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Mindfulness Training and Quality of Life Among Pregnant Women: A Randomized Clinical Trial

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Abstract

Background: The pregnancy period is associated with a variety of physical and psychological changes, which can affect the females' quality of life (QOL).

Objectives: The current study aimed to examine the effect of mindfulness training on QOL among pregnant females.

Methods: In this clinical trial, 80 pregnant females eligible for inclusion were selected by convenience sampling method from Akramian, Taleghani and Ketabchi health centers in Kashan, Iran. The participants were randomly allocated into experimental and control groups (n = 40, each group) by block randomization method. Females in the experimental group received eight sessions of 90-minute mindfulness training, while females in the control group only received routine prenatal care services. Data were collected using a demographic questionnaire and a short-form 36 (SF-36) health survey questionnaire to measure the QOL. Chi-square, independent samples T-test and repeated measures analysis of variance were used to analyze the data.

Results: The results showed that the total QOL score and subscales of emotional role functioning, vitality, mental health, social functioning and general health in the experimental group had significant changes compared to those of the control group. However, there was no significant difference between other subscales. The mean total QOL score before intervention was 44.84 ± 4.44 and after intervention and follow-up was 50.42 ± 3.71 and 49.42 ± 5.24, respectively ($P < 0.05$).

Conclusions: Mindfulness training can be used as a psychological prenatal care to moderate negative emotions, improve social functioning and cope with psychological and physical changes.

Keywords: Mindfulness, Quality of Life, Pregnant Females

1. Background

Pregnancy is one of the most important events in females' lives often associated with major changes. During pregnancy, females should cope with physical and chemical changes in their body. The changes in the endorphin system and organs of the body (1) cause fundamental changes in females' physical and mental health (2). Due to the vulnerability of females during pregnancy, mental health problems are increased in this period (3). Physical symptoms such as nausea, vomiting, pain, hemorrhoids and back pain, and shortness of breath can cause distress and affect pregnant females' mental health (4). Specific concerns related to pregnancy, such as worry about how to pass the course of pregnancy, fear of childbirth, concerns about the health of the fetus, and how parenting can increase the mother's stress during pregnancy (5). In addition, the incidence of these concerns and problems can change females' ability to perform everyday tasks (6). Therefore, many changes can take place in the physical, psychological and social aspects and in overall, can decrease the females' quality of life (QOL) in pregnancy (7). The QOL evaluates areas of physical function (the ability to perform physical activity), psychological well-being, subjective symptoms (such as body pain and fatigue) and the social functioning (8). Epidemiological studies in different countries show that pregnancy significantly affects the QOL in females (9, 10). Also, the study in Iran showed that both physical and psychological aspects of pregnancy affect the females' QOL (11).

Nowadays, in health care centers, prenatal cares are dedicated to physical health care, such as weight control, blood pressure and preparation for childbirth; and less attention is paid to issues related to mental health. One of the interventions for pregnant females in recent years is mindfulness. Mindfulness is a new concept in psychotherapy which helps people to respond to their experience by concentration on the present moment and creating a nonjudgmental attitude in contrast to their experiences (e g, thoughts, emotions and physical sensations). From this perspective, all stressful events can be controlled; however, the response to these events can be controlled and

changed (12). Mindfulness is an immediate attention to all experiences at present moment in non-judgmental attitude with acceptance (13). Non-judgmental attitude toward inner experience and without reacting against them and dealing with acceptance to these experiences (unpleasant) can improve the level of tolerance and the ability to cope with stressful situations and help moderate the psychological distress (14-16).

Mindfulness is a skill that can be trainable (12). Continuous practice can lead to favorable changes in cognitive and behavioral patterns (17). In recent years, mindfulness interventions are used to deal with problems such as depression and anxiety during pregnancy (18-20). Comprehensive studies of the researchers show that this intervention is not used to improve the QOL in pregnant females. Therefore, further studies are necessary to provide sufficient evidence in this area. The brief and non-pharmaceutical nature of mindfulness- based interventions makes them especially good candidates for intervention during pregnancy.

2. Objectives

The current study aimed to examine the effect of mindfulness training on QOL among pregnant females.

3. Methods

3.1. Study Design and Participants

This randomized clinical trial was performed from February 2015 to May 2015 in Kashan, Iran. In this study, three health centers, which had the necessary facilities for the study, were selected using the convenience sampling method. The population consisted of the pregnant females referred to Akramian, Taleghani and Ketabchi health centers in Kashan. A list of females in the second to sixth months of pregnancy provided by midwifery system of every center was used to collect data.

To collect data, females eligible for inclusion in the study were asked to attend these centers. First, the objectives of the study and instructions of completing the questionnaires were explained to the participants, and they were asked to complete the questionnaires.

The inclusion criteria were pregnant females in the second to sixth months, being in the age range of 18 to 50 years, minimum secondary school literacy, no history of psychiatric disorders and chronic physical problems and not receiving psychotherapy or drug therapy for at least the past six months. The exclusion criteria included unwilling to continue the sessions, absence more than two sessions, and premature birth. The sample size consisted of 33 participants in each group, selected by the Cohen's Formula, type I error 0.05, type II error= 0.1 and effect size (d = 0.8) (18)

$$d = \frac{M_1 - M_2}{\sigma\sqrt{2}} \quad (1)$$

$$\begin{aligned} n &= \frac{2\left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2}{d^2} \\ &= \frac{2 \times 10.49}{8^2} \\ &= \frac{20.98}{64} \\ &= 33 \end{aligned} \quad (2)$$

However, considering 10% of drop-out, the sample size consisted of 40 participants in each group. Then, 80 participants were selected among those eligible for the study. The participants were allocated into two groups, experimental and control (n = 40 in each group), randomly using block randomization method, by units of 4 blocks. Then, the participants were asked to complete demographic and QOL questionnaires.

3.2. Instruments

3.2.1. Demographic Questionnaire

Demographic questionnaire included age, the educational level, number of births, gestational age, body mass index (BMI) and employment status for each female.

3.2.2. Quality Of Life Questionnaire

The quality of life (SF-36) questionnaire contains 36 questions in eight subscale including physical functioning, physical role functioning, bodily pain, general health, vitality, mental health, emotional role functioning and social functioning. Total scores of eight dimensions of health are considered from 1 to 100 by which the higher scores indicate better health status.

Scoring questions vary according to the number of options; for example, questions with 1 to 5 options, are rated by 100, 75, 50, 25, and 0; questions with 1 to 3 options, are rated by 0, 50, and 100; questions with 1 to 2 options, are rated by 0 and 100.

Montazeri et al. (21) indicated the reliability of the questionnaire by the internal consistency and its validity by comparing the known groups. The internal consistency analysis revealed that alpha coefficients of the scales were from 0.65 to 0.90.

Table 1. Mindfulness Based Childbirth and Parenting Protocol

	Contents of Sessions
Session 1: Basic information about mindfulness	Delivering basic information about the content and process of meetings: meaning of mindfulness, what is mindful life, effect of mindfulness in pregnancy and child birth, homework assignments
Session2: Concept of autopilot mind in everyday life	Checking the assignments and participants' problems discussion about autopilot mind in living, effect of being mindless on personal life and mental health, adverse outcomes of being mindless in life and specially in pregnancy and child birth, homework assignments
Session 3: Practical mindful breathing	Checking the assignments and participants' problems teaching the elements of mindfulness (subjective evaluations of process of breathing), practical training of mindfulness, breathing as an anchor for mindfulness, homework assignments
Session 4: Mind and body awareness I	Checking the assignments and participants' problems continuing mindful breathing, training body scan and awareness of the visceral sensations (subjective evaluation of body parts, identifying stress and its relaxation) (part I), generalization of body scan skills in pregnancy sensations, homework assignments
Session 5: Mind and body awareness II	Checking the assignments and participants' problems continuing training of body scan (part II) specially pregnancy sensations generalization.Live practice of body scan in session; homework assignments
Session 6: Mindfulness in everyday life	Checking the assignments and participants' problems, training how to use mindfulness in everyday life (mindful eating, mindful watching and mindful walking), homework assignments
Session 7: Pain acceptance training	Checking the assignments and participants' problems, training the acceptance and coping with the problems in life, homework assignments
Session 8: Review of previous matters and assessment	Checking the assignments and participants' problems, review and assessments of participant, homework assignments for maintenance period

3.3. Interventions

Experimental group received the mindfulness training, in addition to the routine prenatal care. This program consisted of eight sessions of 90 minutes with one week interval. The content of this program was as follows:

Before implementing the experiment, rules and regulations of each session were presented and the therapeutic contract was set up. The control group received only routine prenatal care such as weight control, blood pressure and preparation for childbirth. At the end of the study, participants in the control group received training manual of intervention sessions. Participants were divided into two groups (20 participants per group) and intervention sessions were held weekly at Akramian health center on the same day.

The post-test was performed immediately after the intervention, and follow-up was done one month after the intervention. Post-test and follow-up performed at Akramian health center. Intervention was implemented by a clinical psychologist with high qualification in mindfulness interventions.

3.4. Ethical Considerations

The current study was approved by the ethics committee of Kashan University of Medical Sciences, Kashan, Iran, with the approval code P/13/0/3/4005, December 17, 2014. Before implementing the intervention, participants were asked to fill out and sign the informed consent form of the study. Subjects were told about the confidentiality of their personal information and that they could leave the study any time they wished.

This study was registered in the Iranian registry of clinical trials (IRCT) under the registration code: 2015012920869N1.

3.5. Data Analysis

The SPSS version 11.5 was used to analyze the data. Study data were described using frequency tables and the measures of central tendency. Chi-square and independent-samples T-test were used for demographic variables (age, BMI and gestational age were analyzed using T-test; educational level, parity and job status were analyzed by Chi-square test) and a repeated measures ANOVA was used to compare the differences between total scores of QOL and its subscales in three-time measurements.

4. Results

Eighty pregnant females were included in the study (n = 40 in each group). Ten participants in the experimental group and seven in the control group were excluded from the study in the post-test and follow-up stages due to health problems related to pregnancy, and irregular attendance at training sessions (the experimental group). Finally, data analysis was performed on 63 participants (Figure 1).

Table 2 shows the demographic characteristics of the participants. There was no significant difference between the two groups in terms of age, education level, parity, gestational age and BMI. The mean age in the experimental group was 26 $\pm$ 5.82 and in the control group 26.73 $\pm$ 4.54 years. Also, 63.3% of the experimental group and 66.7% of

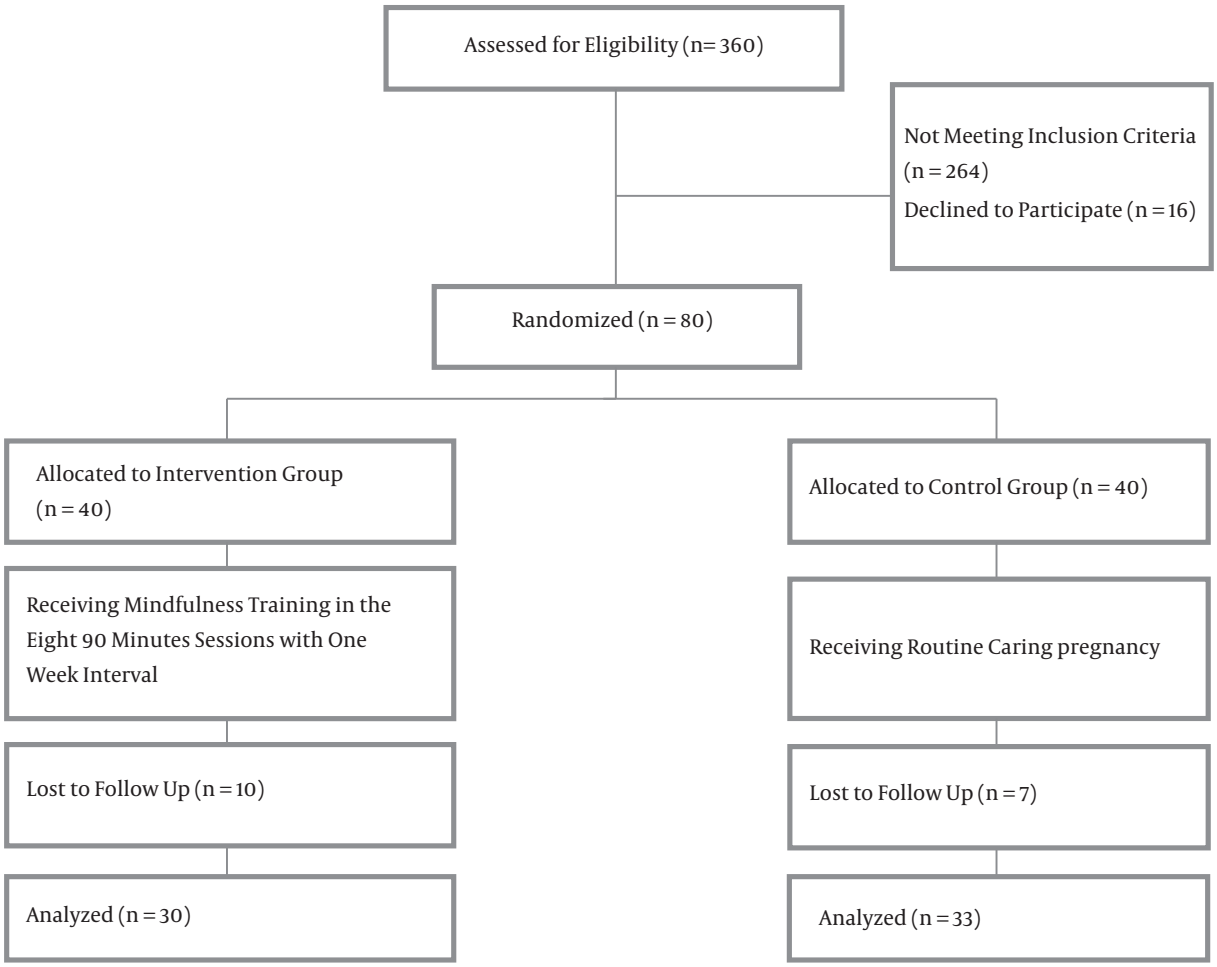

Figure 1. Consort Flow Diagram

the control group experienced their first pregnancy (Table 2). The mean and standard deviation of the pre-test, post-test and follow-up of the QOL and its subscales are shown in Table 3. The mean total QOL scores in the pre-test were 44.84 ± 4.44 and 45.81 ± 2.98 in the experimental and control groups, respectively. Before the intervention, no significant difference was observed in the mean QOL scores between the groups. The mean QOL scores in the post-test were 50.42 ± 3.71 and 43.75 ± 3.14 in the experimental and control groups, respectively. During the follow-up, the mean QOL scores reached 49.42 ± 5.24 and 43 ± 3.25 in the experimental and control groups, respectively. Furthermore, changes in QOL scores and its subscales in the post-test and during the follow-up period are shown in Table 3.

The results of the Mauchly test showed that sphericity assumption was not met (P = 0.000, Greenhouse-Geisser = 0.792). Therefore, the repeated measures ANOVA by Greenhouse-Geisser epsilon was used (Table 3).

To compare changes in QOL scores in three measurement times, repeated measures ANOVA was used. The results showed that the total QOL score and subscales of emotional role functioning, vitality, mental health, social functioning and general health in the experimental group showed significant changes compared to those of the control group. However, no significant difference was observed in other subscales (Table 3). The results revealed the significant effect of time on emotional role functioning, social role functioning, general health perception subscales and QOL total scores. Also interaction between time and type of intervention had a significant effect on emotional role functioning, vitality, mental health, social role functioning, general health perception scales and QOL total scores ($P < 0.05$). The trend of QOL (total score) varia-

Table 2. Demographic Characteristics of the Study Groups[a]

Variables	Groups		P Value
	Intervention	Control	
Age	26 ± 5.82	26.73 ± 4.54	0.569[b]
Educational level			0.693[c]
Secondary school	4 (13.3)	2 (6.1)	
High school diploma	17 (56.7)	21 (63.6)	
Bachelor	9 (30)	10 (30.3)	
Parity			0.782[c]
1	19 (63.3)	22 (66.7)	
2 and more	11 (36.7)	11 (33.3)	
Gestational age in week, in baseline			0.967[b]
8	4 (13.3)	6 (18.2)	
12	6 (20)	6 (18.2)	
16	11 (36.7)	10 (30.3)	
20	8 (26.7)	8 (24.2)	
24	1 (3.3)	3 (9.1)	
BMI[d]	22.91 ± 2.84	23.13 ± 3.27	0.838[b]
Job			0.980[c]
Housewife	19 (63.3)	21 (63.6)	
Employed	11(36.7)	12 (36.4)	

[a] Data are presented as No. (%) or mean ± SD.
[b] Independent-samples T-test.
[c] Chi-square Test.
[d] BMI, body mass index.

Table 3. The Mean and Variance Analysis With Repeated Measures for Total Score of Quality of Life and its Subscales in the Groups

Groups Variables	Pre-Test		Post-Test		Follow-Up		P-Value	
	Intervention	Control	Intervention	Control	Intervention	Control	Time	Time × Group
Physical functioning	43.16 ± 10.94	46.51 ± 9.14	46.33 ± 8.89	46.06 ± 8.81	46.16 ± 8.67	46.06 ± 8.63	0.32	0.50
Physical role functioning	41.66 ± 11.98	40.90 ± 12.21	40.83 ± 12.25	36.36 ± 12.64	40.83± 12.25	36.06 ± 12.24	0.07	0.26
Emotional role functioning	47.77 ± 16.79	47.47 ± 16.72	66.66 ± 15.07	44.44 ± 15.95	66.46± 15.02	41.39 ± 14.49	0.001	< 0.001
Vitality	43.66 ± 7.42	43.63 ± 7.31	46.16 ± 5.97	42.42 ± 6.86	45.66± 6.12	41.66 ± 7.35	0.49	0.02
Mental health	45.43 ± 9.39	47.84 ± 6.94	50.86 ± 8.55	45.48 ± 6.91	51/53 ± 6/54	45/63 ± 6/54	0.14	0.001
Social role functioning	44.33 ± 8.97	43.03 ± 7.89	50.33 ± 8.40	42.42 ± 7.81	51.10± 8.31	42.27± 8.20	0.02	0.004
Bodily pain	43.95 ± 6.44	44.92 ± 7.24	45.53 ± 5.61	44.16 ± 6.86	44.53 ± 6.20	43.10 ± 6.84	0.29	0.15
General health perception	48.83 ± 7.50	51.06 ± 4.28	56.83 ± 6.36	48.63 ± 4.55	55.83 ± 4.92	47.72 ± 4.85	0.01	< 0.001
Total	44.84 ± 4.44	45.81 ± 2.98	50.42 ± 3.71	43.75 ± 3.14	49.42 ± 5.24	43 ± 3.25	0.02	< 0.001

tions is depicted in Figure 2.

5. Discussion

Findings of the current study suggested that mindfulness training can improve the QOL in pregnant females. The difference between the two groups was significant in subscales of emotional role functioning, vitality, mental health, social functioning and general health.

Although the effect of mindfulness-based interventions on the QOL of the other groups is studied, it is not studied in pregnant females yet. However, in recent years several studies are conducted to evaluate the effect of mindfulness training during pregnancy.

Vieten and Astin (18) implemented an eight-session mindfulness-based educational program for pregnant females. Results showed that anxiety and negative factors decreased significantly in females who received the mindfulness intervention. However, the intervention showed no

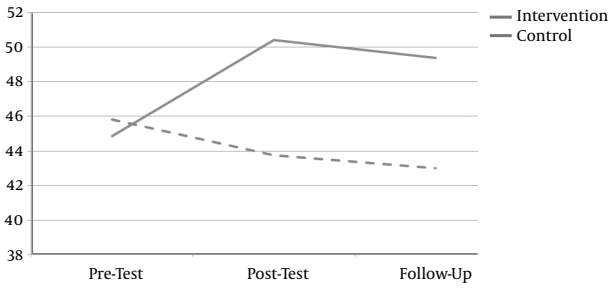

Figure 2. Variations of Quality of Life Score (Total Score) in the Two Study Groups

significant effect on depression, positive factors and regulations.

Dunn et al. (19) conducted a pilot study to examine the effects of mindfulness training on psychological distress among ten multiparous pregnant females. The results showed that mindfulness-based intervention significantly reduced the depression and the psychological distress scores after the intervention and during follow-up compared to those of the period before the intervention.

In another study, Duncan and Bardacke (22) employed a one-group non-controlled design and implemented a mindfulness-based educational program for 27 pregnant females. The results revealed that mindfulness-based training affected alleviating depression, anxiety and negative factors, and enhanced positive factors and well-being. Given the facts that the study was not controlled and some of their participants had previously participated in Yoga training courses, the findings reported by Duncan and Bardacke might have been affected by subjects' previous experience.

Mindfulness taught subjects how to practice staying in the present moment and connect with unfolding experiences. In contrast, when an individual is in mindless state, he largely thinks of the past and gets locked into behavior patterns. For pregnant females, such mindless state might include the view that they should be tired and unhappy and have painful physical symptoms. The purpose of mindfulness is to cultivate into the present moment with an attitude of acceptance, openness and compassion. This attitude can help the pregnant females cope with pregnancy. Preconceptions formed by the society about a pregnant female's physical status can lead to low personal control and learned helplessness (23). Mindfulness allows the person to engage actively in reconstructing the environment and direct attention to the changes occurring during pregnancy as a process, not permanent and that they will pass.

Females' concerns about social evaluation of the changes occurred in their physical shape may lead to avoid social situations (24). Mindfulness training can facilitate social functioning by balancing attentiveness to inner and outer events, and enhancing conscious attention directed to one's own and others' performances. Mindfulness training can provide a self-regulation strategy to females that may help them to cope with stressful situations and management of emotions. By fostering increased awareness for what is happening in each moment, with an accepting attitude, without getting caught up in habitual thoughts, emotions and behavior patterns, females can develop new ways to respond to inner experiences and those of the outside world (25). Part of this issue is related to the point that mindfulness can alter the function of the brain that is responsible for emotion regulation and react to stressful events, and this in turn may normalize body functions such as breathing, heart rate and immune function (26, 27). In fact, mindfulness can act as a buffer in dealing with stressful events (28). More specifically, the purpose of mindfulness is to train people to detect thoughts, emotions and physical sensations at the present moment. Such conscious attention to the individual helps to respond to stressful events more adaptively (29). In fact, by being aware of what is happening at the present moment, females can develop new understanding about pregnancy conditions.

In the study, although the change in total QOL score in the experimental group was statistically significant compared to that of the control group, the changes were not significant in all aspects. Probably one of the reasons that the differences between subscales related to physical health was not significant, is the particular circumstances of the pregnancy; or more time is needed to achieve the desired changes in QOL measures. Also, previous studies that investigate the effectiveness of mindfulness training on QOL in other groups, showed different results. In some studies mindfulness training improved physical aspects of QOL (30, 31), but in some other studies results were not statistically significant (32). It is likely that effects of mindfulness training on physical aspects of QOL are small, and its changes are slow. Further studies can clarify this issue.

The females who learn mindfulness can use the skills to manage stressful aspects of pregnancy, and therefore by reducing psychological distress, improve their psychological well-being and health. Mindfulness training during pregnancy can increase females' coping strategies. When females receive new information and skills during pregnancy, this can help them to adapt better with pregnancy. To spread the scope of this new attitude they can even use mindfulness training in birth preparation classes.

Moreover, studies conducted over the last 30 years revealed that mindfulness training may have dramatic ef-

fects on health and well-being (33). Therefore, mindfulness training can be used as a strategy to moderate the psychological distress and improve mental health during pregnancy.

The main limitations of the study were the lack of necessary facilities to conduct the study in all health centers, lack of follow-up results in the postpartum period, difficulty of doing homework for participants, and attending the mindfulness sessions for the subjects due to their physical and psychological conditions. Also, this study was unable to assess the QOL before pregnancy.

5.1. Conclusion

The results of the current study showed that mindfulness training in the experimental group was effective to improve the pregnant females' QOL, only in the psychological dimensions. In the experimental group, the mean score in the follow-up period decreased compared to the posttest scores, the same thing occurred in the control group. On the other hand, by getting closer to the delivery time, this drop is natural. Mindfulness training can be used as a psychological care during pregnancy, and helps females to moderate negative emotions, improve social functioning and cope with psychological and physical changes.

It is recommended to conduct further studies with long-term follow-up, and investigate the effect of this intervention on other psychological factors. Furthermore, it is suggested to compare the effect of mindfulness training with that of other interventions during pregnancy. Since it is necessary that females attend all training sessions and do regular exercises and they are in especial physical and psychological conditions during pregnancy, may do regular homework and presence in all sessions. So mindfulness training can be started from the initial weeks of pregnancy or before pregnancy for those who are planning to become pregnant. To facilitate access to interventions, future studies can hold online sessions.

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Footnotes

Authors' Contribution: Reza Yazdanimehr and Abdollah Omidi: planning, preparing the first draft and critical revisions of the manuscript; Abdollah Omidi: supervising the study; Hossein Akbari: data analysis; Zohreh Sadat: data collection and critical revision of the manuscript.

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