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The effectiveness of mindfulness-based training on anxiety in pregnant women with gestational diabetes

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A – Study Design, **B** – Data Collection, **C** – Statistical Analysis, **D** – Data Interpretation, **E** – Manuscript Preparation, **F** – Literature Search, **G** – Funds Collection

Summary **Background.** Anxiety is more common during pregnancy than in any other periods. Thus, medical problems such as diabetes can increase the anxiety of pregnant women.

Objectives. The main objective of this study was to investigate the effectiveness of mindfulness-based training on anxiety in pregnant women with gestational diabetes.

Materials and methods. This study was a randomized controlled trial study with a pre-test, post-test and control group. Among 24–28 week pregnant women with diabetes who referred to health centers in Kerman, 88 women were selected. Participants were randomly allocated into intervention and control groups. Mindfulness-based training was used for the intervention group over 8 weeks, and situational and trait anxiety was measured through a Spielberg anxiety questionnaire. The collected data was analyzed using SPSS version 22 software.

Results. There was no significant difference between the mean scores of situational and trait anxiety before intervention in both the intervention and control groups ($p = 0.159$, $p = 0.21$). However, mean situational and trait anxiety decreased in the intervention group and increased in the control group after intervention/treatment. There was significant increase over time. The difference between the two groups was also significant during the intervention and post-intervention periods (p-value < 0.0001).

Conclusions. Mindfulness-based counseling conducted by a midwife decreased the anxiety of pregnant women with gestational diabetes.

Key words: mindfulness, anxiety, gestational diabetes.

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Background

Anxiety is a common mental health problem, which is more common among women than men, especially during pregnancy more than other periods [1]. Anxiety is not constant during pregnancy, so it increases during the first and third trimester, decreases during the second trimester and becomes maximum at childbirth [2]. The prevalence of anxiety in pregnancy is about 18% [3]. Studies show that anxiety during pregnancy can directly affect the growth pattern of the fetus and duration of pregnancy [4]. It leads to side effects, such as preterm labor and low birth weight [5]. Anxiety also causes the secretion of stress hormones (adrenal steroids and corticotrophin releasing hormones), which can influence fetal brain development during weeks 12–22 [6]. 15% of anxiety problems and cognitive delay in children are due to a mother's anxiety during pregnancy [7, 8]. Some of the causes of anxiety disorders in pregnant women include early maternal age, primiparity, hereditary anxiety, physical disease [9], history of preterm labor and high risk of fetal anomalies [10].

A common medical complication during pregnancy is gestational diabetes, defined as carbohydrate intolerance which is diagnosed and commences during pregnancy [10]. The prevalence of gestational diabetes varies from 1% to 14% in different parts of the world [11]. Its prevalence has been reported as being from 1.3% to 8.9% in Iran [12]. Fetal complications of gestational diabetes include fetal macrosomia, injuries during childbirth, hypoglycemia, hypocalcemia, hyperbilirubinemia and respiratory distress syndrome. Maternal complications include preeclampsia, preterm labor, hydramnios, cesarean delivery and type 2 diabetes in the future [13].

Pregnant women with diabetes need special care, because it has a great influence on their physical and mental health and increases their anxiety [14]. The prevalence of anxiety among diabetic people is 20% higher than non-diabetics [15]. Non-pharmacological interventions, such as cognitive-behavioral therapy (CBT) [16] and spiritual trainings [17], have been used to decrease anxiety during pregnancy. Recently, mindfulness-based interventions were developed and used for managing psychological problems during pregnancy [18]. Mindfulness is defined as consciousness and attention to what is happening at the present. It is considered as one of the cognitive-behavioral therapies of the third wave, which is a form of meditation [19]. Mindfulness-based interventions include Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) [20].

In previous studies, the effect of mindfulness-based interventions on reducing anxiety has been studied in different populations, including non-diabetic pregnant women and non-pregnant diabetic women [18, 21, 22]. Many studies have also

been performed to investigate the effect of mindfulness training on self-efficacy and fear of childbirth in pregnant women [23]. A recent study on women aged 20–40 years with type 2 diabetes showed that a mindfulness-based stress reduction program was effective on decreasing anxiety, stress and HbA_{1C}, as well as increasing self-esteem [21]. Another study showed that the MBSR method is effective for diabetic people who suffer from emotional problems, anxiety and depression and can improve their health [24]. However, the effectiveness of this method on diabetic pregnant women has not been studied.

Objectives

To assess the effectiveness of mindfulness-based training on anxiety in pregnant women with gestational diabetes.

Material and methods

Study design

This was a randomized controlled trial study.

Participants

In the present study, pregnant women aged between 18–45 years, a gestational of age 24–28 weeks, with gestational diabetes, having the ability to read and write and having a situational anxiety score of 20–53 and a trait anxiety score of 20–56 were included. Exclusion criteria included a history of receiving mindfulness training, having pre-pregnancy diabetes and exposure to major stress due to unforeseen incidents (grief, divorce). The sample size was determined at 88 participants using G*Power software and was based on a similar article [18].

Sampling method

All pregnant women who were referred to health centers in Kerman were permitted to participate in the study after gaining their written consent and having received an explanation of the research objectives. Sampling was performed using the simple random sampling method. Participants were randomly allocated into intervention and control groups using a random number table.

The first researcher identified those pregnant women who were diagnosed with gestational diabetes in the health centers after reviewing their medical records and contacted them to asked if they were willing to participate in the study. They were later invited to an initial interview and to complete the questionnaire. Data was collected by a demographic questionnaire, an obstetric questionnaire and the Spielberg situational and trait anxiety inventory (STAI).

The STAI includes 40 questions scored on the Likert scale from "very low" to "very high", in which 20 questions are related to a sub-scale of situational anxiety (the emotion that person has), and the other 20 questions are related to a sub-scale of trait anxiety (underlying anxiety of a person and their willingness to be anxious). To determine the situational anxiety, scores of 20–30, 31–42, 43–53 and ≥ 54 show the lowest, mild, moderate and severe levels of anxiety, respectively. To determine trait anxiety, scores of 20–34, 35–45, 46–56 and ≥ 57 show the lowest, mild, moderate and severe levels of anxiety, respectively. The first, second and third evaluations were performed before, immediately after and one month after intervention by STAI in both the intervention and control groups. The questionnaires were completed by participants in the presence of a researcher after explaining how to complete the questionnaires.

The intervention group was treated with mindfulness-based training over 8 sessions. The sessions were held for 120 minutes weekly by the first researcher, a graduate midwife studying MS in counseling in midwifery. During each session, the activities of the previous session were reviewed, and the consultation and concepts related to the meeting were then discussed, and the practical exercises of the session were performed at the end of the session. The control group only received routine pregnancy care and was not aware of the sessions held for the intervention group. At the end of the study, a book related to mindfulness and a training CD of the counseling sessions were presented to all the participants.

The general structure of training sessions for MBSR is presented in Table 1. Data was analyzed using version 22 of SPSS software.

Ethical consideration

The protocol of this study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ref No: 1088.1396IR.AJUMS.REC) and is registered with the Iranian Clinical Trials Centers (Ref No: IRCT20180627040261N1).

Table 1. Structure of training sessions of MBSR

First session: introducing participants, a brief description of 8 sessions, providing introduction on gestational diabetes, introducing a pilot automatic system, practice of eating a raisin and its feedback
Second session: awareness and presence at the moment, tackling barriers, sitting practice with awareness of breathing
Third session: attention, 3-minute respiratory interruption training
Forth session: admission, body scan practice
Fifth session: stress, involving in stressful reactions, response instead of reaction, sitting mediation associated with focus on breathing, body thoughts and sounds
Sixth session: thoughts are not truth, mindfulness practice when moving
Seventh session: self-care, sitting mediation, selecting each method that you want
Eighth session: end session and conclusion

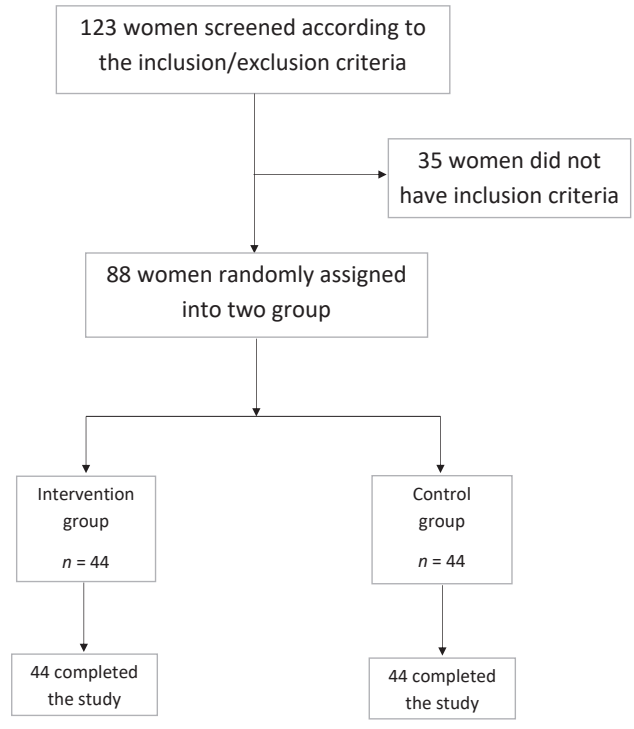

Figure 1. Flow diagram of the recruitment and retention of participants in the study

Results

Table 2. Demographic features of participants by groups

Variable \ Group		Control (n = 44)	Intervention (n = 44)	p
Job*	Housewife Employed	24 (54.5) 20 (45.5)	25 (56.8) 19 (43.2)	0.830
Education*	Diploma and lower Associated degree Bachelor and higher	13 (27.5) 6 (15) 25 (57.5)	10 (20.5) 11 (25.6) 23 (53.8)	0.460
Parity*	1 2 3 4 and more	10 (22.7) 23 (52.3) 8 (18.2) 3 (6.8)	9 (20.5) 18 (40.9) 12 (27.3) 5 (11.4)	0.580
Age**	(mean ± SD)	29.59 ± 4.63	29.5 ± 5.22	0.931
Gestational age**	(mean ± SD)	26.11 ± 0.99	25.83 ± 0.84	0.136

* Chi-square test was used, ** independent-samples *t*-test was used.

Table 3. The mean scores of situational and trait anxiety at the three time points

Variable	Measure time	Intervention group (mean ± SD)	Control group (mean ± SD)	p
Situational anxiety	Before intervention Immediately after intervention One month after intervention	47.09 ± 5.40 33.90 ± 2.86 33.36 ± 2.78	45.95 ± 2.53 46.14 ± 2.86 45.84 ± 2.56	0.210 < 0.000 < 0.000
Trait anxiety	Before intervention Immediately after intervention One month after intervention	47.11 ± 3.16 33.97 ± 2.69 33.14 ± 2.76	46.25 ± 2.50 45.35 ± 2.38 45.23 ± 2.57	0.159 < 0.000 < 0.000

* Repeated measures.

The Kolmogorov–Smirnov test was used to assess normality. Both situational and trait anxiety were normal ($p > 0.05$). Data was analyzed based on repeated measurements and two independent samples *t*-test and paired *t*-test. Two independent samples *t*-test and chi-2 test were also used in the demographic section. To determine the significance level of the tests, the alpha was considered as 0.05.

Table 2 shows the demographic features of women who participated in the study. Two groups did not have any significant differences regarding demographic variables ($p > 0.05$).

Table 3 shows the mean scores of situational and trait anxiety at the three time points in the intervention and control groups. There was no significant difference between the mean of situational and trait anxiety and the control group before intervention ($p = 0.21$, $p = 0.15$). However, immediately after intervention ($p < 0.0001$) and one month after intervention ($p < 0.0001$), a significant difference between the intervention group and control group was found.

Discussion

The aim of this study was to assess the effectiveness of mindfulness training on anxiety among pregnant women with gestational diabetes. The results showed that mindfulness-based counseling provided by a midwife was effective in decreasing situational and trait anxiety in pregnant women with gestational diabetes.

In other studies, cognitive-based training provided by a midwife has been effective in decreasing the fear of delivery and increasing natural childbirth [25]. A cost-effectiveness analysis of cognitive trainings for pregnant women showed that these trainings are effective in decreasing the need for a cesarean section due to decreasing the fear of delivery [26].

In previous studies, the effect of mindfulness on anxiety or other mental health problems among non-diabetic and non-pregnant women [27], the anxiety of diabetic women [22, 24] and the anxiety of pregnant women [18], as well as the effect of similar interventions on anxiety in pregnant women with diabetes [17], has been showed. For example, in a study conducted by Rod, mindfulness-based exercises decreased anxiety and symptoms of depression in patients who suffered from chronic pain [27]. Mindfulness-based intervention decreased anxiety, stress and depression levels and also increased self-confidence and decreased HbA_{1C} and blood glucose [21, 22, 24]. A mindfulness-based training program has also been useful in reducing the anxiety of non-diabetic pregnant women [18].

Training of mindfulness-based skills, both statistically and clinically, significantly decreased the symptoms of vulnerable people and anxiety [28]. It has also been shown that mindfulness-based trainings can increase the self-efficacy of delivery and decrease depression after delivery [29].

It can be said that due to the problems and limitations that gestational diabetes causes for pregnant women, their anxiety will be doubled.

In this situation, these women are strongly prepared to learn new ways for reducing their anxiety. Common approaches used to reduce anxiety and depression and increase quality of life are spiritual training [30] and cognitive-behavioral training [16]. Group spiritual therapy decreased anxiety and increased quality of life in pregnant women with diabetes [30]. It is suggested that midwife-led psychological training approaches should be used to improve the mental health of pregnant women. Thus, training of interdisciplinary skills such as psycho-educational approaches for midwives can be cost-effective.

The current research is the first study on pregnant women with gestational diabetes which investigates the effect of mindfulness-based training on anxiety. In future studies, the effect of mindfulness-based training can be compared with other psychological approaches to decrease the anxiety of pregnant women with gestational diabetes. Additionally, it is suggested that future studies examine the impact of involving a family member in the education process.

Limitations of the study

A number of important limitations need to be considered: first, the uncertainty about the accuracy of information provided by the participants, and the second, self-reporting of the variables examined.

Conclusions

Mindfulness-based counseling is an effective way to decrease the anxiety of pregnant women with gestational diabetes. Therefore, mindfulness-based counseling can be used to improve the mental health of pregnant women with gestational diabetes.

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