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MINDFULNESS-BASED COGNITIVE THERAPY ON ANXIETY OF PREGNANT WOMEN DURING THE COVID-19 OUTBREAK IN TEHRAN, IRAN

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ABSTRACT

Introduction. In the current study the mindfulness-based cognitive therapy on anxiety of pregnant women during the coronavirus outbreak were evaluated.

Materials and methods. A randomized controlled clinical trial was carried out among 72 pregnant women who presented at gynecology clinics in hospitals, Tehran, Iran, for prenatal care during January and April 2019. The 17-item short form of Pregnancy Related Anxiety Questionnaire developed by Vanden Bergh was used to evaluate the prenatal anxiety of young Persian pregnant women at risk of preterm labor. The normality of the data was assessed using the Kolmogorov-Smirnov test. Data analysis was performed using the analysis of variance procedure with the post hoc Bonferroni correction using SPSS 16.0 and the significance level was set at [$P \leq 0.05$]. The comparison of continuous and categorical variables between the two groups was conducted using the independent samples t-tests and Chi square or Fisher's exact tests, respectively.

Result and discussion. The results showed that the majority of participants, divided into intervention (83.3%) and control (91.7%) groups, were assessed as having sufficient economic status. The mean age of pregnancy among women at risk of coronavirus in groups of control and intervention was (26.13 ± 1.45) and (26.02 ± 1.42) years old, respectively. The gestational age of most subjects in intervention and control groups was at 27 week (22.2%) and 28 week (25.0%) respectively.

Conclusion. This study presented a discrepancy with our research framework in terms of hospitalized subjects in the prenatal care unit as well as the number and content of educational sessions. The study revealed the lowest anxiety amounts in the intervened individuals at all the evaluation times were related to the fear of changes in mother's personal life criterion, while the fear of childbirth index caused the highest anxiety level among this group. There was no significant difference in fear of mood changes and its consequences on the child and fear of changes in mother's personal life scores before and after implementing the group educational counseling sessions. However, a highly significant difference was found in fear of bearing a physically or mentally handicapped child, fear of childbirth, and fear of changes and disillusion in the marital relationship-MR scores of the intervention groups over time. According to Bonferroni correction, this variance was observed between before the intervention and the 6th and 10th weeks after the intervention.

KEYWORDS: anxiety, cognitive therapy, pregnant women, Covid-19, Iran.

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INTRODUCTION

In December 2019 several cases of acute respiratory syndrome were identified and led to the introduction of a virus from the coronavirus family, which soon known as COVID-19 [Bedford J et al., 2020]. The COVID-19 spread to more than 190 countries, and the World Health Organization announced the COVID-19 disease as a pandemic on 11 March 2020 [WHO, 2020]. Pregnant women are considered a particularly vulnerable group during a viral outbreak. Mental health disorders are a common cause of morbidity during pregnancy with approximately 12 % of women experiencing depression and up to 22% experiencing high levels of anxiety in late pregnancy [Palladino CL et al., 2011; Woody CA et al., 2017]. The pregnant women are more vulnerable to infections because of their naturally suppressed immune system and are generally considered at increased risk for severe complications [Kourtis AP et al., 2014]. It is worth to underline that the COVID-19 pandemic is not only a public health crisis but also a social, demographic and economic one and it has a substantial negative psychosocial effect on everyone, including pregnant women. The resulting anxiety of pregnant women has a negative impact on pregnancy, such as increased risk of preeclampsia, depression, nausea, vomiting and could even cause preterm labor or miscarriage [Sasaki TK et al., 2013]. What is more, maternal anxiety may lead to adverse effects of the newborns, like low birth weight, growth restriction or low APGAR score [Abazarnejad T et al., 2019; Virgara R et al., 2018]. The anxiety during pregnancy is frequently undetected and untreated [Goodman JH et al., 2010]. Psychotropic medications such as antidepressants and benzodiazepines are often used to treat anxiety; however, the potential risks of fetal exposure make the development of efficacious non-pharmacologic approaches particularly urgent in this context [Hayes RM et al., 2012]. Notably, pregnant women are reluctant to take medication due to potential risks to the developing fetus [Goodman JH et al., 2010]. Psychological therapies, particularly cognitive behavioral therapy [CBT], effectively reduce anxiety in patients with anxiety disorders [Otte C, 2011], yet such therapies have not been tested for treatment of anxiety in pregnant women. Despite a great need for effective, non-pharmacological interventions, research specifically addressing

treatment of anxiety disorders during pregnancy is seriously lacking, with no published studies of psychotherapeutic treatments for anxiety in pregnancy to date [Khoury B et al., 2013]. Mindfulness-based interventions (MBIs) offer a promising development for the treatment of anxiety. One of the most established and studied MBIs is mindfulness-based stress reduction (MBSR) which was developed by [Kabat-Zinn J, 2005] in the 1980s. Mindfulness as a way to alleviate pain and improve physical and emotional well-being for individuals suffering from a variety of diseases and disorders. MBSR is a highly structured 8-week intensive group training in which participants are taught mindfulness practices such as a body scan, formal sitting meditation, and mindful yoga. Through use of these practices, participants are taught to observe thoughts, feelings, and bodily sensations objectively and in the present moment without judging, clinging to, or pushing away their experience [Kabat-Zinn J, 2005]. Mindfulness-based cognitive therapy (MBCT) has shown positive effects in panic and in social anxiety disorder [Arch JJ et al., 2023]. Other interventions in which mindfulness training is an integral component of treatment have also shown favorable results as a clinical intervention for GAD. Mindfulness based interventions may have beneficial effects for pregnant women [Hayes-Skelton SA et al., 2013]. According to [Greeson and Brantley J, 2009] the mindfulness practice offers a fundamentally different way of responding to anxiety in which it is deliberately noticed, allowed, and responded to with openness, curiosity, acceptance, and self-compassion. Therefore, practicing mindfulness may interrupt habitual avoidance, increase distress tolerance, and promote greater behavioral flexibility in response to anxiety, ultimately leading to less anxiety and overall distress [Greeson and Brantley J, 2009; Karamoozian M et al., 2017]. The burden and consequences of anxiety during pregnancy is substantial and there is a recognized need for effective alternatives to pharmacological treatment of anxiety in pregnancy [Van den Bergh B, 1990; Huizink AC et al., 2004]. The objective of the current study was to evaluate the feasibility and acceptability of delivering the pregnancy intervention to pregnant women with high levels of anxiety or worry symptoms during the coronavirus disease outbreak in Iran.

MATERIALS AND METHODS

A randomized controlled clinical trial was carried out among 72 Persian young pregnant women living in Tehran city, referred to the gynecology clinics and the departments of infectious and respiratory diseases in hospitals in Tehran, Iran, to receive prenatal care during the period from January and April 2019. The simple random sampling method was chosen to recruit and allocate the participants into two groups of intervention (n=36) and control (n=36). Sample size of 62 participants (31 person in each group) was calculated to be adequate for assessing a clinically significant difference of 0.2 between groups in decreasing the average anxiety score in pregnant women assuming a standard deviation of 10 using a two tailed t-test of difference between means with 80% power, effect size of 45%, and a 5% level of significance. However, the sample size to compensate for the subject drop-out based on the loss rate of 10% was increased to 72 subjects. The criteria for entering the study were: Iranian nationality; living in Mashhad city; the minimum literacy such as reading and writing skills to understand and answer questions; willingness to participate in the research plan; pregnancy for a healthy single baby; a gestational age between 24 and 28 weeks assessed by the last menstrual period and ultrasound examinations, and obtaining the score ten or more according to the risk scoring system for prediction of PTL [Babanazari L et al., 2008] and no history of specific mental illness, and anxiety scores between 17 and 119 based on the pregnancy-related anxiety questionnaire PRAQ [Askarizadeh G et al., 2017]. The exclusion criteria in this study included failure to attend two sessions of group educational counseling, adverse events, and major stresses during the intervention such as a loss relatives and close friends or migration of pregnant women. In the current study, a single meeting was held for pregnant women and their spouses to explain the research design and objectives. Written informed consent was obtained from all the subjects and their spouses. The pregnant women's involvement was entirely voluntary, and they could quickly leave the study if they no longer wished to continue. All information was confidential and employed exclusively for

scientific purposes. Subjects in the intervention group in addition to the routine pregnancy care programs received educational advice in the form of an audio file through a virtual network.

Content of the pregnancy program of psychoeducation about:

- Stress physiology, anxiety, and depression
- Mindfulness How mindfulness can be utilized in pregnancy, labor and delivery, and parenting, and in everyday life to facilitate more adaptive responses to challenges and distress

Mindfulness practices:

- Body scan
- Mindful yoga
- Various sitting meditations
- Walking meditation
- Mindfulness in everyday life practices
- Mindfulness of baby practices

Cognitive exercises:

- Self-observation and self-monitoring skills development
- Decentering from automatic thoughts
- Self-compassion meditation
- Home practice – 30 to 45 minutes six days a week
- Reading material provided from a variety of sources on aspects of mindfulness practice

The PRAQ by intervened pregnant women virtual network was completed before first session and after the 6th session, and one month post counseling follow-up. Additionally the pregnant women allocated in the control group only received the routine pregnancy care programs. This group also answered queries present in the PRAQ before and after the 6th and 10th weeks of the study. The 17-item short form of PRAQ developed by [Van den Bergh B, 1990] was used to evaluate the prenatal anxiety of Iranian pregnant women at risk of PTL. This questionnaire has five subscales including (i) self-centered fear or fear of the changes in mother's personal life (FC, MPL; three items, 3–21 scores), (ii) fear of bearing a physically or mentally handicapped child FB PMHC; four items, 4–28 scores], (iii) fear of childbirth (FCB; three items, 3–21 scores), (iv) fear of mood changes and its consequences on the child (FMC CC; three items, 3–21 scores), and (v) fear of changes and disillusion in the marital relationship (FCD MR; four items, 4–28 scores). Therefore, each question is graded between 1.0 and 7.0, while the total score range of pregnancy anxiety was between 17 and 119 [Kar-

amoozian M et al,2017; Huizink AC et al.,2020] to evaluate psychometric properties in nulliparous pregnant women with a normal risk status, found that there was an acceptable association between the results obtained from the PRAQ and the state trait anxiety inventory covering general anxiety and depression. They showed that the Cronbach's alpha of 0.76 for all the subscales throughout pregnancy [Huizink AC et al.,2020]. The PRAQ was used with a highly significant validity in Iranian pregnant women. Also [Babanazari L, Kafi M ,2008] earlier confirmed the face validity of the Van den Bergh's PRAQ through evaluation by five psychologists and reported the Cronbach's alpha of 0.81. In the same line [Askarizadeh GH et al., 2025] also demonstrated the coherent validity of the Iranian version of the PRAQ and Beck Anxiety Inventory Questionnaire. Based on the Cronbach's alpha, the PRAQ reliability was assessed to be 0.78, whereas this coefficient for the five subscales ranged from 0.69 to 0.76 [Askarizadeh GH et al., 2025; Curt AS et al., 2012;]. In the current study, the Cronbach's alpha for PRAQ, 17 was estimated to be 0.87, with a value of 0.76–0.89 for the different subscales. All continuous data are presented as mean $\pm$ SD, while categorical variables are expressed as frequency and percentage. The comparison of continuous and categorical variables between the two groups was conducted using the independent samples t-tests and Chi square or Fisher's exact tests, respectively. The normality of data was assessed by the Kolmogorov-Smirnov test statistic. The results were examined using the analysis of variance (ANOVA) procedure with post hoc Bonferroni correction using SPSS 16.0 software SPSS Inc., Chicago, IL, USA and the significance level was set at [$P \leq 0.05$].

RESULTS AND DISCUSSION

The results of the sociodemographic and obstetric information of Persian pregnant women at risk of coronavirus in control and intervention groups showed that there was no significant difference ($P \geq 0.05$) in these primary data between the two groups (Table 1). The mean age of participants in intervention and control groups was 28.06 ± 4.33 and 26.22 ± 4.43 years, respectively. The age groups of 31–35 years and 20–25 years were dominant (36.1%) in the intervention and control groups, respectively. Most pregnant women at risk of coronavirus in both control (58.3%) and intervention

(50.0%) groups had a high school diploma. A sufficient economic status was assessed for most participants allocated in the intervention (83.3%) and control (91.7%) groups. Also, most of them were housewives in the intervention (83.3%) and control (88.9%) groups. The mean pregnancy age of pregnant women at risk of coronavirus in groups of control and intervention was 26.13 ± 1.45 and 26.02 ± 1.42 years, respectively. The gestational age of most subjects in intervention and control groups was 27th week (22.2%) and 28th week (25.0%), respectively. The percentage of stillbirth or abortion and coronavirus infection among pregnant women in the control group was (27.8%) and (22.2%) respectively, whereas the corresponding values for pregnant women present in the intervention group were (22.2%) and (36.1%) respectively. Most of the pregnancies among pregnant women in the intervention

TABLE 1.

Basic sociodemographic and obstetric information of pregnant women

Characteristics	Control [n=36]	Intervention [n=36]	Significance level
Pregnant women age [year]			t=1.77, P=0.08
<20	11.1 [n=4]	0.0 [n=0]	
20-25	36.1 [n=13]	33.3 [n=12]	
26_30	33.3 [n=12]	30.6 [n=11]	
31_35	19.5 [n=7]	36.1 [n=13]	
Pregnant women's education status			$\chi^2=1.87$, P=0.39
Under diploma	33.3 [n=12]	30.6 [n=11]	
Diploma	58.3 [n=21]	50.0 [n=18]	
University education	8.4 [n=3]	19.4 [n=7]	
Level of economic status (Fisher's exact test)			P=0.71
Low	2.8 [n=1]	2.8 [n=1]	
Average	91.7 [n=33]	83.3 [n=30]	
High	5.5 [n=2]	13.9 [n=5]	
Pregnant women's occupation			$\chi^2=0.46$, P=0.49
Housewife	88.9 [n=32]	83.3 [n=30]	
Employee	11.1 [n=4]	16.7 [n=6]	
Pregnancy age [week]			t = -0.32, P=0.74
24th	17.6 [n=6]	19.4 [n=7]	
25th	22.2 [n=8]	19.4 [n=7]	
26th	16.7 [n=6]	19.4 [n=7]	
27th	19.4 [n=7]	22.2 [n=8]	
28th	25.0 [n=9]	19.4 [n=7]	
Pregnancy history [number]			$\chi^2=0.24$, P=0.88
1	44.4 [n=16]	38.9 [n=14]	
2	38.9 [n=14]	41.7 [n=15]	
3	16.7 [n=6]	19.4 [n=7]	

(80.6%) and control (77.8%) groups were wanted. Moreover, (41.7%) and (38.9%) of pregnant women in intervention and control groups, respectively, experienced vaginal delivery in previous pregnancies. The Kolmogorov-Smirnov test was used to assess the data normality of pregnancy anxiety and its five dimensions (FC-MPL, FB-PMHC, FCB, FMC-CC, and FCD-MR) defined in the PRAQ 17.

Results in table 2 demonstrated that the anxiety related data were normal in both groups at three evaluation times specially before and after the 6th and 10th weeks of the study. Thus, the parametric tests were thus used to analyze normally distributed data. The lowest anxiety amounts in the intervened individuals at all the evaluation times were related to the FC-MPL criterion, while the FCB index caused the highest anxiety level among this group. There was no significant difference in FMC-CC and FC-MPL scores between before and after implementing the group educational counseling sessions. There was a highly significant difference ($P \leq 0.001$) in FB-PMHC, FCB, and FCD-MR scores of the intervention group over time. The Bonferroni correction results showed that this variance between before and the 6th and 10th weeks after the intervention. Accordingly, the FB-PMHC, FCB and FCD-MR scores on the 6th and 10th week were meaningfully reduced compared to those of before the intervention, while no significant differences in FB-PMHC ($P=0.60$), FCB ($P=0.20$) and FCD-MR ($P=0.11$) scores between the 6th and 10th weeks were observed. A significant difference in the mean anxiety score of the intervention group was found over time. The Bonferroni correction analysis also confirmed that the mean anxiety score on the 6th and 10th weeks was significantly lower than that of before the group educational counseling

sessions. However, there was no significant difference in the mean anxiety score between the 6th and 10th weeks after the intervention ($P=0.068$). In the control group, the FC-MPL had the lowest impact on pregnancy anxiety beforehand after 6 weeks since the beginning of the study. By the 10th week, FMC-CC had the smallest impact on the pregnancy anxiety of this group. The highest anxiety level in the control group at all times was related to the FB-PMHC. There was no significant difference in FCD-MR scores across the three time points. However a substantial increase in the scores of other dimensions causing the pregnancy-related anxiety was obtained. Additionally, a similar tendency was found in the overall mean anxiety scores, with a significant difference in pregnancy anxiety detected between the 6th and 10th weeks.

Although there is no direct relationship between the maternal and fetal nervous systems, a relationship between maternal mood before birth and fetal behavior can be found. Exposure to the long term effects of prenatal anxiety causes various mechanisms at different stages of fetal growth and development. With increased anxiety, cortisol hormone appears to cross the placenta and affect the fetus, disrupting ongoing processes, affecting the limbic and prefrontal cortex, and releasing chemicals such as acetylcholine and adrenaline in the mother's body. The chemicals pass through the placenta into the fetus and have detrimental effect on proper fetal growth [Curt AS et al., 2017]. Therefore, there is a necessity to reduce pregnancy-related anxiety to promote healthy growth and development of newborns. The success in implementing this prenatal care in reducing anxiety requires the collaboration and coordination between pregnant women and primary care providers, such as family physicians, midwives, and nurse practitioners.

TABLE 2.

The normality of pregnancy anxiety and pregnancy-related anxiety questionnaire dimensions in pregnant women at risk of preterm labor in the two groups

Pregnancy anxiety and pregnancy-related anxiety questionnaire dimensions	Before		the 6 th week		the 10 th week	
	Cnt.	Int.	Cnt.	Int.	Cnt.	Int.
Fear of changes in mother's personal life	0.20	0.10	0.14	0.15	0.20	0.17
Fear of bearing a physically or mentally handicapped child	0.069	0.07	0.20	0.16	0.18	0.22
Fear of childbirth	0.19	0.052	0.061	0.19	0.20	0.20
Fear of mood changes and its consequences on the child	0.058	0.06	0.16	0.28	0.22	0.21
Fear of changes and disillusion in the marital relationship	0.13	0.10	0.18	0.26	0.20	0.23
Anxiety	0.20	0.22	0.20	0.20	0.20	0.15

NOTE. **CntT-** Control group; **Int.-** Intervention group;

In this study, the two groups statistically were homogeneous in terms of demographic characteristics and all dimensions of pregnancy anxiety. However, the mean anxiety score in the intervention and control groups was significantly different. Implementing the group educational counseling sessions under the planned primary care practice is an effective way to reduce this risk factor among Iranian pregnant women. In this line [Düzgün AA, Ege E, 2017] found that the application of relaxation exercises by 60 hospitalized primiparous pregnant women could significantly reduce the pregnancy anxiety level after two and four month follow-ups. The relaxation exercises were trained through the educational booklet and CD [Bazrafshan S et al., 2020] controlling the anxiety to reduce preterm labor through face-to-face sessions and question-and-answer communications, which were in agreement with the research methodology applied in our study. Nevertheless, the selected subjects [primiparous and hospitalized] and the intervention duration differed from those in present study. However, the samples in our study were randomly divided into two groups. This study was similar to ours in terms of the type of therapeutic intervention and the psychological variable. Additionally [Kao M, Chen CCP, 2017] also evaluated the effect of two-week support interventions on 240 Taiwanese nation hospitalized pregnant women at risk of PTL in the 1st week of admission. They showed that instructing the participants to perform techniques involving psychophysiological relaxation in the hospital and the following practicing at home could significantly contribute to decreasing feelings of anxiety and depression. However, one of the limitations of this study was the excessively large sample size that can highly attenuate the quality and conditions of educational intervention as well as the limited number of training sessions. Recently, several clinical studies have been conducted to reduce the pregnancy-related depression and anxiety among Iranian pregnant women [Moghadasi M et al., 2016; Azogh M et al., 2018]. Also [Samani E et al., 2020] found that the use of cognitive behavioral counseling could positively improve the mental health of mothers of premature infants in neonatal intensive care units. Thus, mothers who receive the essential pregnancy-related education and engage in primary care practices, they tend to show appropriate reactions under critical mental conditions. The high social interactions and relationships of pregnant women undergoing this counseling group intervention have a high potential in decreasing

anxiety and stress and adverse pregnancy outcomes such as PTL [Khanzadeh AAH et al., 2018]. They also assessed the efficiency of twelve 90-minute sessions of cognitive behavioral training on the pregnancy anxiety and delivery mode in 24 primiparous pregnant women. Those researchers found that the prenatal cognitive behavioral education was a powerful tool in decreasing the pregnancy anxiety in pregnant women and increasing the participant's preference for vaginal delivery over cesarean section. In a quasi-experimental study, the role of psycho education in reducing pregnancy anxiety was investigated in 100 pregnant women with a history of stillbirth [Azogh M et al., 2018]. In their analysis of Van den Bergh's PRAQ results after an eight week follow up proved that pregnancy anxiety was significantly lower in the intervention group after the psychological training than in the control group. Although none of these studies were conducted on the anxiety reduction in pregnant women at risk of PTL, [Moghadasi M et al., 2016] the results indicated the effect of educational intervention as an important indicator in reducing pregnancy anxiety. However, they found that the participation of pregnant women at risk of PTL in two 60-minute supportive counseling sessions could lead to a significant reduction in the state-trait anxiety (STA) level. A slight increase in trait anxiety of the control of pregnant women at risk of PTL was recorded, while their situational anxiety decreased. This fact may be contributed to counseling received from a trusted physician or midwife.

CONCLUSION

This study showed a discrepancy with our research framework in terms of the inclusion of hospitalized subjects in the prenatal care unit and the number and content of educational sessions. The study revealed that the lowest anxiety amounts in the intervened individuals at all the evaluation times were related to the FC-MPL criterion, while the FCB index caused the highest anxiety level in this group. There was no significant difference in FMC-CC and FC-MPL scores between before and after implementing the group educational counseling sessions. There was a significant difference in FB-PMHC, FCB, and FCD-MR scores of the intervention groups over time. The Bonferroni correction results showed that this variance occurred between before the intervention and the 6th and 10th weeks after the intervention.

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