



## The Effect of Oat Bran Supplement on Fasting Blood Sugar and Glycosylated Hemoglobin in Patients with Gestational Diabetes Mellitus: Single-blind Randomized Clinical Trial

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### ABSTRACT

**Background:** Gestational diabetes mellitus (GDM) is known as a degree of glucose intolerance that occurs for the first time during pregnancy. There is paucity of evidence regarding the effect of oat bran on GDM. Oat as a source of  $\beta$ -glucan can be effective in reducing the blood sugar levels. This study aimed to investigate the effect of oat bran on fasting blood sugar (FBS) and glycosylated hemoglobin (HbA1c) in patients with GDM. **Method:** This single-blind clinical trial was conducted on 90 pregnant women with GDM. The experimental group (EG) consumed 30 g of oat bran daily with 100 g of low-fat yogurt before lunch and dinner for 4 weeks. The control group (CG) consumed only low-fat yogurt and both groups received nutrition counseling. The present study investigated the FBS, HbA1c, and weight gain at the beginning and after four weeks of intervention. **Results:** Out of 90 patients, 80 completed the study. FBS decreased in the EG ( $P = 0.04$ ,  $-2.75 \pm 8.22$ ), whereas, it increased in the CG ( $P = 0.003$ ,  $4.37 \pm 8.72$ ). No significant difference was observed between the two groups in terms of HbA1c levels. Weight gain was controlled more efficiently in the EG than the CG ( $P = 0.001$ ). **Conclusion:** The use of oat bran for four weeks decreased the FBS; whereas, it did not affect HbA1c levels. Weight gain was controlled better in the EG than the CG.

**Keywords:** Diabetes; Pregnancy; Gestational diabetes mellitus;  $\beta$ -glucan; Blood glucose.

### Introduction

Gestational diabetes (GDM) is known as a degree of glucose intolerance, which occurs for the first time during pregnancy (Association, 2014). The prevalence of GDM fluctuated

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between 1.7- 11.6percent in different studies (Viana *et al.*, 2014). Today, the increasing trend of obesity in women is associated with the increase of GDM incidence (Jarmuzek *et al.*, 2015). Studies showed that GDM caused many complications in the mother and fetus (Bellamy *et al.*, 2009a, Gilmartin *et al.*, 2008, Gunderson *et al.*, 2014, Metzger *et al.*, 2008). The main complication of the disease is the birth of a large baby regarding the gestational age. High birth weight is associated with birth trauma, infant hypoglycemia and respiratory distress syndrome (Jarmuzek *et al.*, 2015), hypercalcemia and polycythemia (Jonsdottir, 2009), child obesity (Wei *et al.*, 2007), cardiovascular disease and atherosclerosis (Gunderson *et al.*, 2014, Wang *et al.*, 2007), and diabetes (Wei *et al.*, 2007) in the next years of the child's life. Shortly after the delivery, mother's glucose levels return to the normal rate, but the risk of developing postpartum type2 diabetes is seven times higher in women with GDM(Bellamy *et al.*, 2009b). Although various treatments are suggested for GDM, nutritional control seems to be the first solution (Asemi *et al.*, 2013, Moreno-Castilla *et al.*, 2016). The most important part of the nutritional intervention for controlling the hyperglycemia is reducing the consumption of refined carbohydrates and increasing the consumption of fiber from various sources, such as oat bran, green leaves, etc. (Brennan, 2005, Raninen *et al.*, 2011). Some studies indicated that a carbohydrate-restricted diet was effective on metabolic control (Acheson, 2010) and resulted in better pregnancy outcomes (Lim *et al.*, 2007) in women with GDM. In addition, a low glycemic index (LGI) diet was considered as a strategy to manage GDM (McGowan and McAuliffe, 2010). Several studies reported the improvement of lipid profiles with the use of oat bran (Berg *et al.*, 2003). Consumption of oat bran (for four weeks) led to a significant increase in HDL-c and a decrease in the total cholesterol in obese postmenopausal women (Robitaille *et al.*, 2005). A meta-analysis showed that daily intake of approximately 3 g of soluble fiber from oat-

containing products reduced the plasma total cholesterol in hyperlipidemic and normolipidemic individuals (Ripsin *et al.*, 1992). It was also reported in another meta-analysis that receiving 3g or higher amounts of  $\beta$ -glucan in the oats reduced the LDL-c and total cholesterol levels without altering the HDL-c and triglyceride levels (Whitehead *et al.*, 2014). Oat bran reduced glucose levels after eating in both humans and animals (He *et al.*, 2016, Montminy and Galibois, 1994). The hypoglycemic and hypolipidemic effects of the oat bran are due to the presence of  $\beta$ -glucan (Kerckhoffs *et al.*, 2003).  $\beta$ -glucan in oats is useful for the treatment and prevention of type 2 diabetes (Braaten *et al.*, 1994, Tapola *et al.*, 2005).  $\beta$ -glucan can cause positive changes in the blood sugar and insulin response after consuming glucose (Wood *et al.*, 2000). Despite many human studies and the fact that oat fiber compounds are almost different from other fibers, the effect of oat bran on pregnant women with GDM has not yet been studied. This study aimed to investigate the effect of the consumption of oat bran on fasting blood sugar (FBS), HbA1c, and weight changes in patients with GDM.

### Materials and Methods

*Type of study and participants:* This single-blind clinical trial was conducted on 90 patients aged 20 to 40 years with GDM in the Imam Ali Clinic in Yazd, from December 2014 to September 2015. The inclusion criteria were the diagnosis of GDM by an endocrinologist based on the protocol (Metzger *et al.*, 2010) (FBS of greater than 92 mg/dL, blood sugar higher than 180 mg/dL one hour after taking 75 g glucose, and blood sugar greater than 153 mg/dL two hours after consuming 75 g glucose in two consecutive experiments). The oral glucose tolerance test (OGTT) was performed after consuming 75 g of glucose by all the participants who enrolled in the study. The inclusion criteria consisted of lack of heart, liver, kidney diseases, andhypertension problems, willingness to participate in the study, non-participation in other research projects, lack of smoking, lack of

excessive activity, lack of fiber supplementation (such as fiber clear or similar products), and non-compliance with other diets. The exclusion criteria were the presence of severe nausea and vomiting during pregnancy, a history of cancer/ celiac disease or other digestive diseases, allergic reactions to oats, twin pregnancy, breastfeeding in the past three months, hypertriglyceridemia-inducing syndromes (familial hypercholesterolemia), the presence of hypercholesterolemic syndromes, pre-pregnancy diabetes, and individuals who consumed less than 80 percent of the oat bran packs. Among those referring to the clinics affiliated to the Yazd University of Medical Sciences, 100 patients were eligible to enter the study.

Patients were randomly assigned to experimental (EG) and control groups (CG) using a random number table in each treatment group. The EG received 30 g of oat bran per day in addition to the nutritional counseling. The CG received only nutritional counseling. The oat bran supplement was purchased from Jam Noore Talaie Co. (Tehran, Iran). In order to remove the interfering effect of insulin or metformin, the group who needed insulin or metformin treatment was initially put on a two-week run-in period. Then, the participants with GDM received the recommended treatment regimen during the period mentioned above. When the insulin levels reached the fixed levels.

The CG and the EG received 100 g of low-fat yogurt and 100 g of low-fat yogurt plus 15 g of oat bran (a total of 30 g per day) before lunch and dinner, respectively. Allocation concealment was carried out using envelopes, in which the individual's group, A or B, was written on a piece of paper and placed inside the envelope. The individual's row number was also written on the envelope.

The dietary adherence rate was measured using the food frequency questionnaire that was completed by the nutritionist at each visit. Patients were also asked to bring in the unused packages of the bran during each visit (every two weeks) so that their consumption rate could be accurately measured. The patients were also given

the supplements supposed to be consumed during the next two weeks; the participants were monitored via telephone weekly during the study period. A table was also designed and provided to the patients to mark their consumption in the related cell. The adherence rate was estimated at 85 percent. Patients were advised to avoid changing their physical activity during the intervention. After the end of the four-week period of the study

*Measurements:* A form containing demographic and anthropometric indicators such as age, height, weight, gestational age, type of treatment, etc. were obtained from the patients. In order to investigate the individuals' diet status, a 24-hour dietary recall (24HR) was also taken from them. The patients were referred again to the laboratory for experiments the end of intervention. In order to control diet changes, anthropometric indices and 24HR were obtained from the patients after the intervention. The level of physical activity was measured using Iranian version of international Physical Activity Questionnaire (Moghaddam *et al.*, 2012). Blood samples were taken to determine the FBS and HbA1c levels after 12 hours of fasting. The FBS levels were measured using an enzyme colorimetric method based on the glucose level and by an auto-analyzer. The HbA1c levels were measured using the ion exchange chromatography.

*Data analysis:* The dietary intake and data analyses were performed by the Nutritionist IV and SPSS ver. 18, respectively. The Kolmogorov-Smirnov test was run to determine the distribution of the quantitative data. The paired *t-test* was applied to determine the significant differences at different times between the groups. The student *t-test* and ANCOVA were used to compare the changes of the continuous variables between the two groups. The confounders adjusted in the present study were changes in the energy and fiber intake, treatment protocol, and the third trimester of pregnancy. Furthermore, the Pearson chi-square test was used to compare the qualitative variables between the two studied groups. The data were reported as Mean  $\pm$  SD,

frequency, and percent. Moreover,  $P < 0.05$  was considered as the significance level.

**Ethical considerations:** The subject, purpose, and method of the study were explained to all the participants by the researcher. Then, in the case of participants' willingness to cooperate in the study, they were asked to sign the written informed consent forms. To the best of our knowledge, no studies have ever been conducted on the adverse effects of bran and fiber on pregnant women (Afaghi *et al.*, 2011). The proposal of this dissertation was presented at the Ethics Committee of the Vice-Chancellor of Research and Technology in Shahid Sadoughi University of Medical Sciences in Yazd in March 2014. This study was also ethically permitted with the Ethics Code of "164964/1/17 C". It was also registered in the Clinical Trials website of the Vice Chancellor for Research and Technology, Ministry of Health and Medical Education of Iran ([www.irct.ir](http://www.irct.ir)) with IRCT2014112720114N1 code.

## Results

Of the 100 patients who were enrolled in the study, five, two, and three individuals were excluded due to reluctance to cooperate, unreasonable abortion, and other reasons, respectively. Consequently, a total of 90 individuals cooperated in the study, 10 of whom (five individuals from each group) were excluded during the intervention period due to personal reasons, lack of cooperation, and traveling. Finally, the data of 80 respondents were analyzed (**Figure 1**). Details of the primary characteristics of the patients are presented in **Table 1**. A total of 40, 20, and 20 patients were treated with the insulin (50%), metformin (25%), and treatment regimens (25%), respectively. None of the patients had diabetes before pregnancy. A total of seven (17.5%), 19 (47.5%), and 14 (35%) patients

in the EG were in the first, second, and third trimester of pregnancy, respectively. A total of eight (20%), 17 (42.5%), and 15 (37.5%) patients in the CG were in the first, second, and third trimester of pregnancy, respectively. We observed no significant difference between the two groups in terms of indices except for the patients' height ( $P = 0.02$ ). The level of physical activity in women with GDM was not significantly different between the two groups ( $P = 0.9$ ).

The daily intake of energy and consumption of some nutrients before and after the intervention are shown in **Table 2**. The results show a significant difference between the two groups in terms of the fiber intake ( $P < 0.005$ ).

As represented in **Table 3**, the weight gain was more evident in the CG than the oat bran group. In addition, changes in the mean weight, energy and fiber intake, treatment protocol, and the third trimester of pregnancy were significantly lower in the EG than the CG ( $P = 0.001$ ). An increase was observed in the mean body mass index (BMI) of the CG at the end of the study ( $P < 0.005$ ). The decrease in the mean fasting blood sugar levels was significant ( $P = 0.04$ ) in the EG (**Table 3**). The increase in the mean FBS levels was also significant in the CG ( $P = 0.003$ ). We adjusted for the difference in the initial concentration of the FBS level and by controlling the initial level, changes in the energy and fiber intake, the treatment protocol, and the third trimester of pregnancy. The results of ANCOVA on changes of the FBS indicated a significant statistical difference between the two groups ( $P = 0.006$ ). As shown in **Table 3**, no significant difference was observed in the mean HbA1c level for the EG at the end of the study ( $P = 0.3$ ). However, a significant difference was seen between the two groups at the end of the study ( $P = 0.05$ ).

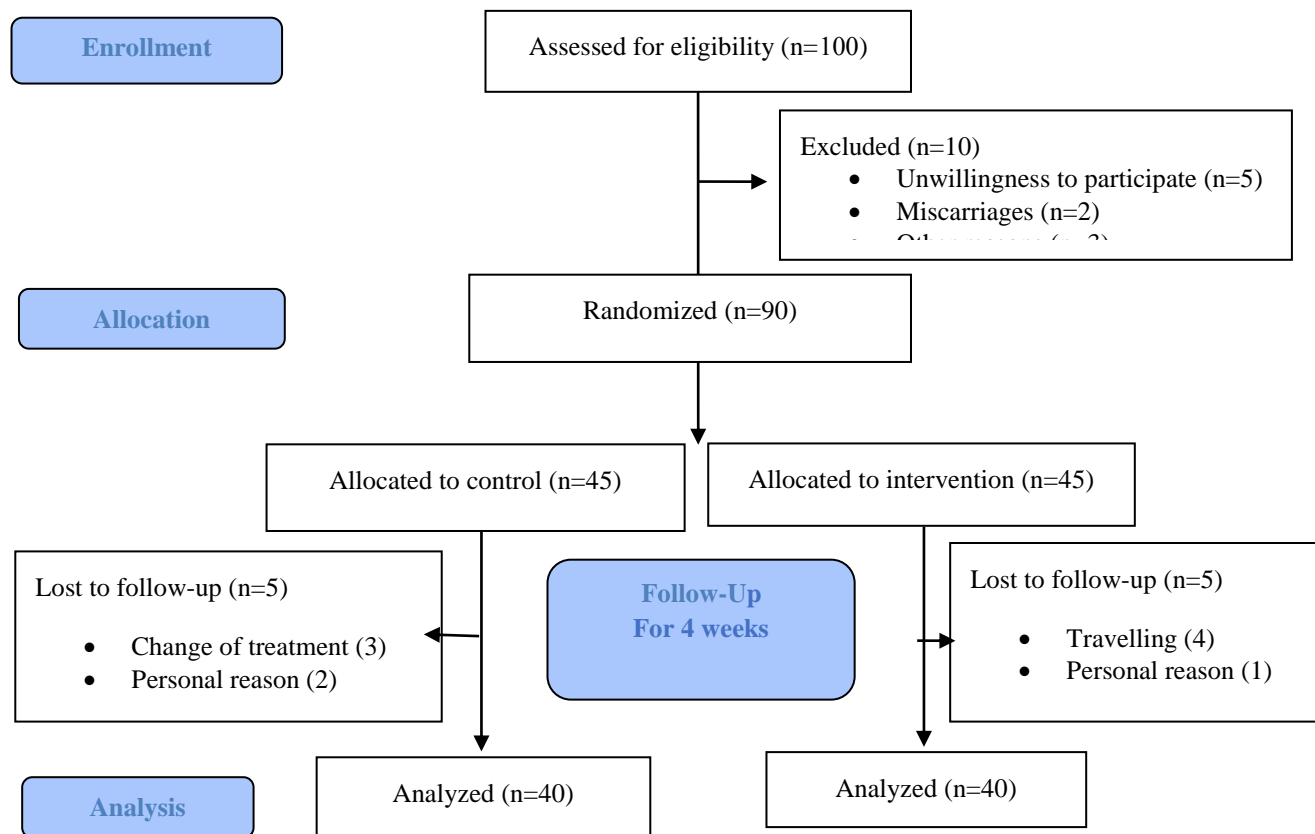


Figure 1. Flow chart of the study

Table 1. Primary characteristics of patients

Variables	Experimental group (n = 40) Mean ± SD	Control group (n = 40) Mean ± SD	P-value <sup>a</sup>
<b>Quantitative variables</b>			
Age (year)	29.26 ± 4.60	28.57 ± 5.17	0.50
Height (m)	1.58 ± 0.05	1.60 ± 0.05	0.02
Weight (kg)	74.30 ± 13.24	76.54 ± 13.24	0.40
Pre-pregnancy weight (kg)	71.35 ± 13.68	72.50 ± 13.73	0.70
Body mass index Pre-pregnancy (Kg/m <sup>2</sup> )	28.50 ± 4.92	28.30 ± 5.21	0.60
Gestational age (week)	20.47 ± 5.57	20.15 ± 8.26	0.80
Physical activity (MET / week)	5003.26 ± 1533.18	5028.90 ± 2417.08	0.90
<b>Qualitative variables</b>			
	Number (%)	Number (%)	
<b>Undergoing treatments</b>			
Insulin	20 (50)	20 (50)	1.0 <sup>b</sup>
Metformin	10 (25)	10 (25)	
Treatment regimen	10 (25)	10 (25)	
<b>Trimester of pregnancy</b>			
First	7 (17.5)	8 (20.0)	0.8 <sup>b</sup>
Second	19 (47.5)	19 (42.5)	
Third	14 (35.0)	15 (37.5)	

<sup>a</sup>:Student *t*-test; <sup>b</sup>: Chi-square test

**Table 2.** Comparison of the mean of daily intake at the beginning and at the end of the study between the two groups

Variables	Experimental group (n = 40) Mean ± SD	Control group (n = 40) Mean ± SD	p-value <sup>b</sup>
Energy (kcal)			
Before	1420 ± 229	1533 ± 291	0.061
After	1358 ± 249	1532 ± 302	0.007
Changes	-62 ± 167	-1 ± 183	0.132
p-value <sup>a</sup>	0.028	0.962	
Carbohydrate (g)			
Before	196.20 ± 43.64	186.21 ± 34.43	0.267
After	194.97 ± 43.55	185.21 ± 34.21	0.276
Changes	-1.23 ± 1.08	-1.00 ± 0.66	0.259
p-value	<0.005	<0.005	
Protein (g)			
Before	62.67 ± 13.36	54.64 ± 11.47	0.006
After	62.32 ± 13.29	54.10 ± 11.34	0.004
Changes	-0.79 ± 0.57	-0.64 ± 0.49	0.257
p-value	<0.005	<0.005	
Fat (g)			
Before	56.71 ± 16.57	45.19 ± 16.78	0.003
After	55.59 ± 16.39	44.55 ± 16.71	0.003
Changes	-0.79 ± 0.57	-0.64 ± 0.49	0.222
p-value	<0.005	<0.005	
Fiber (g)			
Before	10.09 ± 3.12	12.75 ± 3.18	<0.005
After	17.68 ± 2.00	14.20 ± 2.10	<0.005
Changes	7.59 ± 2.75	1.44 ± 2.05	
p-value	<0.005	<0.005	

<sup>a</sup>: Paired *t*-test; <sup>b</sup>: Student *t*-test

**Table 3.** Comparison of the mean fasting blood sugar, glycosylated hemoglobin A1c, weight, and body mass index at the baseline and the end of the study between the two groups

Variables	Before	After	Changes	p-value <sup>a</sup>
<b>Control group (n =40)</b>				
Fasting blood sugar (mg/dL)	81.75 ± 10.36	86.12 ± 9.44	8.72 ± 4.37	0.003
Glycosylated hemoglobin A1c (%)	5.5 ± 0.5	5.2 ± 0.7	-0.3 ± 0.6	0.06
Weight (kg)	76.54 ± 13.24	78.32 ± 13.11	1.7 ± 1.5	<0.005
Body mass index (kg/m)	29.59 ± 5.04	30.29 ± 5.05	0.69 ± 0.61	<0.005
<b>Experimental group (n =40)</b>				
Fasting blood sugar (mg/dL)	87.47 ± 7.90	84.72 ± 9.52	-2.75 ± 8.22	0.04
Glycosylated hemoglobin A1c (%)	5.7 ± 0.7	5.5 ± 0.7	-0.02 ± 0.7	0.3
Weight (kg)	74.30 ± 13.24	74.75 ± 12.97	0.44 ± 1.55	0.07
Body mass index (kg/m)	29.69 ± 4.68	29.87 ± 4.81	0.17 ± 0.62	0.08

<sup>a</sup>: Paired *t*-test

### Discussion

The present study showed that the consumption of oat bran by patients with GDM caused a decrease in their FBS levels. However, it caused no

significant difference in the level of HbA1c glycosylated hemoglobin. On the other hand, the consumption of oat bran led to a better control of the weight gain of diabetic pregnant mothers and,

consequently, improved their BMI status. The present research was the first clinical study on the effects of oat bran on GDM. Recent studies indicated the effect of oat bran and  $\beta$ -glucan on diabetic patients (Afaghi *et al.*, 2013, Boulet *et al.*, 2003, Chen and Raymond, 2008, Group, 2006, Gupta *et al.*, 2004, Hernandez-Cordero *et al.*, 2008, Tapola *et al.*, 2005). The findings of Pick *et al.*'s study, which are similar to those of the present study, showed that the insulin and glycemic responses were improved in eight men with type2 diabetes who consumed nine grams of oat bran for 12 weeks (Pick *et al.*, 1996). In another study, Grove *et al.*, showed that the fasting blood sugar levels were improved after consumption of 20gr of oat bran after for eight weeks (three grams of  $\beta$ -glucan) (Lovegrove *et al.*, 2000). This effect can be explained by a possible mechanism: the viscosity of food increases inside the stomach (bolus) after consuming soluble fiber, which leads to an increase in the duration of gastric emptying and an increase in the bowel transit time (Wood, 2007). Moreover, a diet rich in fiber with low glycemic load causes a delay in the digestion and absorption of carbohydrates and thus, improves the fasting blood sugar status (Afaghi *et al.*, 2013, Battilana *et al.*, 2001). The effect of  $\beta$ -glucan can be explained by a possible mechanism: dosage, viscosity, and the formation of a gelatinous layer by  $\beta$ -glucan prevent from glucose uptake by enterocytes (Rebello *et al.*, 2013, Reyna *et al.*, 2003, Wood, 2007).  $\beta$ -glucans (and other soluble fibers) are known to slow down the blood sugar and insulin concentrations after taking a meal in both healthy people and people with type 2 diabetes (Tappy *et al.*, 1996). Cugnet-Anceau *et al.* showed that there was no change in the HbA1c levels among 53 patients with type 2 diabetes who consumed 3.5gr of  $\beta$ -glucan and had a normal diet for two months (Cugnet-Anceau *et al.*, 2010). In addition, taking breakfast with LGI rather than breakfast with HGI over a four-week period had no effect on the HbA1c level in 13 men with type 2 diabetes (Kabir *et al.*, 2002). Considering a 10-week meta-analysis, Brand-Miller *et al.* indicated that prescribing a LGI diet instead of a HGI diet

had significantly decreased the HbA1c levels in people with type1 and type2 diabetes (Brand-Miller *et al.*, 2003). Despite the decrease in the HbA1c levels from  $5.72 \pm 0.79$  to  $5.61 \pm 0.48\%$ , this decrease was not significant. The possible mechanism for explaining this effect can be related to the duration of the intervention; it seems that the four-week period is insufficient to make changes in the HbA1c level. Another reason that might be considered for the lack of significant difference in the HbA1c level is that both groups received the same diet, which can partly justify the fact that a diet can affect all people with GDM. Therefore, no difference was observed in the HbA1c levels since both groups received the dietary counseling. The findings of many studies have proved the positive effects of nutrition counseling and full grain intake on weight loss (Afaghi *et al.*, 2013, Muktabhant *et al.*, 2015). Weight gain during pregnancy is inevitable, but the weight gain in the control group was more evident than the experimental group and the mean weight changes in the two groups showed a significant difference. The weight may be affected by diet through several mechanisms, such as appetite control by the diet, improved metabolic function, or changes in insulin secretion and function. The results of several studies showed that consuming whole grain products and the LGI diet led to an increased sense of satiety, reduced the energy consumption, and controlled the appetite status by delaying the intake of carbohydrates, which resulted in weight loss (Porikos *et al.*, 1982, Roberts and Heyman, 2000). Laboratory information suggests that consuming refined grains, unlike whole grains, increases fat synthesis in animals (Denyer, 1998), even when the total energy consumption is unchanged and the body weight remains constant. Although the incidence of GDM depends on the individuals' overweight and obesity before and during the pregnancy (Liu *et al.*, 2003), we found that the oat bran prevented from excess weight gain during this period. One of the important limitations of this study was the lack of a placebo for the control group. Moreover, the short duration of the study limited the use of HbA1c as a reliable indicator of glucose control.

## Conclusion

The results of the present study showed that consumption of 30g of the oat bran for four weeks reduced the level of fasting blood sugar and also controlled the weight gain in patients with GDM during pregnancy; whereas, it did not affect the HbA1c level.

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## Authors' contribution

Shahzeidi M, Nadjarzadeh A, Rahmanian M participated in design, and coordinated the study and helped in the drafting and editing of the manuscript. Fallahzadeh H and Salehi Abarghuoei A participated in the statistical analyses, and participated in the drafting of the article. Mogibian M. participated in the design and the drafting of the article. Abdolahi S helped in drafting and editing the manuscript. All authors have read and approved the final version of the manuscript.

## Conflict of interest

The authors of this article state no conflicts of interest regarding this study.

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