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Health Education in Gestational Diabetes Mellitus and Quality of Life

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ARTICLE INFO	ABSTRACT
<i>Article type:</i> Original article	Background & aim: Incidence rate of gestational diabetes mellitus (GDM) has been estimated to be 18.5%. GDM is associated with various challenges in terms of care and public health. The present study aimed to investigate the effects of health education and
Article History: Received: 09- Oct -2016 Accepted: 19- Jul -2017	behavioral interventions on the quality of life in the patients diagnosed with gestational diabetes mellitus (GDM). Methods : This randomized controlled trial was conducted on 149 eligible participants, who were randomly assigned to the intervention and control group
<i>Key words:</i> Education Gestational Diabetes Mellitus Quality of Life	with the allocation ratio of 1:1. Participants were divided into four groups, including nutrition therapy with and without education and insulin therapy with and without education and insulin therapy with and without education. Follow-up of the patients was performed during 12 weeks (January 2014-April 2015). The educational intervention consisted of various aspects, including diet, exercise, glycemic control, postpartum diabetes control and recommendations for delivery. Primary and secondary outcomes were the effects of the educational intervention on the metabolic control and quality of life, respectively. All the women completed the Iranian version of the Diabetes Quality of Life Brief Clinical Inventory (IDQL-BCI) prior to and after the educational intervention. Data analysis was performed using variance, covariance and Chi-square in SPSS version 15, at the significance level of 0.05. Results: No significant difference was observed between the four groups in terms of the quality of life score in the DQOL-BCL before the educational program. However, this score increased in all study groups, especially in the insulin therapy group (mean difference=16.43). Conclusion: According to the results, health education program could be effective in enhancing health-related quality of life in the women with GDM.

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Introduction

Gestational diabetes mellitus (GDM) is the most important health-related concern in pregnancy in the 21th century (1). In recent years, the prevalence rate of GDM has increased globally (2), with its incidence varying from 1.4% to 18.5% in different countries (3, 4). High prevalence rate of GDM depends on several factors, such as the growing number of diabetic patients, prolonged procreation period, obesity, high-risk ethnic groups, and genetic factors (2, 5).

GDM is associated with significant health issues in the mother and infant (3, 6); therefore, proper screening, diagnosis and management of GDM is greatly important. Treatment of GDM reduces prenatal morbidity and may also improve the health-related quality of life in women (3, 7). Poor quality of life has been reported in almost half the populations with

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diabetes mellitus, and manifestation of diabetes is particularly associated with low quality of life in health-related fields. Considering that the short-term and long-term quality of life is significantly low in GDM patients, proper interventions are required to improve this parameter through promoting illness acceptance and healthy lifestyle behaviors (e.g., telemedicine and educational interventions) (8-11).

Geographical area of residence (i.e., the country where patients live) and the adopted healthcare system could cause discomfort or deteriorate the quality of life in this population. Presence of a specialized medical team dedicated to the care and assistance of diabetic patients and their chronic complications is equally important in this regard (8, 11). Therefore, identifying and controlling the risk factors for decreased quality of life must be considered, which requires adequate knowledge of GDM and commitment to complex self-care behaviors, such as proper glucose monitoring, dietary adjustments, and physical exercise to boost metabolism (2).

Self-management of diabetes plays a key role in the care of women with GDM, including educating the patients for glycemic control and dietary adjustment. According to the literature, self-efficacy is an essential element in the selfmanagement and self-control of gestational diabetes (12). Furthermore, findings of another study demonstrated that lifestyle interventions and self-management programs had the greatest impact on the psychosocial factors and quality of life in the women with prediabetes following GDM (13).

Many factors are involved in the successful outcome of self-efficacy in GDM treatment, and health education is the most important component in this regard. Methods of health education and behavioral improvement could be effective in preventing and controlling diabetes, while also encouraging individuals to change their attitude toward their life style (14, 15).

Self-care consists of the activities that individuals initiate and perform on their own to maintain their quality of life and wellbeing (16). Women with GDM need help with decision-making, behavioral control and acquiring the necessary knowledge and skills for self-care.

The present study aimed to assess the effects of self-efficacy and self-care on the quality of life in the women diagnosed with GDM.

Materials and Methods

This randomized controlled trial was conducted at an endocrinology specialist clinic for the evaluation and treatment of 149 pregnant women at the risk of GDM during January 2014-April 2015. Study protocol was approved by the Ethics Committee of the Islamic Azad University (Karaj Branch), Iran. Moreover, written informed consent was obtained from all the participants prior to the study.

Inclusion criteria were as follows: 1) recent diagnosis of GDM based on an elevated 2-hour 75g oral glucose challenge test (GCT), which was interpreted by an internist in accordance with the American Diabetes Association (ADA) guidelines (2014); 2) absence of severe diabetic complications and other diseases (e.g., asthma, multiple sclerosis, cardiac failure, psychological complications and 3) informed consent to be enrolled in the study. Patients who failed to complete the study were excluded.

All the women with GDM received comprehensive dietary recommendations from a dietician and were instructed on the regular self-monitoring of blood glucose by a nurse trained in diabetes care. In addition, decisions regarding additional insulin therapy or nutrition therapy were based on the ADA 2014 guidelines.

All the participants completed a demographic questionnaire (Table 1), and the eligible women were randomly assigned to the intervention and control groups (randomization was stratified for the clinic). Within each stratum, block randomization with the block size of 4 was used. Random sequence was generated using the RAS software (17).

Participants were divided into four groups of insulin therapy with educational intervention (n=47), insulin therapy control (n=35), nutrition therapy with educational intervention (n=32), and nutrition therapy control (n=35). Antepartum care and educational intervention were conducted by a multidisciplinary team, including a clinician,

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Variable	Mean (SD)	Nutrition Therapy with Education (N=32)	Insulin Therapy with Education (N=47)	Nutrition Therapy without Education (N=35)	Insulin Therapy without Education (N=35)	P-value
Maternal Age (year)	35.46 (5.36)	33.59 (5.10)	35.85 (5.47)	36.54 (6.49)	35.54 (3.76)	.037 @&
Paternal Age (year)	31.84 (5.07)	29.59 (5.21)	32.17 (5.21)	32.89 (5.47)	32.40 (3.77)	.134@
Gestational Age (week)	22.78 (7.95)	23.28 (7.20)	22.36 (7.50)	22.14 (8.74)	23.51 (8.59)	.857@
Paternal Education Level University/High School Diploma	52 (34.9%)	9 (28.1%)	14 (29.8%)	8 (22.9%)	21 (60.0%)	0.004 #
Maternal Education Level University/High School Diploma	54 (36.2%)	10 (31.3%)	17 (36.2%)	6 (17.1%)	21 (60.0%)	.002 #
Occupation Status Housewife Employee	77 (51.7%)	15 (46.9%)	26 (55.3%)	19 (54.3%)	17 (48.6%)	.586 #
Economic Status	42 (28.2%)	6 18.8% ()	18 (38.3%)	8 (22.9%)	10 (28.6%)	.236 #
Abortion Rate	43 (28.9%)	11 (34.4%)	16 (34.0%)	5 (14.3%)	11 (31.4%)	.189 #
History of Gestational Diabetes Mellitus	29 (18.2%)	4(27.3%)	9(30.8%)	8(36.4%)	8(28.2%)	.588 #
Family History of Diabetes Mellitus	76 (51.0%)	14(43.8%)	30(63.8%)	14(40.0%)	18(51.4%)	.143#
Fetal Sex (Male)	50 (51.0%)	15 (65.2%)	15 (53.6%)	8 (40.0%)	12 (44.4%)	.343#

Table 1. Demographic Characteristics of Participants

@: ANOVA for general comparison; &: significant difference between nutrition therapy with education and insulin therapy without education based on Tukey's post-hoc test; #: based on Chi-square using exact P-value; mean (SD) is presented for quantitative variables and N (%) is presented for qualitative variables.

dietitian, nurse educator and an obstetric clinical nurse specialist. It is notable that the patients and statistician were blinded to allocation after randomization

Diabetes and obstetric management protocols were similar for all the study groups. Metabolic goals were fasting blood glucose level of <95 mg/dL and 1-hour postprandial glucose level of <120 mg/dL. Moreover, compliance with the self-monitoring of blood glucose and diet was reassessed at each prenatal visit.

Educational intervention continued for two months, and every session was held for four patients for 45 minutes per week. Considered concepts in the training schedule were the nature of GDM, complications caused by suboptimal disease management (hypoglycemia and hyperglycemia), proper dietary regimen and exercise, self-monitoring of blood glucose (SMBG), maintaining blood glucose in special conditions, guidelines for delivery, and postpartum diabetes control. Women in the control group only received prenatal care without additional training and had no contact with the intervention group.

In the first visit, all the women received individualized consultation regarding their dietary regimen and physical exercise. Educational intervention was performed by the face-to-face and distance learning methods. At the end of each session, a booklet was provided for the pregnant women, which contained the treatment-related issues of GDM.

All the pregnant women had telecommunication with their team practitioner twice per month for two months and were visited by an internist at the end of each month as well. Quality of life in GDM was evaluated using the Iranian version of the Diabetes Quality of Life Brief Clinical Inventory questioner (IDQL-BCI), which is based on the World Health Organization Quality of Life Questionnaire (WHOQOL)-BREF, as well as a study by Mirfeizi M et al. (18).

Internal consistency and test-retest reliability were assessed in 30 patients using Cronbach's alpha and intraclass correlation-coefficient (ICC). IDQOL-BCI in GDM showed good content validity (CVI>0.75 for all the items, CVR>0.99 for all the items), internal consistency (α =0.844>0.7), and test-retest reliability (ICC=0.64).

IDQOL for GDM is a cross-culturally valid and reliable tool with 28 items. In addition, it consists of two sections with 9 and 19 items. Score range of IDQOL-BCI is 28-140 (low quality of life-highest quality of life). In the present study, all the participants completed the questionnaire prior to and after the educational intervention.

Sample size of the study was calculated using the main outcome of the quality of life, the primary data of which were obtained in a pilot study of five participants in the intervention and control groups. Considering 15% of change in the outcome of the intervention group compared to the control group (α =0.05; test power=0.80) and utilizing the G-Power software (ref), sample size was estimated at a minimum of 35 participants per each group. By considering a 30% attrition rate, final sample size increased to 45 subjects per each study group.

Data analysis was performed using mean (standard deviation) and frequency (percentage) for the quantitative and qualitative variables, respectively. Assumption of normal data distribution was assessed and confirmed by the one-sample Kolmogorov- Smirnov test. Comparison of the participants in the study groups of nutrition therapy with education (n= 32), insulin therapy with education (n=47), nutrition therapy without education (n= 35), and insulin therapy without education (n= 35) was carried out using the analysis of variance and Chi-square for the normal quantitative and qualitative data, respectively. Each of the comparisons was followed by a proper post-hoc test where needed. In addition to adjusting the effect of possible confounders and baseline values, analysis of covariance was used for the comparison of the posttest values in the study

groups. All the statistical analyses were performed in SPSS version 15, at the significance level of 0.05.

Results

This randomized controlled trial was conducted on 149 participants, who were randomly allocated to the groups of nutrition therapy with education (n= 32), insulin therapy with education (n=47), nutrition therapy without education (n= 35), and insulin therapy without education (n= 35). Demographic data and clinical characteristics of the patients are presented in Table 1.

Mean maternal age was 35.46±5.36 years, and a significant difference was observed between the groups in this regard. On the other hand, paternal age was not significantly different between the groups (mean: 31.84±5.07 years). Gestational age was equally distributed in the study groups, and mean gestational age of the pregnant women was 22.78±7.95 weeks.

According to the findings, there was a significant difference between the groups in terms of paternal and maternal education level, while no significant differences were observed in the occupation and economic status of the participants. Rate of abortion was equal in the study groups, and no significant difference was observed in the familial history of GDM between the groups. Additionally, fetal sex was equally distrusted among the groups (Table 1). Parameters relating to GDM in the study groups are shown in Table 2.

Baseline measurement of the parameters (before the educational intervention) demonstrated significant differences in the fasting blood glucose (FBG) and 1-hour blood glucose (BG), which were not considered significant for 2-hour BG and HbA1C. Measurements after the educational intervention revealed a significant difference in the 1-hour BG, while the differences were not considered significant for FBG, 2-hour BG and HbA1C. Furthermore, there was no significant difference between the four study groups in terms of the quality of life score in the IDQOL-BCI before the educational intervention.

Compared to the pre-intervention analysis, quality of life score increased in all the groups after diabetes training, with the maximum and

Table 2. Gestational Diabetes-Related Parameters in Stud	y Groups

	Mean (SD)	Nutrition Therapy with Education (N=32)	Insulin Therapy with Education (N=47)	Nutrition Therapy without Education (N=35)	Insulin Therapy without Education (N=35)	P-value	
Fasting Blood Glucose (mg/dL)	99.49 (20.56)	94.59 (17.25)	102.83	93.29	105.69	.023 @	
Before Intervention		(17.25)	(20.83)	(8.26)	(28.24)		
After Intervention	84.87 (5.68)	85.38 (5.86)	81.50 (3.54)			.388 @	
1-h Blood Glucose (mg/dL)	450.05 (00.00)	168.33	189.60	162.21	193.93	.001 @	
Before Intervention	1/9.97 (30.38)	(30.65)	(24.78)	(30.47)	(25.78)	<.001@	
1-h Blood Glucose (mg/dL)	104.05 (07.40)	133.67	123.80	110.40	139.50	< 0.01 @ 9	
After Intervention	124.95 (27.45)	(10.69)	(32.12)	(27.08)	(20.09)	<.001@&	
2-h Blood Glucose (mg/dL)	107 05 (04 00)	132.23	122.27	133.71	128.50	245 @	
Before Intervention	127.33 (24.23)	(35.71)	(16.88)	(27.78)	(23.32)	.345 @	
2-h Blood Glucose (mg/dL)	124 52 (22 12)	131.05	124.19	120.45	125.11	160 @	
After Intervention	124.32 (23.12)	(27.66)	(17.07)	(24.73)	(23.85)	.400 @	
HbA1C% Before Intervention	5.66 (.72)	5.57 (.64)	5.79 (.67)	5.52 (.72)	5.61 (.88)	.637 @	
HbA1C% After Intervention	5.10 (.46)	5.22 (.36)	5.06 (.49)			.376@	

@: ANOVA for general comparison; &: significant difference between all groups based on Tukey's post-hoc test

minimum scores reported in the insulin therapy and nutrition therapy groups, respectively (16.43 versus 7.27) (Table 3).Moreover, there were no significant differences between the groups in terms of the maternal age, baseline BG, and baseline FBG (P>0.05) according to the analysis of covariance adjusted for the baseline measurements (P=0.814).

Table 3. Results of Within-Group Comparison of Quality of Life before and After Intervention in All Study

 Groups

Study Group	Time	Mean	Standard Deviation	P-value \$	P-value @	P-value @@
Exp-Diet	Before Intervention	61.1886	16.90580			
	After Intervention	49.5536	15.76937			
Mean Difference	, P-value#		11.64, <.001			
Exp-Ins	Before Intervention	63.5258	15.09726	-		
	After Intervention	47.0935	12.74231			
Mean Difference, P-value#			16.43, <.001		0.120	0.014
Cont-Diet	Before Intervention	59.1071	19.70816	0.239	0.130	0.814
	After Intervention	51.8367	17.64573			
Mean Difference, P-value#			7.27, <.001	_		
Cont-Ins	Before Intervention	59.2347	17.40357	-		
	After Intervention	50.2296	15.17138			
Mean Difference, P-value#			9.01, <.001			

#: P-value based on paired t-test for within-group comparisons; **\$:** P-value based on analysis of variance for between-group comparisons at baseline; **@:** P-value based on analysis of covariance for between-group comparisons after intervention (adjusted for baseline measurements); **@@:** P-value based on analysis of covariance for between-group comparisons after intervention (adjusted for baseline measurements, maternal age, baseline BG and baseline FBG. In all study groups, there was a significant increase in the score of quality of life in after intervention, compared to baseline measurements (P<0.05).

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Discussion

The present study aimed to investigate the effect of self-efficacy and self-care training on the quality of life in the women with GDM, as well as the impact of the treatment type on their quality of life. With the Cronbach's alpha of 0.88, IDQOL-BCI was a proper tool to evaluate the quality of life in GDM women, and this is consistent with another study in this regard (18).

In the validation of IDQOL-BCI, total score was correlated with the full DQOL scale, individual DQOL, subscales, self-care behaviors, satisfaction with diabetes control, diabetic complications, and type of treatment, suggesting that this questionnaire could explain most of the variations in the total scores of DQOL.

In the present study, effects of the intervention on the score of quality of life, FBG, and 1-hour BG were demonstrated. There are scarce conflicting data regarding the effect of GDM on the quality of life. In the study of Langer et al., no differences were found between the psychological profiles of GDM and normal pregnant women, and the findings were confirmed by Spirito et al., who suggested that most pregnant women are able to cope with an unexpected diagnosis of diabetes during pregnancy (19-21). On the other hand, M. G. Dalfra et al. believed that pregnancy is associated with a perception of poor general health in women with both type 1 diabetes mellitus and GDM (22).

In a long-term study, Feig et al. reported that women affected by GDM in Canada have lower health-related quality of life (HRQOL) within 2-5 years after delivery (23). However, the results obtained by Danyliv et al. suggested that GDM diagnosis does not have an adverse effect on the HRQOL within 2-5 years after index pregnancy. On the contrary, GDM diagnosis might lead to the development of coping strategies (i.e. proper treatment and monitoring of glucose levels), which may consequently attenuate the adverse effect of postpartum abnormal glucose tolerance on the HRQOL (24).

In order to reduce maternal and fetal complications and improve their quality of life, it is reasonable to help patients learn proper coping strategies and resolve the issues caused by the illness. To this end, self-care training and self-management education are necessary. Therefore, we evaluated the role of self-care education during pregnancy on the HRQOL of GDM patients.

There are abundant literature on diabetes education and its effectiveness in type 1 and 2 diabetes. Diabetes self-management education (DSME) and education intervention can certainly improve the knowledge levels in this regard. Although the relationship between knowledge and behavior is unclear, a minimum threshold of knowledge is probably required for optimal self-management.

Self-management education improves the short-term and long-term outcomes of diabetes, such as quality of life (25). Educating the subjects about the disease, its complications and treatment will go a long way in improving the quality of life (26). Furthermore, self-management education is cost-efficient for diabetes patients and their families (27) According to some studies, proper treatment and education plans help women with GDM in their self-care and childcare skills (10).

DSME provides a better understanding of diabetes and its complications. In a cohort study, Karen Cauch Dudack observed that only one in five individuals with nearly-diagnosed diabetes in the publicity funded healthcare system of Ontario attended a DSME program. Younger patients were more likely to attend the educational program compared to the older patients (27).

Diagnosis of GDM causes distress and anxiety in the affected women (28). Women with a history of GDM are at the lifelong risk of developing type 2 diabetes mellitus, the rate of which exceeds 70% (4). Pregnant women with diabetes feel stressed when they see the burden of the disease on their families. There is a close correlation between anxiety and learning, which is even higher in the event of immediate diagnosis (29). In order to overcome this problem, providing patients with the diseaserelated information is essential (8). GDM experiences in some women show that continuous care may provide further psychological support for the patients, so that they could adopt the proper mindset and attitude needed for adapting to and overcoming their GDM diagnosis (30).

An important finding of the present study

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was that effective education is of paramount importance. Targeted education should be provided for the families of the women diagnosed with GDM as a form of social support. Moreover, diabetes educators should be involved in the related problem-solving.

In the research conducted by Lapolla, it was claimed that cooperation between diabetic specialists and gynecologists was unsatisfactory (25%), which undermines the pivotal role of these professionals in diabetes care (8). According to Petkova et al., GDM education in pharmacy conductions enhances the global knowledge on GDM and GDM-associated quality of life in the patients (15). In a related study, role of the nursing staff in the implementation of educational plans was reported to be of great importance (16).

Gestational diabetes prevention program is expected to decrease the overall risk of diabetes in the future (28). Extensive research shows that the effective treatment of GDM reduces severe perinatal morbidity and improves HRQOL in the antenatal and postnatal periods, which is also associated with the lower incidence of depression (31).

Education is the first step to diabetes treatment. Women with GDM diagnosis need help with decision-making, behavior control and acquiring the necessary knowledge and skills (27). In the present study, we assessed the effects of factors such as type of treatment (insulin or nutrition therapy) and education on diabetes-related quality of life and metabolic control. In this regard, Trutnovsky et al. reported that the initial treatment motivation, satisfaction with treatment and wellbeing of the patients increased toward the end of pregnancy, especially in the women receiving insulin Additionally, providing adequate therapy. information through proper training could help the GDM women overcome fear of injection (16).

The main strengths of the current study were the prospective design, evaluation by comprehensive qualitative/quantitative methods and use of a recent, validated questionnaire with high reliability to assess the quality of life in the Iranian women with GDM diagnosis. IDQOL-BCI is a measure of diabetic-specific quality of life, which has been modified for the Iranian patient populations (18). Data of the study facilitate the identification of specific care dimensions (e.g., educational interventions) in order to improve the quality of life in the women diagnosed with GDM. Moreover, the findings could predict certain maternal and fetal outcomes. It is advisable to employ a multidisciplinary healthcare team to encourage better communication between diabetic patients and care educators.

One of the limitations of the study was the small sample size and lack of postpartum data, such as maternal and fetal outcomes. In addition, a proper dietary regimen or regular exercise plan could not be maintained. Our findings may be helpful in reducing psychological distress and improving the quality of life and treatment compliance in the women with GDM. It is suggested that longitudinal prospective studies be conducted on larger sample sizes in multiple clinical centers by collecting the postpartum data.

Conclusion

According to the results, educational interventions for the women with GDM could enhance the patient's health status and perceived ability to control disease outcomes, thereby increasing their quality of life. Use of effective quality of life measures is essential to evaluating the outcomes and treatment of GDM.

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Conflicts of interest

Authors declared no conflicts of interest.

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