



Investigating the Effect of Men's Participation on the Treatment Adherence of the Women Receiving the Gestational Diabetes Care

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Abstract

Background: Women with gestational diabetes are at the increased risk for type 2 diabetes. Men's participation during the pregnancy plays a vital role in the safety of the pregnant mothers by ensuring the access to care and providing the financial and emotional support. Therefore, this study was conducted to determine the effect of education based on the spouses' participation on the treatment adherence in the women with gestational diabetes.

Methods: This non-randomized clinical trial study was performed on 80 women with gestational diabetes mellitus (40 in the control group and 40 in the intervention group) referred to the Bahar educational and medical center affiliated to the Shahroud university of medical sciences (Shahroud, Semnan province, Iran). The control group received the routine care and training. In addition to the usual training, the intervention group received the training in terms of gestational diabetes care along with their spouses. The testing of diabetes activities questionnaire (TDAQ) was completed by both study groups before and 5 weeks after the intervention. The p-value of 0.05 was considered as statistically significant.

Results: The results showed that in the post-intervention phase, the treatment adherence score was not statistically significant in both study groups.

Conclusions: Results of the study showed no remarkable effect for the education based on the spouses' participation on the treatment adherence of the women with gestational diabetes therefore; further studies are suggested to investigate the lack of effect of the educational intervention reported in the present study. On the other hand, there is a need to repeat this research in the societies with poor treatment adherence.

Keywords: Gestational diabetes, Adherence treatment, Spouse participation, Education.

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mother and fetus during the pregnancy and later in life.^{5,6} Adherence to the medical advice is one of the principles of controlling the diabetes resulting in the improved blood glucose control, reduced morbidity, and reduced costs.⁷

Concerning the adherence to drug therapy, numerous studies have shown the poor adherence to drug therapy among the patients with type 2 diabetes, leading to the increased complications of the disease.^{8,9} Pregnant women with diabetes not only face the mental and physical stresses of the pregnancy but also the factors, such as the complexity and multidimensionality of the recommended treatment regimen and self-care behaviors, such as self-monitoring of the blood glucose levels, diet, weight control, as well as the regular insulin administration and frequent and timely pregnancy visits. These reduce their adherence to the treatment regimens day by day.^{10,11} Controlling the blood glucose during the pregnancy requires training the patients and their family.¹² Hence, there is a need for family empowerment in the related educational programs to achieve the optimal adherence to the treatment recommendations.¹³ In a study conducted on 442 women at the Kathmandu hospital in Nepal to investigate the effect of husbands' participation in the prenatal health education services on the maternal health knowledge, the results showed that women who had participated in the program along with their husbands had less pregnancy complications than the women who had participated alone. Women received the most information while learning with their husbands.¹⁴ However, sometimes over-family support and continued monitoring of a pregnant woman can lead to a feeling of being under control or feeling overwhelmed, which in turn can influence the adherence to treatment.^{15,16} For example, Maillet Deramo and Melkus found that the women with non-insulin-dependent diabetes usually had the full support of their husbands, but at times, this constant support was associated with the feeling of being restricted and controlled in their daily choices.¹⁶

Despite the importance of treatment adherence, very few interventional studies have been conducted in this regard, and given the contradictory results on the men's participation in the pregnancy (the delivery time has not been effectively improved globally)¹⁷ and also considering that, the lack of adherence to treatment in this group of women can lead to the complications of diabetes, future type 2 diabetes, frequent hospitalizations, sudden death of infant, fetal anomaly, difficult labor, and so on, this study was designed to determine the effect of the spouse-based education on the treatment adherence in the women with gestational diabetes.

Introduction

Gestational diabetes, as a growing problem worldwide is one of the most common complications of the pregnancy.¹ People with gestational diabetes usually return to their normal condition after the pregnancy, but women with a history of gestational diabetes will have a 15-20% increased risk of diabetes in the next 5-10 years.² The prevalence of gestational diabetes is increasing in many developed and developing countries dramatically, ranging from 1-14 % worldwide.³ The prevalence of this disorder has been estimated by 3.4% in Iran.⁴ Gestational diabetes is associated with an increased risk for the

Materials and Methods

This non-randomized clinical trial was conducted at the Bahar educational and medical center affiliated to Shahroud university of medical sciences (Shahroud, Semnan province, Iran) in accordance with the principles of the consolidated standards of reporting trials (CONSORT) statement. The subjects were selected from September 2018 to March 2019. Non-random sampling was performed in two groups of control and intervention. Thus, first the sampling of the control group was continuously completed and then, the sampling was performed in the intervention group. First, the control groups information and then those of the intervention group were assessed to prevent the data contamination.

Participants of the study included 80 women with gestational diabetes (40 in the control group and 40 in the intervention group). Inclusion criteria included the diagnosis of gestational diabetes by a specialist physician, treated and controlled through the diet, taking oral or insulin medications, having a spouse and living together, couples over 18 years of age, literacy, no history of other diseases, chronic mental and neurotic disorders, early pregnancy, mononucleosis without abnormalities, gestational age of 20-30 weeks as well as having a mobile phone with operating systems of Android OS or iOS and the ability to work with it. Exclusion criteria included the preterm labor, separation or death of a spouse, couples' unwillingness to continue his participation in the educational sessions, and lack of studying the messages. In this study, two tools of demographic profile questionnaire and testing of diabetes activities questionnaire (TDAQ) were used. Demographic questionnaire was made by the researcher and was consisted of the information on age, educational level of the pregnant woman and her husband, economic status, history of hospitalization due to the diabetes, and treatment method. The content validity of the questionnaire was confirmed by the three faculty members at the Iran university of medical sciences (Tehran province, Iran). The questionnaire was completed at the time of enrollment into the study by the pregnant diabetic women.

The TDAQ questionnaire was developed by Hernandez in 1997. This questionnaire has 13 items and its visual analogue scale (VAS) has been recorded in 100 mm of length. The score of each answer is determined by measuring in mm from the left to the mark on the scale. It is consisted of 2 subscales including the lifestyle/monitoring and drug/treatment, respectively. Items 1, 2, 3, 4, 5, 9, and 10 belong to the lifestyle/monitoring subscale covering the areas related to diet, exercise, and blood glucose testing. Items 6, 7, 8, and 12 belong to the subscale of drug use/treatment covering the used medications (pills, insulin). Item 11 is related to the care in hypoglycemia and item 13 is related to the foot examination. The total score for the TDAQ ranges between 0-100. Scores related to the lifestyle and monitoring subscale range between 0-700 and those of the drug use/treatment subscale range between 0- 400. The highest score indicates the greater compliance.¹⁸

The content validity method was used to determine the scientific validity of the TDAQ questionnaire in this way; the mentioned tool was given to the three faculty members in Iran university of medical sciences. Then, after obtaining the

consent of 30 women with gestational diabetes who met the inclusion criteria, they were given a family social support questionnaire to determine the reliability of the scale, and then the Cronbach's alpha method was used and the alpha coefficient of 0.85 was obtained.

Pregnant women with diabetes in the control group completed the demographic information questionnaire and TDAQ on the first day of meeting with the researcher, and received the regular training from the physicians and health care providers and then, they were contacted by the control team and were asked to complete the TDAQ and submit it to the researcher at the time of referral to the medical center. On the other hand, pregnant women with diabetes in the intervention group completed both above-mentioned questionnaires on the first day of their acquaintance with the researcher, and in addition to receiving the usual training they underwent an intervention program. The intervention included two face-to-face training sessions and its continuation through the virtual networks of Telegram or WhatsApp so that, the first individual training session was attended by the pregnant women and their spouses and they were given the explanations about the gestational diabetes, symptoms, and complications for the mother and fetus. The e-learning booklet was also sent by the researcher to their mobile phone for study (including the contents related to early acquaintance with gestational diabetes and its effects on the mother and fetus, symptoms, diet, exercise, treatment, etc.); the couple was asked to read the textbook before attending the second session. The second training session was held 7 days after the first training session during the next visit to the medical center, with the presence of pregnant women and their spouses and the contents including the treatment, importance of the medication, self-monitoring of the blood glucose, as well as the role of spouses in controlling the disease were presented. Earlier data were provided in the completion of the presented information. In the training sessions, short speech methods, PowerPoint slides, and educational videos were used in accordance with the understanding level of the learners and the educational content. At the end of the sessions, time was allocated to answer the questions of the participants. Also, after the first face-to-face meeting throughout the intervention, the participants received text messages, audio, short videos ,and animations via Telegram or WhatsApp regarding the gestational diabetes, its complications on the mother and fetus, the importance of compliance with the diet and physical activity, medication intake, blood glucose monitoring and insulin injections, as well as the importance and way of being supported by the husband for pregnant women with diabetes so that, on average, between 4-5 messages were sent per week and throughout the study, on average, 20-25 messages were sent to the pregnant women and their spouses.

It should be noted that, the researcher made sure that the participants have received the message in a timely and correct manner by checking the reading status of the messages, and if the participants did not read more than two messages, they were called through their mobile numbers and the reason was asked. Also, once a week, the researcher established the telephone calls throughout the program to track and respond to the training provided to the patients and their spouses. Five weeks after the intervention, participants in the intervention

group were contacted and asked to complete the TDAQ and submit it to the researcher at the time of referral to the treatment center. Then, the data were analyzed using the SPSS software (Chicago, Illinois, USA).¹⁶ The data were also evaluated separately using the independent-samples t-test, paired-samples t-test, and chi-square test.

This study was approved by the ethics Committee of Iran university of medical sciences (IRB approve: IUMS1396.9311686020). The protocol of this clinical trial was registered in the Iranian registry of clinical trials (IRCT2017050509279N4). A written consent was obtained from all the participants before participating in the research. The principle of confidentiality was also observed. If desired, subjects were free to leave the study at any time.

According to Figure 1, a non-randomized clinical trial with two groups (control and intervention) was carried out in the Bahar educational and medical center affiliated to Shahroud university of medical sciences in accordance with the principles of the CONSORT statement. The participants were selected through the convenience sampling from September 2018 to March 2019. The participants were non-randomly allocated to the control and intervention groups so that, the participants in the control group were selected through continuous sampling (n=40) and then, the participants in the intervention group were selected (n=40). The information of the control group was collected first followed by those of the intervention group to prevent the data contamination.

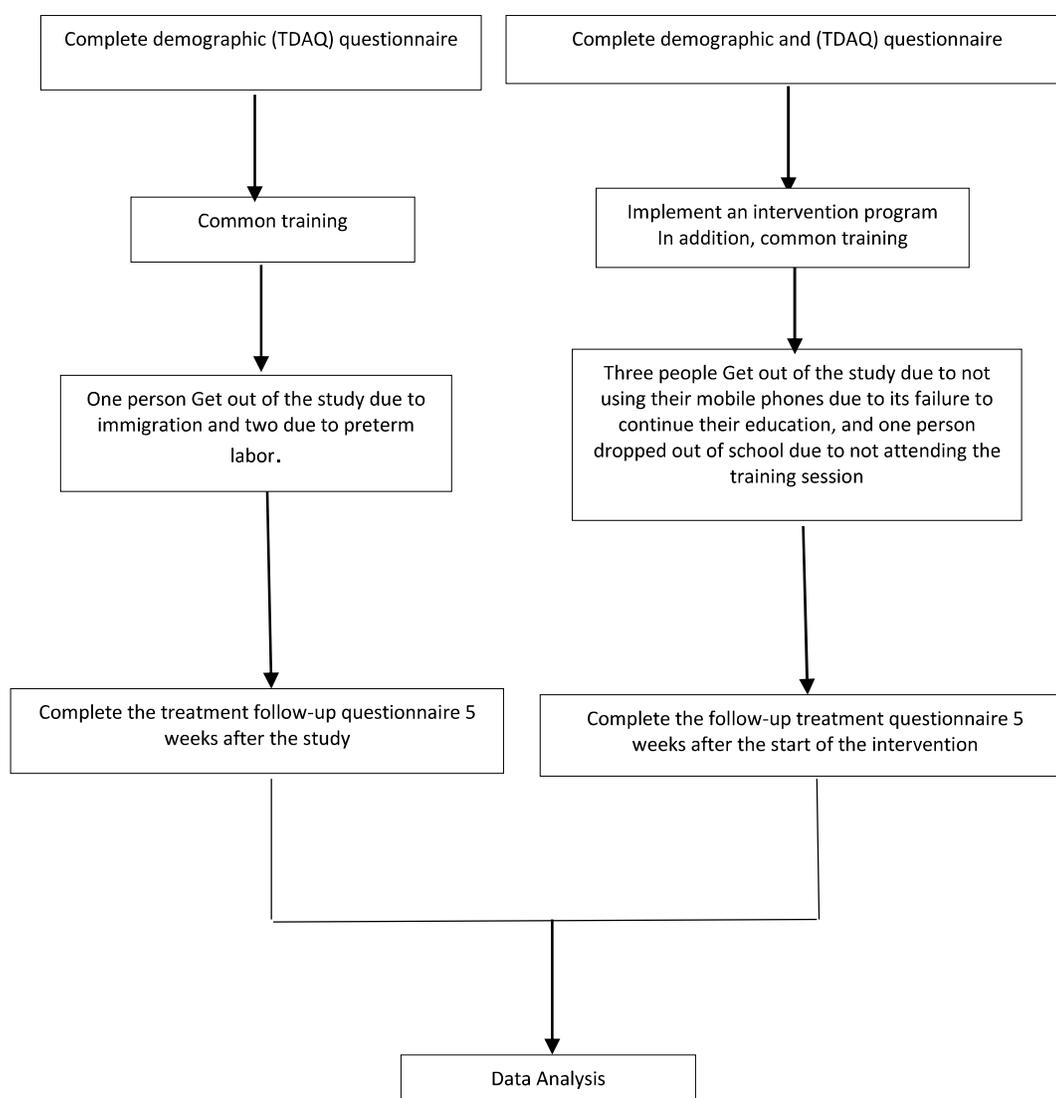


Figure 1. Participant recruitment flow chart

Results

Among the 80 subjects included in the study, in the control group, two participants due to preterm labor and one because of migration to the other city were excluded from the study and in the intervention group, three subjects were excluded because of not using a smartphone and one subject because of not attending a training session. The obtained data regarding the demographic characteristics of the study units indicated that the participants in the control and intervention groups were not statistically different in terms of variables including the age of pregnant women and their spouses, gestational age, employment status of the women, educational level of pregnant women and their spouses, occupation of the spouses, economic

status, history of hospitalization due to diabetes and treatment and the two groups were homogeneous in terms of these characteristics.

As shown in Table 2, in the control group, adherence to treatment was significantly increased after 5 weeks (P-value=0.016), but this difference was not significant in the intervention group.

Changes in the adherence to treatment in both groups before and 5 weeks after the intervention showed that although, the increase in the treatment adherence score and its dimensions was more in the intervention group than the control group, this difference was not statistically significant (table 3).

Table 1. Comparison of the demographic characteristics in the intervention and control groups

| Group | Control | | | Intervention | | | Statistical test results |
|-----------------------------|---------------------|------------|------|--------------|------------|------|---|
| | M(SD) | % | N | M(SD) | % | N | |
| Pregnant woman's age | Less than 25 years | | 13.5 | 5 | 13.9 | 5 | *t=1.447 df=71, Pvalue=0.152 |
| | 25-29 | 75.29±87.4 | 35.1 | 13 | 55.31±72.5 | 16.7 | |
| | 30-34 | | 35.1 | 13 | 44.4 | 16 | |
| | 35 and above | | 16.2 | 6 | 25 | 9 | |
| Pregnant woman's education | Reading and writing | | 8.1 | 3 | 8.3 | 3 | ***Pvalue=0.22 |
| | Secondary education | | 29.7 | 11 | 11.1 | 4 | |
| | Diploma | | 35.1 | 13 | 52.8 | 19 | |
| | Academic | | 27 | 10 | 27.8 | 10 | |
| The job of a pregnant woman | housewife | 59.27±22.3 | 81.1 | 30 | 58.27±25.3 | 77.8 | **χ ² =0.122 df=1, Pvalue=0.727 |
| | Employed | | 18.9 | 7 | 22.2 | 8 | |
| Pregnancy age | Under 25 | | 18.9 | 7 | 19.4 | 7 | t=0.015 *df=71 Pvalue=0.988 |
| | 25-27 | | 11.1 | 5 | 11.1 | 4 | |
| | 28 and above | | 69.4 | 25 | 69.4 | 25 | |
| Age of wife | Under 30 years | | 13.5 | 5 | 19.4 | 7 | *t=0.343 df=71 Pvalue=0.733 |
| | 30-34 | 11.34±18.5 | 45.9 | 17 | 51.34±84.4 | 33.3 | |
| | 35-39 | | 16.2 | 6 | 27.8 | 10 | |
| | 40 and above | | 24.3 | 9 | 19.4 | 7 | |
| Spouse education | Reading and writing | | 10.8 | 4 | 16.7 | 6 | **χ ² =1.43 df=3 Pvalue=0.699 |
| | Secondary education | | 29.7 | 11 | 33.3 | 12 | |
| | Diploma | | 32.4 | 12 | 33.3 | 12 | |
| | Academic | | 27 | 10 | 16.7 | 6 | |
| Wife's job | Employee | | 27 | 10 | 22.2 | 8 | Pvalue=0.384 |
| | Self employed | | 62.2 | 23 | 72.2 | 26 | |
| | Manual worker | | 10.8 | 4 | 2.8 | 1 | |
| | Unemployed | | 0 | 0 | 2.8 | 1 | |
| The economic situation | Bad | | 5.4 | 2 | 5.6 | 2 | ***Pvalue=0.999 |
| | Medium | | 81.1 | 30 | 83.3 | 30 | |
| | Good | | 13.5 | 5 | 11.1 | 4 | |
| History of hospitalization | Not | | 48.6 | 18 | 38.9 | 14 | **χ ² =0.706 df=1 Pvalue=0.401 |
| | Yes | | 51.4 | 19 | 61.1 | 22 | |
| Treatment method | Diet | | 27 | 10 | 36.1 | 13 | ***Pvalue=0.297 |
| | Oral medicine | | 45.9 | 17 | 25 | 9 | |
| | Insulin | | 21.6 | 8 | 27.8 | 10 | |

*** Fisher exact test ** Chi-square test * Independent T-test

Table 2. Numerical indices of treatment adherence in the pregnant women before and 5 weeks after the intervention

| Adherence to treatment | Control | | Intervention | | Paired t-test results in control and intervention groups |
|--------------------------------|--------------------|---------|--------------------|---------|--|
| | Standard deviation | Average | Standard deviation | Average | |
| Before | 224.17 | 845.21 | 242.88 | 826.36 | t=1.982, df=35 Pvalue=0.055 Intervention group |
| 5 weeks after the intervention | 221.43 | 851.97 | 207.77 | 899.49 | t=2.523, df=36 Pvalue=0.016 Control group |

Table 3. Variations in the numerical indices of treatment adherence before and 5 weeks after administration of the social support in the pregnant women

| Changes | Control | | Intervention | | Independent t-test results |
|------------------------|--------------------|---------|--------------------|---------|--------------------------------|
| | Standard deviation | Average | Standard deviation | Average | |
| Adherence to treatment | 16.28 | 6.75 | 4.112 | 13.37 | t=1.605, df=71 Pvalue=0.108 |

Discussion

The results of the independent-samples t-test showed no significant differences in the numerical indices of adherence to treatment and its dimensions between the two study groups 5 weeks after the intervention. Therefore, it seems that the education based on the spouses' participation not been effective in adhering to the treatment regimen. Results of the independent-samples t-test regarding comparing the changes in treatment adherence and its dimensions before and 5 weeks after the intervention in the control and intervention groups showed that although, the increase in the treatment adherence score and its dimensions was more in the intervention group than the control group, this difference was not statistically significant. Thus, it can be concluded that, the education based on the spouses' participation has failed to increase the adherence to treatment in the pregnant women with diabetes.

Adherence to treatment is the most important goal in the management of diabetes requiring the multiple regimens.¹⁸ Achieving a balance between the needs of a healthy pregnancy, controlling the blood glucose level within the normal range, and achieving these goals through the adherence to the recommended treatment regimen^{19,20} are among the goals of metabolic management in the pregnant women with gestational diabetes. Criswell et al.,²¹ and Huidobro et al., in their studies showed no significant difference between the control and intervention groups after the intervention, which is in accordance with the present study.²² Withidpanyawong found that the family-centered education improved the diabetes management in the people with poor glycemic control and poor medication adherence.²³ Also, Wichit et al., indicated that the family-centered training improved the self-efficacy and self-management in the people with type 2 diabetes,²⁴ which is not consistent with the present study. This inconsistency between the results of the reviewed studies with the present study is probably due to the fact that the subjects in the present study had relatively high adherence, which led to less opportunity for measurable improvement and further reduced the variability in the data. On the other hand, in the previous studies, the number of training sessions was higher than 3 sessions with longer duration (9 months in the study by Withidpanyawong and 9 weeks in the study by Wichit). However, in the present study, only two training sessions were considered due to the limitations regarding the men's occupations, as most of them were young and at working age.

On the other hand, although in the previous studies, the highest support has been reported by the patients, their spouses have been introduced as the biggest obstacle to self-care conversely.²⁵ Spouses' warning and encouragement are associated with the adherence to the recommended diabetic diet, but conversely, as the spouses' warning leads to the poor patients' adherence the encouragement is associated with better adherence. Thus, psychological interventions should focus on the ways to help the spouses in developing the appropriate and effective coping strategies.²⁶ Conducting the behavioral, family, and psychological counseling sessions is essential to improve the patients' perceived self-efficacy for achieving the therapeutic and control goals and reducing the complications of the disease. Therefore, it is recommended to add the

psychological and behavioral counseling programs to the interventions.²⁵

Berry et al., indicated that the mismatch in treatment process of the diabetes may represent the problems with the couples' relationship regarding the disease, which in turn influences the way they support each other. Negative beliefs about type 2 diabetes and incompatibility between the couples' beliefs may influence the emotional support unless an appropriate psychological intervention is actively performed.²⁷ Given that, the women with the perinatal disorder are highly stressed, family members, and especially spouses also experience the psychological reactions, such as anxiety and fear while diagnosing the gestational diabetes. This can influence the process of adherence to the treatment regimen. Therefore, health care professionals need to evaluate their spouses in terms of stress and anxiety while taking care of the pregnant women with pregnancy distress. Plans should also be designed to strengthen the bond between the family members and support the self-care activities in order to control the disease and prevent or delay the serious complications.²⁸

Educating the family members about diabetes or family involvement in caring for the patients without any management to reduce the family's distressing behaviors may lead to the adverse outcomes in the therapeutic follow-up of the people with diabetes.²⁹ Stress and distressing behaviors help the patients and their families to manage it.³⁰ The lack of effect of educational intervention reported in the present study needs to be investigated in further studies including the studies on the relationship between the couples before the study, family's stress level, and the interventions to manage it, in a larger community with low economic level, and among the people with poor treatment adherence. For making a comparison with a community of high economic level, appropriate psychological interventions and psychological counseling sessions should be administered for educating the spouses preferably the men as the gender is a barrier to the education to address the existing challenges and evaluate the outcomes.

The beliefs and attitudes of men and women from a social-cultural perspective, cultural traditions and social norms, religious beliefs, and socioeconomic status as the determinants of attitudes, and also the dominant role of men in the pregnancy care should be considered.³¹ Perhaps another reason for the difference between the results of our study and other studies may be due to the differences in the location of the study and the cultural and social issues dominating the community under study.

The dominant cultural and religious issues in the country regarding the presence of fathers in the pregnancy care training classes was one of the limitations of this study, and the lack of male trainers for the fathers, and the need for a male counseling psychologist were among the educational barriers. Another limitation of this study was that the treatment adherence score was above the average in both control and intervention groups at the beginning of the study and the changes due to the necessary educational intervention in the treatment adherence were not clearly observed. Therefore, more research is needed in the societies with poor treatment adherence.

Implementation of the education based on the spouses' participation in the present study did not cause any statistically significant difference in the treatment adherence score of the women with gestational diabetes. This can be due to the fact that the topic of men's participation in women's health issues is relatively new, especially in our country, and given the cultural barriers, addressing them in the media, particularly broadcasting media can provide effective assistance to the women. Administrating the psychological interventions with the help of same-sex counselors can also contribute to achieve these goals. On the other hand, there is a need to repeat this research in the wider societies with poor treatment adherence.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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