Effect of Educational Package on Self-care Behavior, Quality of Life, and Blood Glucose Levels in Pregnant Women with Gestational Diabetes: A Randomized Controlled Trial

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Abstract

Background: Gestational diabetes is a particular disorder during pregnancy which can cause complications for mother and fetus. One reason for the limited success in the treatment of diabetes is the lack of patient participation in the process of treatment. Self-care education is an important principle in the treatment of diabetes that can enhance the quality of life.

Objectives: This study aimed to determine the effect of educational package on self-care behavior, quality of life, FBS (Fasting Blood Sugar), and GTT (Glucose Tolerance Test) among women with gestational diabetes.

Methods: This randomized controlled clinical trial was performed on 92 pregnant women with gestational diabetes (n = 46 in each group) referring to diabetes clinic of Tohid hospital in Sanandaj, Iran. The educational program was designed in four sessions (one session per week) for the intervention group and included routine prenatal care along with education on self-care through lecture and question and answer. The participants also received educational booklet at the end of the first session. The control group received only routine prenatal care. Before and four weeks after the intervention, self-care and quality of life questionnaires were completed by the participants in both groups, and fasting blood glucose and GTT were measured.

Results: After adjusting for the baseline score, the mean score of self-care behaviors was significantly higher in the intervention group than the control group four weeks after the intervention [adjusted mean difference: 19.5; 95% confidence interval: 14.4 to 24.6; P < 0.001]. Also, by adjusting for the baseline values, there was a statistically significant difference in the mean level of blood glucose at the time points of one hour after GTT [-21.6; -32.1 TO -11.1; P < 0.001] and two hours after GTT [-17.3; -23.0 to -11.6; P < 0.001]. No statistically significant difference was seen in the FBS (P = 0.443) and quality of life (P = 0.264) four weeks after the intervention.

Conclusions: Self-care education can improve self-care behavior in women with gestational diabetes and it is also effective in impaired glucose tolerance.

Keywords: Education, Self-care, Quality of Life, Pregnancy, Diabetes, Gestational

1. Background

Gestational diabetes mellitus (GDM) refers to the extent of glucose intolerance during pregnancy for the first time (1). The World Health Organization has predicted that from 1995 to 2025, the prevalence of diabetes will increase 35% and approximately 3 to 5 percent of pregnant women will face the complications of diabetes (2). A population based study in Canada showed that the risk of diabetes type 2 in patients with GDM increases by 18.9% within 9 years after birth (3). According to a systematic review in Iran, the prevalence of GDM was 3.41% (the highest and the lowest prevalence rates were 18.6% and 1.3%, respectively) (4).

The World Health Organization and Working Group of the International Association of gestational diabetes (IADPSG) in 2013 officially recommended single-stage of OGTT (Oral Glucose Tolerance Test) (two-hour GTT with 75 g glucose) for screening and diagnosis of GDM. The diagnosis of GDM, according to the progress of science, is through OGTT conducted between weeks 24 - 28 of pregnancy using a 75 g oral glucose in non-fasting conditions (5). Clinical diagnosis of GDM is very important and its management includes diet and insulin, if necessary, and taking care of the fetus before birth. Thus, its complications including death, fetal damage, injuries or the number of caesarean delivery and maternal complications such as chronic blood pressure will be lowered (1, 6, 7).

Self-care is a practice in which every person uses his

knowledge, skills and power as a source to independently take care of her/his health (8). The benefits of self-care education in diabetes and other chronic diseases have been significantly proven (9). In general, self-care is affected by attitudes, personal beliefs and community culture in which one lives, and it is a concept that requires further investigation in patients with diabetes. A study has shown that lack of awareness, lack of correct information about the disease, and lack of patients' skill can prevent the disease improvement (10).

Scientifically, quality of life is a concept that considers how human needs are met. It is a measure of perceived satisfaction or dissatisfaction of people with different aspects of life. According to the World Health Organization, quality of life is people's perception of their position in life in terms of culture, value system where they live, goals, expectations, standards, and their top priority; it is quite subjective and cannot be viewed by others because it is based on individuals' perceptions of various aspects of life (11). Quality of life is one of the main concerns of health providers and plays an important role in measuring health status. Being aware of quality of life of people may lead to more effective interventions (12).

In previous studies, the impact of diabetes self-management training has been reported in the prevention of diabetic foot ulcers and reduced hemoglobin A1c amount. Also, it has been shown that quality of life in patients receiving self-care training increased significantly compared to before the intervention (13, 14).

Based on literature review, only one study has focused on this issue during pregnancy in Australia. In this study, pregnancy complications had a significant decrease in pregnant women with diabetes self-care education (6), whereas no study has been performed on this subject in Iran. Considering that the GDM is a major cause of perinatal maternal morbidity and mortality (15) and given the importance of self-care behaviors in the prevention of complications (16) and improvement of quality of life (10) and due to the high prevalence of GDM during pregnancy and its associated adverse effects (2, 4), this study aimed to determine the effect of educational package on self-care behavior, quality of life, fasting blood glucose levels, and GTT in women with GDM.

2. Methods

2.1. Study Design, Participants and Setting

This study is a randomized controlled clinical trial on pregnant women with GDM referring to diabetes clinic of Tohid Hospital in Sanandaj - Iran.

The inclusion criteria were: GDM diagnosed by OGTT between 24 - 28 weeks of pregnancy; singleton pregnancy;

ability to care for self; willingness to participate in research; having at least secondary school education; and no other physical diseases (asthma and heart disease) or any known mental disease.

2.2. Sampling and Randomization

Sampling began after getting the sample code from ethics committee of Tabriz University of Medical Sciences (ethical code: TBZMED.REC.1394.286) as well as proposal registration at the clinical trial registry of Iran (code: IRCT2015080510324N25). The present study was carried out in diabetes clinic of Tohid hospital in Sanandaj - Iran. This clinic is governmental and referral. For sampling, the researcher visited all pregnant women in their 28^{t}h to 30th weeks of pregnancy among those who referred to the diabetes clinic. The women who had impaired two-hour oral glucose tolerance test with 75 g glucose were selected using convenience sampling method. Objectives and methodology of the study were explained by the researcher and their willingness to participate in the study and also the eligibility criteria were assessed. The written informed consent was obtained from those having eligibility criteria. The basic questionnaires including socio-demographic characteristics, self-care behaviors, and quality of life were completed through interview.

Eligible participants were assigned into two groups of intervention (a group receiving educational package) and control by block randomization with block sizes of 4 and 6 and the allocation ratio of 1:1. Randomization was performed by a person not involved in the sampling and data analysis. To this end, the type of offered intervention was written on paper and placed in consecutively numbered opaque envelopes (Allocation Concealment).

Four weeks after the intervention, the questionnaires of self-care behaviors and quality of life were completed by the participants. The blood samples were taken from the participants for the measurement of fasting blood glucose and blood glucose level at time points of one hour and two hours after oral glucose consumption. The samples were sent to the laboratory of Tohid hospital in Sanandaj- Iran.

2.3. Sample Size

Based on information obtained from Sakar and colleagues (17) about self-care behaviors and $m_1 = 62.9$, by considering 20% increase in the self-care behaviors due to the intervention ($m_2 = 75.48$), $sd_1 = sd_2 = 17.3$, $\alpha = 0.05$, and power = 95%, the sample size was determined 42 for each group. Taking into account the probable attrition rate of 10%, the final sample size was 46.

2.4. Intervention

Participants in the intervention group received self-care education on diabetes in four sessions (one session per week) along with routine prenatal care. The sessions were held in the form of lectures and question and answer. Each participant was provided with a booklet at the end of the first session. The definition of diabetes, causes, symptoms, treatment and prevention of complications of the disease with the emphasis on physical activity and proper nutrition were the content of the educational booklet. The educational sessions were in groups of 7 to 14 participants. The control group received only routine prenatal care.

2.5. Data Collection Tools

Data collection tools were socio-demographic characteristics questionnaire, self-care behaviors questionnaire, and Quality of Life Questionnaire for pregnancy (QOL-GRAV).

Socio-demographic characteristics questionnaire included questions on age, education, occupation, and spouse's age, occupation and education, Body Mass Index, family history of diabetes, history of previously diagnosed diabetes, parity and the number of living children.

Self-care behaviors questionnaire was a researcher-made tool composed of 30 questions about physical activity, diet, and medication. The items are scored based on a four-point Likert scale comprising always (score 4), often (score 3), sometimes (score 2), and never (score 1). The total score ranged from 30 to 120, with higher scores indicating better self-care. The validity of the questionnaire was measured by content validity index (CVI) and content validity ratio (CVR) as 0.90 and 0.94, respectively. The reliability of the scale was also assessed through pretest and posttest on 20 participants which gave intra-class correlation coefficient (ICC) and Cronbach's alpha coefficient of 0.95 and 0.76, respectively.

Quality of Life Questionnaire (QOL-GRAV) was created by Vachkova and colleagues in 2013 based on the World Health Organization Quality of Life Questionnaire (WHOQOL- BREF). This questionnaire has nine questions in four dimensions (physical, psychological, social relations and environment) to evaluate individual experiences of the quality of life during pregnancy. The scoring was based on a Likert scale for any item ranging from never (score 0) to absolutely (score 4). The last three questions of questionnaire (questions seven, eight, and nine) have reversed scoring (18). The reliability of the scale in Iran was confirmed by Mirghafourvand et al. (19). Internal consistency of the questionnaire was above 0.7 (alpha = 0.79). In addition, ICC (Internal Consistency Coefficient) was 0.86. In the present study, the reliability of the instrument was assessed by measuring the ICC and Cronbach's alpha that were respectively 0.62 and 0.74.

2.6. Statistical Analysis

The Statistical Package for the Social Sciences (SPSS) version 19 was used for analyses. The normality of quantitative data was assessed using the K-S test which showed that all quantitative variables had normal distribution. Independent T, chi-square, chi-square for trend, and Fisher exact tests were used to assess homogeneity of the groups. To compare self-care, quality of life, fasting blood glucose, and blood glucose level at 1 hour and 2 hours after GTT, the independent t-test was used before the intervention. ANCOVA with adjusting for baseline values was used to compare the results four weeks after the intervention. $P < 0.05$ was considered statistically significant. All analyses were conducted based on intention to treat.

3. Results

Between 18 January 2015 and 20 May 2016, 150 pregnant women with GDM were studied. Fifty-eight women were excluded for not meeting the eligibility criteria. Thus, the remained 92 women participated in the study. They were equally allocated to the intervention and control groups (n = 46 in each group) and were evaluated until the end of the follow-up period (Figure 1).

The mean (SD) age of the participants was 31.0 (5.0) years, while it was 35.0 (5.0) for the spouses. More than half of the participants (54%) had high school education, whereas the majority of the spouses (41%) had university education. Most women (89%) were housewives and over half of husbands (54%) were employees. Almost all women (98%) stated that they had no previously diagnosed diabetes and hypertension. More than three-quarters of participants (77%) did not report any family history of diabetes. Nearly half of women (40%) had two pregnancies and three-quarters of them (71%) had a living child. The mean (SD) body mass index was 27.1 (3.3) kg/m². No statistically significant difference was observed in terms of socio-demographic and obstetric characteristics between the two groups (P > 0.05) (Table 1).

The mean (SD) baseline scores of self-care behaviors were 76.9 (13.4) and 73.1 (13.0) in the intervention and control groups, respectively, while the attainable score was in range of 30 to 120. After adjusting for the self-care behaviors score obtained before the intervention, the results showed that the mean score of self-care behaviors was significantly higher in the intervention group than the control group four weeks after the intervention [Adjusted
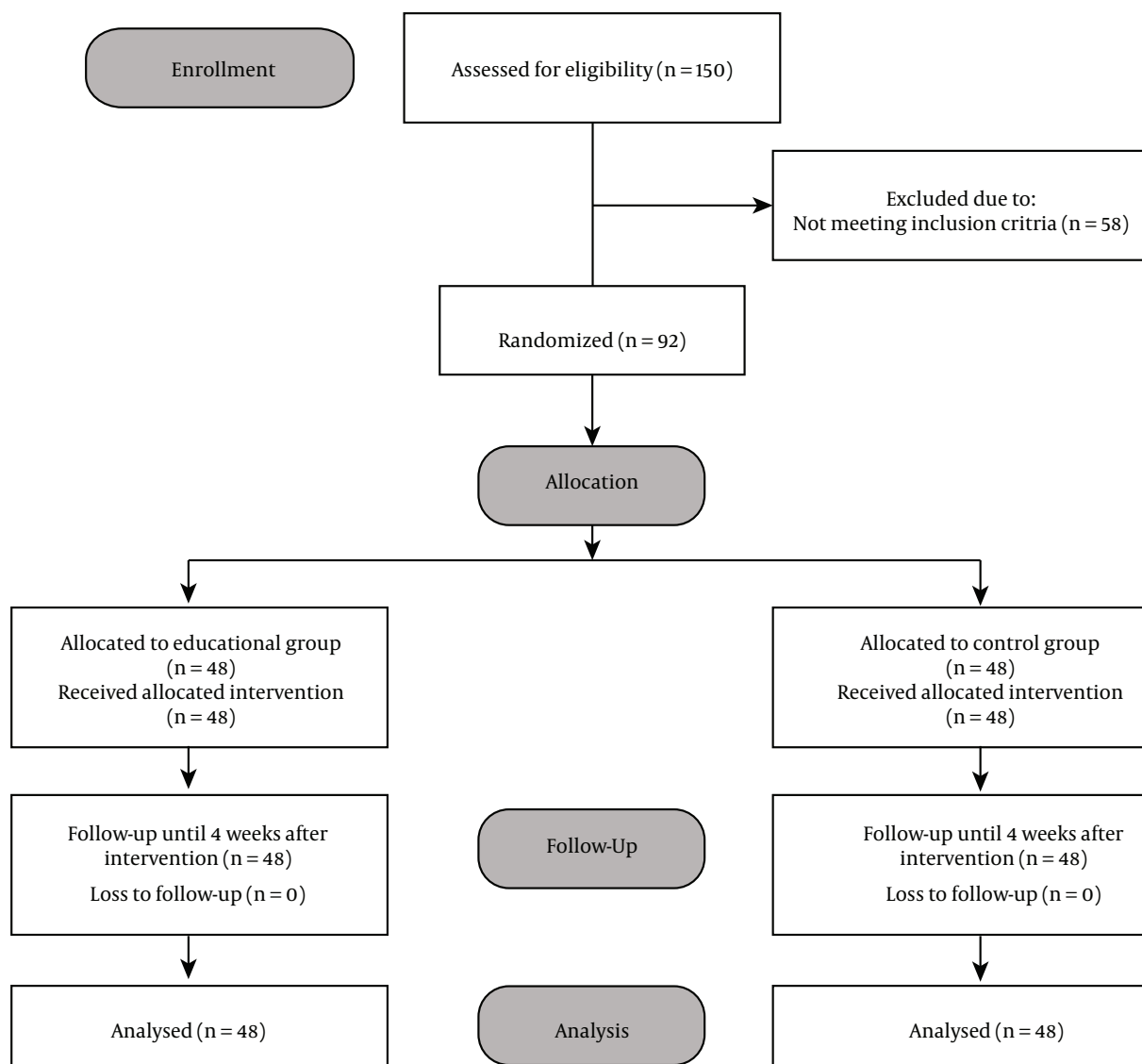
Figure 1. Flowchart of the Study in Women with GDM Referring to Diabetes Clinic of Tohid Hospital, Sanandaj, Iran, in 2015 - 2016

mean difference: 19.5; 95% confidence interval: 14.4 to 24.6; P < 0.001].

The mean (SD) baseline scores of quality of life were 21.4 (4.8) and 19.8 (3. 5) in the intervention and control groups, respectively, while the attainable score was from 0 to 36. After adjusting for the quality of life score obtained before the intervention, no statistically significant difference was observed between the two groups four weeks after the intervention [-0.82; -2.2 to 0.6; P = 0.264].

The mean (SD) baseline levels of fasting blood glucose were 94.0 (9.5) and 92.9 (12.4) in the intervention and control groups, respectively. After adjusting for the baseline values, no statistically significant difference was detected between the two groups four weeks after the intervention [-1.09; -3.8 to 1.7; P = 0.443].

The mean (SD) baseline values of blood glucose at the time points of one hour and two hours after GTT were 177.8 (32.7) and 139.2 (28.3) in the intervention group and 172.1 (34.4) and 136.3 (25.8) in the control group, respectively. After adjusting for the baseline values, a statistically significant difference was observed between the two groups four weeks after the intervention in terms of both values of blood glucose at one hour after GTT [-21.6; -32.1 TO -11.1; P < 0.001] and two hours after GTT [-17.3; -23.0 to -11.6; P <

Table 1. Socio-Demographic and Obstetrics Characteristics of Women with GDM in the Two Study Groups Referring to Diabetes Clinic of Tohid Hospital, Sanandaj, Iran, in 2015 - 2016

Variable	Education (n = 46) N. (%)	Control (n = 46) N. (%)	P value
Age (years)[a]	30.3 (5.1)	31.7 (4.8)	0.979[b]
Education			1.000[c]
Secondary school	2 (4.3)	2 (4.3)	
High school	25 (54.3)	25 (54.3)	
University	19 (41.3)	19 (41.3)	
Job			0.635[b]
Housewife	43 (93.5)	39 (84.8)	
Employee	3 (6.5)	7 (15.2)	
Husband's Age (years)[a]	34.2 (5.4)	35.8 (5.7)	0.635[b]
Husband's Education			1.000[c]
Illiterate	8 (17.4)	9 (19.6)	
Secondary school	20 (43.5)	18 (39.1)	
High school	18 (39.1)	19 (41.3)	
Husband's job			0.817[d]
Unemployed	9 (19.6)	7 (15.2)	
Worker	12 (26.1)	14 (30.4)	
Employee	25 (54.3)	25 (54.3)	
Body Mass Index (kg/m²)[a]	26.7 (3.0)	27.6 (3.5)	0.233[b]
Having familial diabetes	14 (30.4)	7 (15.2)	0.082[d]
Having previously diagnosed diabetes	1 (2.2)	0 (0)	1.000[d]
Parity			0.834[d]
1	14 (30.4)	19 (41.3)	
2	21 (45.7)	16 (34.8)	
3 and more	11 (23.9)	11 (23.9)	
The number of living children			0.331[d]
1	19 (76.0)	19 (67.9)	
2	6 (24.0)	7 (25.0)	
3	0 (0)	2 (7.1)	

[a] Mean (SD).
[b] Independent T-test.
[c] Linear-by-Linear Chi-square.
[d] Chi-square test.

0.001] (Table 2, Figures 2 and 3).

4. Discussion

The findings of this study showed that self-care education can improve self-care behaviors and GTT in women with GDM; however, it had no effect on the quality of life of pregnant women with gestational diabetes and also fasting blood glucose levels.

The results showed that there was a significant difference between the intervention group and the control group in self-care behaviors. Our results are consistent with the results of a study conducted by Jalilean and colleagues. In their study (20), diabetic patients who referred to health centers in Gachsaran city, Iran, were allocated into two groups. In the intervention group, 6 sessions of 60-minute were held as lecture and group discussion for patients and their families. Two months after the intervention, the results showed the positive effect of education on awareness and self-care in the intervention group. Self-care in chronic diseases such as diabetes can greatly reduce the use of resources in the health care system (20). Also, the results of a study conducted in Yzmir, Turkey, revealed that education has a positive effect in terms of adopting healthy lifestyle behaviors by women with gestational diabetes (21). It seems that by enhancing the self-care, complications of pregnancy and postpartum period are prevented. Thus, the implementation of training programs about self-care in women with GDM is recommended.

The results also showed that, there is no statistically significant difference between the intervention and control groups in terms of quality of life. The results of this study are not consistent with those of the study of Saeidpour and colleagues. Saeidpour and colleagues (22) examined 60 diabetic patients by dividing them randomly into two groups. Self-care education was implemented in three one-hour sessions over three weeks for the intervention group. After two months of completion of the intervention, the results showed the positive effect of self-care educational program on quality of life in the intervention group. In the study of Baghianimoghadam et al. (23), the quality of life of people increased after receiving self-care education compared to before the education. Also, in a study conducted by Petkova et al., the results proved that the educational approach has a potential to improve quality of life in women with GDM. Petkova et al. confirmed the need for consistent education of patients, using variety of educational models, as an essential part of diabetes care program that will result in the improvement of patient's quality of life. The results of the mentioned studies are not in agreement with ours (24). Quality of life score in the

Table 2. Comparison of Self-care Behavior, Quality of Life, FBS, and GTT of Women with GDM in the Two Study Groups Referring to Diabetes Clinic of Tohid Hospital in Sanandaj, Iran, in 2015 - 2016

Variable	Education (n = 46) Mean (SD)[a]	Control (n = 46) Mean (SD)	Mean Difference (CI 95%)[b]	P value
Self-Care Behavior Score (30 - 120)				
Before Intervention[c]	76.9 (13.4)	73.1 (13.0)	3.7 (-1.7 to 9.2)	0.534
Four weeks after intervention	97.4 (9.3)	74.6 (14.6)	19.5 (14.4 to 24.6)	0.001
Quality of life score (0 - 36)				
Before Intervention[c]	21.4 (4.8)	19.8 (5.3)	1.6 (-0.49 to 3.7)	0.620
Four weeks after intervention[d]	20.6 (4.06)	20.6 (4.7)	-0.82 (-2.2 to 0.6)	0.264
FBS				
Before Intervention[c]	94 (9.5)	92.9 (12.4)	1.1 (-3.4 to 5.7)	0.620
Four weeks after intervention[d]	90.2 (7.2)	90.7 (10.7)	-1.09 (-3.8 to 1.7)	0.443
GTT				
One hour after GTT test				
Before Intervention[c]	177.8 (32.7)	172.1 (34.4)	5.6 (-8.2 to 19.6)	0.325
Four weeks after intervention[d]	134.5 (25.4)	153.9 (30.6)	-21.6 (-32.1 to -11.1)	< 0.001
Two hours after GTT test				
Before Intervention[c]	139.2 (28.3)	136.3 (25.8)	2.9 (-8.3 to 14.1)	0.610
Four weeks after intervention[d]	120.6 (17.8)	136.2 (23.9)	-17.3 (-23.0 to -11.6)	< 0.001

[a] Standard Deviation.
[b] 95% Confidence Interval.
[c] Independent T-test.
[d] ANCOVA.

mentioned studies was assessed two months after the education, while in our study it was measured four weeks after the intervention. Given that quality of life varies in the long run, so the lack of long-term follow-up of quality of life in our study may be a probable reason for the inconsistent results.

The results of our study showed that there was no statistically significant difference in fasting blood glucose between the intervention group and the control group. Zareban et al. (10) studied 138 patients with diabetes randomly divided into two groups. The intervention group attended 6 educational sessions for a month as lectures, video demonstrations, and discussion. The control group received routine care. Three months following the intervention, no significant difference was observed between the two groups in terms of mean FBS. The results of this study were consistent with those of our study. Tan and colleagues (25) noted in their study that self-care education three months following the intervention could reduce the FBS. The discrepancy between the findings of Zareban et al. study and those of our study could be due to the lack of follow-up three months after the self-care education.

In this study, a statistically significant difference was observed between the two groups in terms of GTT results.

Petkova et al. (24) in a pilot study divided 30 pregnant women with GDM into intervention and control groups and found out that after a month of education, the blood glucose level after GTT was lower in the intervention group than the control group; a finding that is consistent with ours. Increased knowledge and skills of patients after education can promote self-care and hence, improve the condition of diabetes. Continuous monitoring and raising awareness through educational programs can promote behaviors such as exercise, proper diet, etc., and thereby improve the disease (9, 26).

The strength of this study was the observance of the clinical trials principles including randomization and allocation concealment. Using standard, specific questionnaire for assessing the quality of life in participants was another strong point of this study. One limitation of this study was the short duration of follow-up after completion of the intervention. Also, self-care behaviors questionnaire was a researcher-made scale rather than a standard questionnaire. To reduce the effect of this limitation, we determined the indices of content validity (CVI and CVR) and reliability of this questionnaire before starting the study. Therefore, it is recommended to conduct further studies with a long duration and evaluate the outcomes of preg-
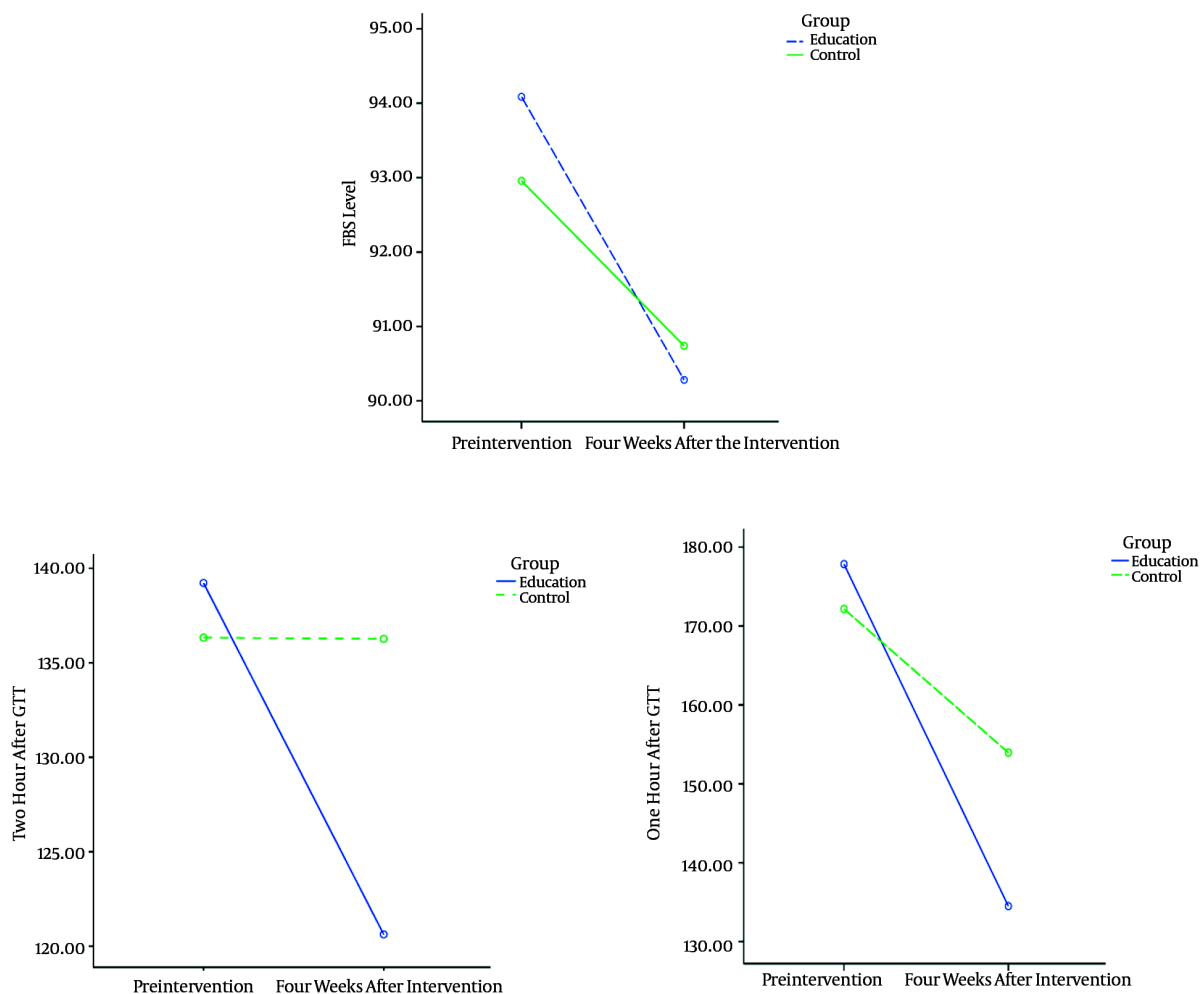
Figure 2. Trend of FBS at one hour and two hours after GTT before and four weeks after intervention according to repeated measurement analysis in women with GDM referring to diabetes clinic of Tohid hospital in Sanandaj, Iran, in 2015 - 2016.

nancy and delivery in this group of women.

4.1. Conclusion

The results of this study showed that self-care education can improve self-care behaviors and impaired glucose tolerance in women with GDM, although it has no effect on the quality of life and fasting blood glucose. Given the importance of GDM and its potential effects on maternal and fetal complications, proper education can increase awareness and improve self-care behaviors and decrease potential complications of GDM.

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Footnote

Conflict of Interest: The authors declare no conflict of interest in this study.

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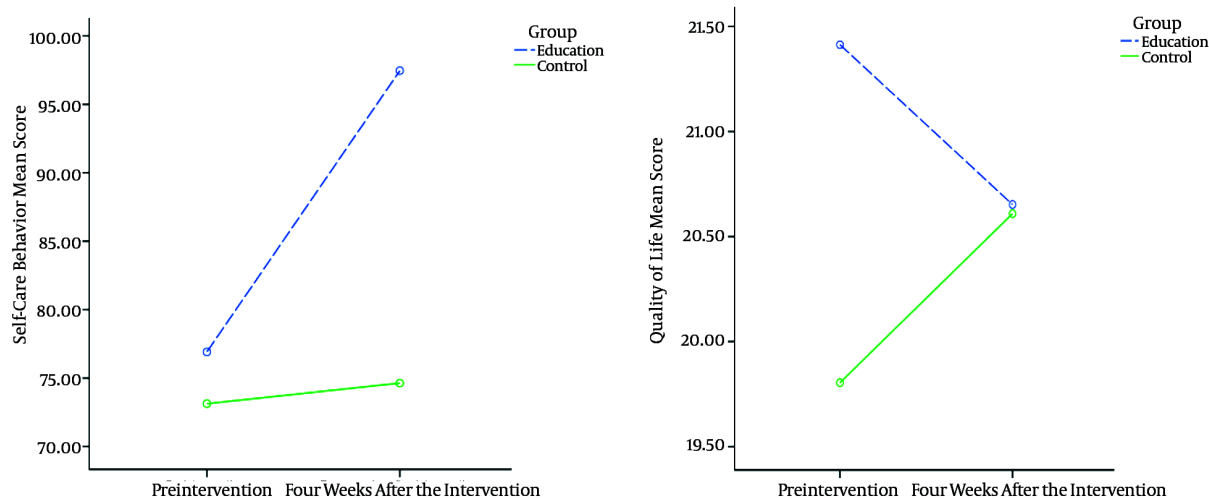
Figure 3. Trend in the mean score of self-care behavior and quality of life before and four weeks after intervention according to repeated measurement analysis in women with GDM referring to diabetes clinic of Tohid hospital in Sanandaj, Iran, in 2015 - 2016.

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