half did not have a history of diabetes among first-degree relatives (I: 71.3%; C: 90.9).

The average pre-test knowledge score for women in the intervention group was 2.82 ± 1.33 and the pre-test knowledge score for women in the control group was 2.91 ± 1.38. The pre-test knowledge scores of women in both groups were similar ($p > 0.05$). The mean score of post-test knowledge for women in the intervention group was 8.43 ± 1.53 and the mean post-test knowledge for women in the control group was 3.1 ± 0.99. The difference between the intervention and control groups was found to be statistically significant in terms of the mean post-test knowledge score ($p < 0.05$) (Table 2).

There was no statistically significant difference between diet compliance rates of the women in the intervention and control groups (I: 34.8%; C: 40.9%) the first week after the diagnosis ($p > 0.05$), while there was a significant difference between the two groups at the end of the 14th week (I:78.3%; C:59.1%) ($p < 0.05$). Among women in the intervention and control group, physical activity in the first week (I: 34.8% C: 22.7%) was not statistically significant, but there was a statistically significant difference between the two groups in terms of physical activity at the end of the 14th week (I: 78.3%, C: 27.3%) ($p < 0.05$). One of the women in the

Table 1 Demographic and obstetric characteristics

	Intervention group $n=23$ (%)	Control group $n=22$ (%)	p-value[a]
Age			
18–34	15 (65.2)	17 (77.3)	.372
35–45	8 (34.8)	5 (22.7)	
Body mass index			
> 18.5	1 (4.3)	-	
18.5–24.9	16 (69.6)	18 (81.8)	.473
25–29.9	6 (26.1)	4 (18.2)	
Number of births			
Nullipar	12 (52.2)	14 (63.6)	.436
Primipar	11 (47.8)	8 (36.4)	
Education			
Secondary school graduate	3 (13.1)	1 (4.5)	.184
High school graduate	13 (56.5)	18 (81.8)	
Graduated from a University	7 (30.4)	3 (13.6)	
Smoking status			
Yes	1 (4.3)	4 (18.2)	.187[b]
No	22 (95.7)	18 (81.8)	
Curettage/abortion			
Yes	5 (21.7)	3 (13.6)	.699[b]
No	18 (78.3)	19 (86.4)	
History of large infants ($n=12$)			
Yes	1 (14.3)	2 (40.0)	.523[b]
No	6 (85.7)	3 (60.0)	
History of GDM in previous pregnancy	1 (4.3)	3 (13.6)	.346[b]
Yes	22 (95.7)	19 (86.4)	
No			
History of diabetes in first-degree relatives			
Yes	5 (21.7)	2 (9.1)	.414[b]
No	18 (71.3)	20 (90.9)	

[a]Pearson's chi-squared test

[b]Fisher's exact test

Table 2 Knowledge difference between intervention and standard care groups before and the end of the intervention

Groups	Knowledge score average		
	Pre-test knowledge score average	Post-test knowledge score average	p-value[a]
	$\bar{X} \pm ss$	$\bar{X} \pm ss$	
Intervention	2.82 ± 1.33	8.43 ± 1.53	.001**
Control	2.91 ± 1.38	3.1 ± .99	.650**
p-value[b]	.838*	.001*	

[a]statistical analysis within group

[b]statistical analysis between groups

*Wilcoxon t test

**Independent samples t test

intervention group (4.3%) started insulin therapy in the first week and this number did not change at the end of the 14th week ($p > 0.05$) (Table 3). In the control group, there was no woman who started insulin in the first week, and 6 women (27.3%) had started to use insulin at the end of the 14th week. The increase in the number of women using insulin in the control group was noted.

There was no significant difference between the two groups in terms of fasting, 1-h postprandial, and 2-h postprandial blood glucose values in the first week and 14th week in the intervention and control groups ($p > 0.05$) (Table 4). In the intragroup comparison of women in the intervention group, there was a decrease in fasting blood sugar at the 1st and 14th weeks (94.0 ± 8.1; 92.1 ± 6.7) but not statistically significant ($p > 0.05$). It was determined that the 1st hour (148.4 ± 19.2; 116.1 ± 13.3) and 2nd hour (132.0 ± 25.6; 110.6 ± 11.0) postprandial blood

Table 3 Difference of adherence to diet physical activity and start insulin therapy between intervention and standard care groups at the beginning and at end of the intervention

	Intervention group ($n=23$)				p-value within group	Control group ($n=22$)				p-value within group	p-value between groups
	First week		14th week			First week		14th week			
	S	%	S	%		S	%	S	%		
Adherence to diet											
Adherence	8	34.8	18	78.3	.002*	6	27.3	9	40.9	.250 *	.586[a]
Non-adherence	15	65.2	5	21.7		16	72.7	13	59.1		.011[b]
Physical Activity Status											
Doing	8	34.8	18	78.3	.002*	5	22.7	6	27.3		.372[a]
Not doing	15	65.2	5	21.7		17	77.3	16	72.7	1.000*	.001[b]
Frequency of physical activity (week)											
2 days in a week	7	87.5	2	11.1	.025**	3	60.0	4	66.7	.317**	.510[a]
3 days in a week	1	12.5	8	44.4		2	40.0	1	16.7		.025[b]
4 days in a week	-	-	8	44.4		-	-	1	16.7		
Duration of physical activity (min/day)											
15	4	50.0	1	5.6	.083**	3	60.0	4	66.7	.317**	
20	4	50.0	10	55.6		2	40.0	1	16.7		1.000[a]
30	-	-	7	38.9		-	-	1	16.7		.006[b]
Start insulin therapy											
Yes	1	4.3	1	4.3	1.00*	-	-	6	27.3	.031*	1.000[a]
No	22	95.7	22	95.7		22	100.0	16	72.7		.047[b]

*McNemar test

**Friedman test

[a]First week differences of intervention and control groups; Pearson's chi-squared test

[b]14th week difference of intervention and control groups; Fisher's exact test

Table 4 Blood glucose values

Blood glucose values	Intervention group ($n=23$)		p-value within group	Control group ($n=22$)		p-value within group	p-value between groups
	First week	14th week		First week	14th week		
	$\bar{X} \pm ss$	$\bar{X} \pm ss$		$\bar{X} \pm ss$	$\bar{X} \pm ss$		
Fasting (mg/dl)	94.0 ± 8.1	92.1 ± 6.7	.140[a]	96.1 ± 7.8	93.8 ± 8.2	.340[a]	*.876 **.772
1-h Postprandial (mg/dl)	148.4 ± 19.2	116.1 ± 13.3	.001[a]	156.8 ± 23.1	126.7 ± 11.9	.001[a]	*.183 **.586
2-h Postprandial (mg/dl)	132.0 ± 25.6	110.6 ± 11.0	.001[a]	140.0 ± 31.4	121.1 ± 13.8	.002[a]	*.206 **.158

[a]Wilcoxon tests

*First week differences of intervention and control groups; independent samples t test

**14th week difference of intervention and control groups; independent samples t test

glucose values also decreased at the 14th week compared to 1st week. and the difference was statistically significant ($p<0.05$) (Table 4). In the intragroup comparison of women in the control group, there was a decrease in fasting blood sugar at the 1st and 14th weeks, (96.1 ± 7.8; 93.8 ± 8.2) but not statistically significant ($p>0.05$). It was determined that the 1st hour (156.8 ± 23.1; 126.7 ± 11.9) and 2nd hour (140.0 ± 31.4; 121.1 ± 13.8) postprandial blood glucose values also decreased at the 14th week compared to 1st week. and the difference was statistically significant ($p<0.05$) (Table 4).

Women in the intervention group stated that the web-based counseling service increased their knowledge level (65%), reduced fear and stress related to the baby and health (65%), motivated them (60%), and increased their physical activity levels (56.5%). Receiving instant answers to their questions made them feel valued (56.5%) (Table 5).

Table 5 Women's satisfaction with the web-based counseling service

Women's expressions ($n = 23$)	*S*	%
Increased my knowledge	15	65
It reduced my fears and anxiety about my baby and myself	15	65
It made me very motivated	14	60
Increased my physical activity level	13	56.5
Getting immediate answers to our questions made me feel valuable	13	56.5
It made easier to adherence my diet	11	47.8
It saved my time	10	43.4
It provided the opportunity to ask all my questions to the health staff	8	34.7
Learning by listening made me not interrupt my daily work	6	26.0
İnformed my family and pleased them	4	17.3
Having phone application provided ease of use	4	17.3
Offered the opportunity to repeat the information as much as I want	3	13.0
It made me feel lucky to be in the program	3	13.0

Discussion

With the development of technology, web-based mobile applications, one of the innovative approaches in the field of health, provide healthcare professionals with new ways to educate patients [20]. These practices are also effective in strengthening self-management skills for disease and raising the level of knowledge [21]. In our study, women in both groups had insufficient knowledge (I: 2.82 ± 1.33, C: 2.91 ± 1.38). Salvi et al. [21] indicated that women had insufficient knowledge about GDM-related risk factors, GDM screening, treatment, and outcomes [22]. In our study, GDM knowledge of the women in the intervention group increased at the end of the intervention and this increase was statistically significant ($p < 0.05$). Although there was an increase for knowledge of women in the control group at the 14th week, this increase was not statistically significant ($p > 0.05$). It is thought that the increase in knowledge of women in the control group is because they had information about GDM in routine care, even if it is not planned education. Previous research stated that web-based education is more effective in increasing knowledge and creating individual behavior changes compared to face-to-face education [23].

Women's compliance with diets given by dietitians is very effective in improving pregnancy outcomes of GDM [24]. In our study, there was no difference in the rates of compliance with diets given by a dietician between intervention and control group in the first week (I:34.8%; C:40.9%). The rate of dietary compliance in the intervention group was higher than the control group in the 14th week (I:78.3%; C:59.1%) and the difference was statistically significant ($p < 0.05$). Miremberg et al. similar to our study results, found that smartphone feedback facilitated compliance with diets given by a dietician for women with GDM [25]. In our study, the probable reason for this result in the intervention group is that women had effective communication with health personnel and discussed the factors that made it difficult to adapt to their diets with health personnel. Also using reminders and receiving feedback may motivate the women, while group discussions with other women on a common platform may affect compliance to diet. Regular physical activity in women with GDM is recommended because of its positive effect on perinatal outcomes [4]. Previous research indicated that web-based mobile applications are effective in increasing physical activity levels [26]. In our study, there was a significant increase in physical activity levels in the intervention group in the 14th week compared to the control group ($p < 0.05$).

The use of digital technologies in GDM management offers women an opportunity to follow blood glucose values from home and share them simultaneously with health personnel without going to the health facility [26]. In our study, there was no significant difference between fasting and postprandial blood glucose levels in the first week and in the 14th week of the study between the intervention and control group ($p > 0.05$). However, although the changes in women's blood sugar were similar, at the end of the treatment 1 patient from the intervention group and 6 women from the control group started insulin therapy. Miremberg et al. reported that web-based mobile applications reduced the rate of initiation of insulin therapy in women with GDM, similar to our results [25]. Possible explanations for this result in the intervention group may be that women entered their blood glucose values into the system regularly and received rapid feedback and individual counseling if they could not manage their blood glucose levels. It is thought that possible reasons that are effective in keeping blood sugars under normal limits; the genetic characteristics of women are different from each other, the predominance of carbohydrate-based diet in our food culture, and the cultural belief that overnutrition during pregnancy will be beneficial for the mother and child. However, in comparisons within the group in both groups, it was determined that there was a decrease in fasting ($p > 0.05$) 1st and 2nd-hour postprandial blood glucose level ($p < 0.05$). This result may be due to the increase in the frequency of perinatal control as pregnancy progresses, the increase in women's adaptation to pregnancy and diabetes, and the development of self-management.

The experience and satisfaction of patients are an important criteria for evaluating the quality of health services [20]. In our study, women were most satisfied because of their increasing knowledge level, reduced fear and stress about their baby and their health, motivation, and increased physical activity levels and making them feel valued. In studies evaluating the satisfaction of women receiving web-based health services, women stated that they spent less time, were motivated, it helped control diabetes, and was easy to use and fun [27].

Strengths and limitations

The strengths of this study include the randomized design. It is the first study which used a smartphone-based intervention for patients with GDM in Turkey. This study has some limitations. The study was done at a single center with a small sample group. Results cannot be generalized to other locations.

Conclusion

In conclusion, the present study provides an important contribution to the literature; a smartphone-based nursing counseling and feedback system can be used for women with GDM and improves health outcomes. In our study, all GDM patients did not report similar benefits; compliance diet and physical activity, knowledge about GDM, and improved glycemic control were better in the intervention arm compared with control group.

Declarations

Conflict of interest The authors declare no competing interests.

Ethical approval Ethical approval was given by Hacettepe University Ethics Commitee (number 16969557-615). Written informed consent was obtained from women after they had agreed to participate in the study.

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