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The effectiveness of transdiagnostic integrative treatment on sleep quality and symptoms of premenstrual syndrome: A trial study

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ABSTRACT

Purpose: The present study was aimed at determining the effectiveness of integrative transdiagnostic treatment on sleep quality and premenstrual symptoms. *Method:* This study was carried out based on clinical trial including pre-test, post-test, and follow-up with control group. The participants of the study included all women in reproductive ages with a diagnosis of premenstrual syndrome who had referred to Shahid Beheshti University of Medical Sciences in during November 2020 to December 2021. Forty participants were selected via purposive sampling. Twenty participants were then assigned into each group. Experimental group participants received 8 transdiagnostic treatment sessions. To collect data, Pittsburgh Sleep Quality Index and Premenstrual Symptoms Screening Tool were employed and analyze the data was done by SPSS statistical software; and paired t-test, and repeated measures analysis. *Results:* The mean and standard deviation of participants' age were 30.90 ± 8.06 for experimental group and 33.25 ± 9.58 for control group. Based on the results of repeated measures analysis, there was a significant difference between experimental and control groups with respect to sleep quality and PMS. Moreover, according to the results of paired t-test, there was a significant difference between groups in post-test and follow-up phases with regard to sleep quality and PMS. *Conclusion:* Therefore, transdiagnostic treatment has significant effects on sleep quality and PMS. It is thus suggested that gynecologists, clinics, and medical centers concerned with PMS patients can use the results of the present study as a guide.

Keywords: Premenstrual Syndrome, Sleep Quality, Integrative Transdiagnostic Treatment

1. INTRODUCTION

Menstruation is the periodic vaginal bleeding that occurs with the fall of the uterine mucosa and is considered as one the important symptoms of maturity. It occurs one to two years after the appearance of secondary sexual

characteristics (Sapkota et al., 2013). The first period of menstruation happens between ages 11 to 15 years and with the average age of 13 (Dasgupta et al., 2008). Menarche or the first occurrence of menstruation is a turning point in the life of young woman indicating the transition from childhood to puberty (Padmanabhanunni et al., 2018). Many girls are not prepared for the onset of menstruation due to taboos against sexual matters and pregnancy that forbid any discussion of these issues (Mason et al., 2013; McMahon et al., 2011). Results of previous studies have shown that symptoms related to menstruation including premenstrual syndrome and menstrual cramps are connected with most of psychological symptoms of young women (Sahin et al., 2018).

One of the common problems that women are faced with due to menstruation is premenstrual syndrome (PMS). PMS involves a set of physical symptoms such as gaining weight, headache, etc. and Psychological complaints for instance, irritability, anxiety, and depression and influences many women 7 to 14 days before menstruation (Abdnezhad et al., 2017; Brahmbhatt et al., 2013; Direkvand-Moghadam et al., 2014; Raval et al., 2016). PMS symptoms are likely to appear differently in different people (Halbreich et al., 2006). The incidence rate of PMS depends on conditions and sociocultural characteristics of women and diagnosis methods. However, the prevalence of PMS is estimated about 30 to 40 percent in reproductive ages and around 20 to 32 percent in ages before menopause. The main cause of PMS is still unknown and it is assumed that it occurs due to multiple factors (Sut et al., 2016). Based on the results of the available studies, women with PMS experience many sleep problems (Nowakowski et al., 2013).

Women with PMS experience sleeplessness and sleepiness at least twice as much as women without PMS (Baker et al., 2012). Besides, they have reported other complaints related to sleep during menstruation period for example: frequent awakenings, problems in falling sleep, sleepiness, fatigue, lethargy and decreased concentration (Van Reen et al., 2016). Sleep composes one third of people's life (8 hours in day and night) and sleep is therefore a basic need for physical emotional rest and a healthy life (Demir et al., 2017).

According to existing evidence, the quality of women's sleep is typically faced with disorder in premenstrual period. The prevalence of sleep disorders in women with PMS varies between 15.4 to 75.6 percent (Guvenc et al., 2012; Karaman et al., 2012). Given that there are many factors contribute to PMS, multiple treatment methods have been suggested for controlling PMS including medication (such as nutritional supplements and anti-depression drugs), diets, psychological treatments, and relaxation exercises like yoga (Freeman, 2010). Based on the findings of the previous studies, 80 percent of women with PMS tend to use appropriate and economic treatments (Babazadeh et al., 2011). In the past, cognitive-behavioral therapies have been extensively used to treat PMS symptoms. The existing evidence indicates that cognitive-behavioral therapy is exclusively effective in mood disorders as well as anxiety disorders (Butler et al., 2006; Davidson, 2004). However, given that many women experience a lot of psychological symptoms during menstruation, the use a treatment focused on comorbidity of these symptoms is of paramount importance (Mansell et al., 2008; McHugh et al., 2009; Sahin et al., 2018).

The emphasis on comorbidity of psychological symptoms led to extensive research on determining transdiagnostic factors and common factors of concomitant disorders (Barlow et al., 2010; McEvoy et al., 2009). According to the results of these studies, it has been suggested that transdiagnostic treatment is likely to be more effective than specific treatments for concomitant disorders. Thus, Barlow et al., (2010) developed an integrative transdiagnostic protocol for emotional disorders. This protocol is a combination of transdiagnostic treatment and cognitive-behavioral therapy focused on emotion that is applicable to a wide range of emotional disorders by using emotion regulation skills. In addition, treatment with the integrative protocol remarkably highlights the functional and consistent nature of emotions, increased awareness of the role of cognitions, physical feelings, emotions and behaviors (Farchione et al., 2012). Therefore, based on the points highlighted above and given that there is limited research on the effectiveness of transdiagnostic treatments for women's symptoms during menstruation, the present study seems to be of high significance.

Hence, the current study was aimed to determining the effectiveness of the integrative transdiagnostic treatment on sleep quality and symptoms of premenstrual syndrome.

2. MATERIALS AND METHODS

The present study was carried out based on clinical trial including pre-test, post-test, and follow-up with control group. The participants of the current study included all women in reproductive ages with a diagnosis of premenstrual syndrome that had referred to treatment centers affiliated with hospitals of Shahid Beheshti University of Medical Sciences in Tehran during November 2020 to December 2021. Initially, the research sample was selected as purposive sampling based on the participation criteria and the purposes of the study. The sample size of present study was calculated based on the study done by Hooman et al., (2016) and Formula 1. The effect size for depression, anxiety, and positive cognitive emotion regulation were 0.80, 0.76, and 0.66, respectively in the study done by Hooman et al., (2016). Moreover, alpha and beta calculated via Formula 1 was 0.05 and 0.20, respectively. Therefore, given the points highlighted above and the probability of participants' withdrawal from the different phases of the

study, the sample size=n=80 was considered for each group in the present study. The participants were then randomly assigned into control and experimental groups. Each group included 40 participants.

$$d = \frac{\mu_2 - \mu_1}{\sigma}$$

$$n \geq \left(\frac{1+r}{r}\right)\frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{d^2} + \frac{Z_{1-\alpha/2}^2}{2(1+r)}$$

The criteria to participate in the current study were being in reproductive ages, having minimum basic literacy skills for responding to questionnaires, lacking an IUD or the use of hormonal contraception methods, not suffering from any severe mental or physical illness restricting the participation rate, lacking addiction to drugs and alcohol, no addiction to cigarette smoking or hookah smoking, and not simultaneously receiving any other forms of psychotherapy. The criteria for withdrawal from the present study included variations in physical activity, variations in marital status or sexual activity, suffering from a severe mental illness (severe depression or anxiety disorders, psychotic disorders, and substance use disorder) or physical illness that hinder the implementation of the protocol, changes in dose or the type of psychiatric drugs, painkillers, hormonal drugs, or herbal medicinal products, stressful life event (such as death of a loved one), and being absent from more than two treatment sessions. Next, the transdiagnostic protocol based on improvement in the symptoms of premenstrual syndrome was implemented for the experimental group.

From the ethical point of view, it should be noted that participants from the control group who tended to receive transdiagnostic treatment protocol were treated after conducting the study. The transdiagnostic treatment was administered in eight sessions and the follow-up phase was studied one month later. In this study, demographic information collection form, Pittsburgh Sleep Quality Index (PSQI), and Premenstrual Symptoms Screening Tool (PSST) were employed.

Demographic Information Collection Form
This form was developed by the researcher and included information about age, marital status, and education level of the participants in groups.

Pittsburgh Sleep Quality Index (PSQI)
This questionnaire was developed by Buysse et al., (1989) at Pittsburgh Psychiatry Institute. Originally, it has 9 items but since question no. 5 includes 10 sub items, the total questionnaire involves 18 items that are scored on a four-point Likert continuum. This questionnaire also contains 7 subscales, namely mental quality of sleep, delay in falling sleep, sleep efficiency, sleep duration, sleep disorder, the use of hypnotics, and sleep dysfunction. The internal consistency of this questionnaire calculated via Cronbach's alpha was 0.83 as reported by Buysse et al., (1989). Zaghimi et al., (2012) reported a test-retest reliability of r=0.80 in their study. Besides, the reliability and validity of this questionnaire have been reported as acceptable and certifiable in other studies (Ghaljaei et al., 2011; Ghoreishi et al., 2008).

Premenstrual Symptoms Screening Tool (PSST)
This questionnaire developed by Steiner et al., (2003). It was aimed at screening and identifying women and girls with severe symptoms of premenstrual syndrome and premenstrual dysphoric disorder (PMDD) based on diagnostic and statistical criteria for mental disorders of the fourth edition (DSM-IV). This questionnaire includes 19 items. Moreover, PSST has two subscales, namely behavioral, physical and mood symptoms (14 items), and the effects of behavioral, physical and mood symptoms on the life of a person (5 items). All items are scored on a Likert continuum from 0=never to 3=severe (Steiner et al., 2003). Siah Bazi et al., (2011) reported the reliability of 0.90 for this questionnaire as calculated via Cronbach's alpha. Furthermore, in their study, content validity and content validity index were reported as 0.70 and 0.80, respectively.

Ethical Considerations
The qualified participants were informed of the purposes of this study, criteria, and research conditions. Along with the oral consent from the participants to involve in the study, they were also required to fill out an informed written consent. In addition,

this study was confirmed by the ethics committee of Shahid Beheshti University of Medical Sciences with the ethics code of IR.SBMU.MSP.REC.1398.668.

Statistical Analysis

SPSS software was employed to analyze the data. Initially, descriptive statistics were used to examine demographic and descriptive findings. Next, normality assumption, homogeneity of variances and homogeneity of the covariance matrix were investigated. Finally, analysis of variance with repeated measures was used to examine the results of the research hypotheses.

3. RESULTS

Forty women with PMS symptoms participated in the present study. Twenty women were assigned in experimental group and twenty women were assigned in control group. The mean and the standard deviation of age were 30.90 ± 8.06, 33.25 ± 9.58 and 32.07± 8.82 for experimental group, control group and the total sample, respectively. Besides, the participants' age ranged between 18 and 48. Moreover, the frequency and percentages of demographic information for the participants of the experimental and control groups have been presented in Table 1.

Table 1 Frequency and Percentages of Demographic Information for the Participants of Experimental and Control Groups

Variable		Experimental Group		Control Group	
		Frequency	Percentage	Frequency	Percentage
Marital Status	Single	9	45	12	60
	Married	11	55	8	40
Education Level	High School	3	15	5	25
	Diploma	5	25	5	25
	AD	3	15	3	15
	BA	5	25	4	20
	MA	4	20	3	15

As it has been displayed in (Table 1) 11 participants (55%) in experimental group were married and 12 participants (60%) in control group were single. Besides, information about the education level of the participants in experimental and control groups has been reported in Table 1. In Table 2, descriptive statistics for sleep quality and PMS of the participants in Control and Experimental Groups have been presented based on the different phases of the study.

Table 2 Descriptive Statistics for Sleep Quality and PMS of the Participants in Control and Experimental Groups in Different Phases of the Study

Variables	Group	Pre-test (Mean ± SD)	Post-test (Mean ± SD)	Follow-up (Mean ± SD)
Sleep Quality	Experimental	10.3 ± 4.08	6.65 ± 2.72	7.5 ± 1.85
	Control	10.35 ± 2.56	10.10 ± 2.22	9.45 ± 1.93
Premenstrual Syndrome (PMS)	Experimental	34.85 ± 4.97	29.7 ± 3.03	29.25 ± 2.65
	Control	33.55 ± 2.68	33.65 ± 2.43	34.05 ± 2.42

As it has been shown in Table 2, descriptive statistics for sleep quality and PMS of the participants in Control and Experimental Groups have been presented based on the different phases of the study. Variance analysis with repeated measures was employed to examine the research hypotheses of the present study. Therefore, normality assumption and homogeneity of variances were initially investigated and confirmed. In addition, Box's M test was used to assure equality of covariance matrices. The results of this test were F=2.347, P=0.029, Box's M= 15.407 for sleep quality and F=5.788, P=0.005, Box's M= 38.00 for PMS, indicating that this assumption was not observed. Besides, since Mocheli sphericity test should be initially examined in using variance analysis with repeated measures, the results of this test were W=0.734, P=0.005 for sleep quality and W=0.636, P= 0.005 for PMS, indicating that the sphericity assumption was not observed. Given that some of the assumptions of variance analysis with repeated measures were not observed, Pillai's Trace and huynh-feldt corrected values were used to make comparisons. In Table 3, the results of within-group effect, Pillai's Trace, and time-group interaction for sleep quality and PMS have been presented.

Table 3 Results of Within-group Effect, Pillai's Trace, and Time-group interaction for Sleep Quality and PMS

Variable	Within-Group Effect	Pillai's effect	F	P-value	Eta Squared	p
Sleep Quality	Time	0.514	19.580	0.0001	0.514	0.925
	Time × Group	.501	18.594	0.0001	0.501	0.945
Premenstrual Syndrome (PMS)	Time	0.540	2.00	0.0005	0.540	1
	Time × Group	0.583	25.893	0.0005	0.583	1

As it has been indicated in Table 3, the effect of measurement time on linear composition of sleep quality was significant. Therefore, huynh-feldt test was used to examine univariate results of this test in Pillai's Trace and time-group interaction. In Table 4, the univariate results of this test in Pillai's Trace and time-group interaction via huynh-feldt test for sleep quality and PMS have been presented.

Table 4 Univariate results of huynh-feldt test according to the effect of time and time interaction with the group for sleep quality and PMS

| Variable	Effect	Test	Total Squares	df	Mean Squares	F	P-value	Eta Squared
Sleep Quality	time	huynh-feldt	96.467	1.580	61.045	21.296	0.0001	0.359
	Time.group	huynh-feldt	58.067	1.681	34.549	12.819	0.0001	0.252
Premenstrual Syndrome (PMS)	time	huynh-feldt	171.717	1.551	110.710	33.411	0.0005	0.468
	Time.group	huynh-feldt	218.317	1.551	140.754	42.478	0.0005	0.528

As it has been shown in Table 4, the time effect suggests that this rate has been significant for sleep quality and PMS. Moreover, concerning the interaction effect, it was revealed that this effect has been significant for sleep quality and PMS. In Table 5, the results of independent t-test have been presented to make paired comparisons of the interaction effect of time with group for sleep quality and PMS.

Table 5 Results of Independent t-test to Make Paired Comparisons of the Interaction Effect of Time with Group for Sleep Quality and PMS

Variable	Test	Group		Mean Differences	Standard Error	P-value
Sleep Quality	Pre-test	Experimental	Control	0.050	1.077	0.963
	Pre-test	Experimental	Control	3.450	0.785	0.0001
	Follow-up	Experimental	Control	1.950	0.589	0.002
Premenstrual Syndrome (PMS)	Pre-test	Experimental	Control	1.300	1.262	0.310
	Post-test	Experimental	Control	-3.950	0.869	0.0005
	Follow-up	Experimental	Control	-4.800	0.802	0.0005

As it has been indicated in Table 5, there were not significant differences between control and experimental groups with respect to pre-test scores of sleep quality and PMS. However, there existed significant differences between control and experimental groups

with regard to post-test and follow-up scores of sleep quality and PMS, highlighting the effectiveness of transdiagnostic treatment on sleep quality and PMS. Therefore, research hypotheses about the positive significant effects of transdiagnostic treatment on sleep quality and PMS have been confirmed. In Graph 1, the time-group interaction effect for sleep quality has been presented. Besides, in Graph 2, the time-group interaction effect for PMS has been displayed.
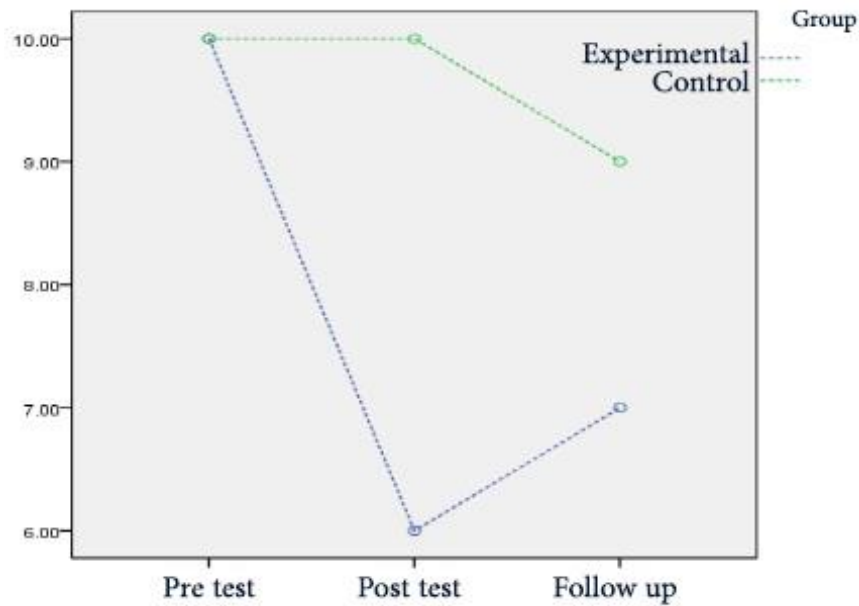
Graph 1 Time-Group Interaction Effect for Sleep Quality
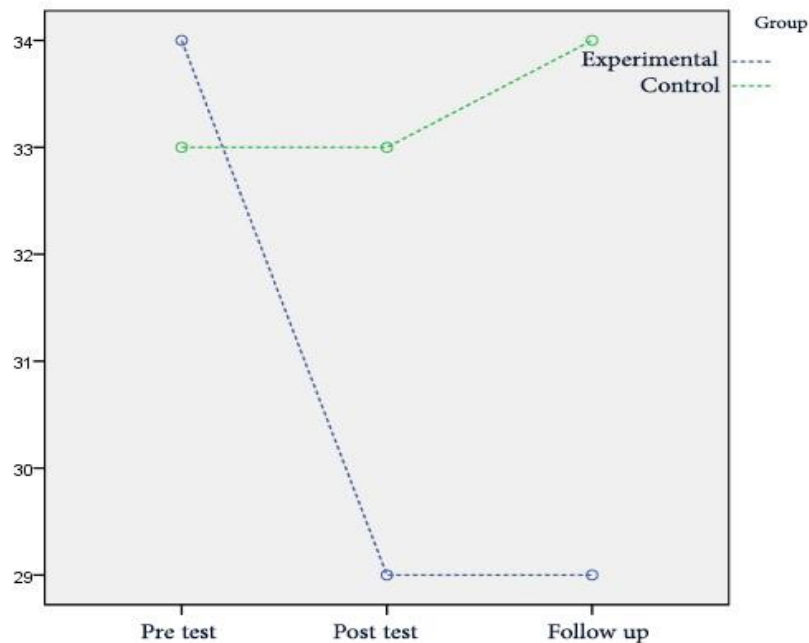
Graph 2 Time-Group Interaction Effect for PMS

4. DISCUSSION

The present study was aimed at investigating the effectiveness of integrative transdiagnostic treatment on sleep quality and symptoms of premenstrual syndrome. The results of the current study revealed that integrative transdiagnostic treatment has positive significant effects on sleep quality and symptoms of premenstrual syndrome. There was no study concerning the effects of transdiagnostic treatment on women's sleep quality. However, the results of a study done by Harvey et al., (2021) investigating

adults with mental disorders showed the effectiveness of transdiagnostic treatment on sleep disorders, sleep hours, and being awake and efficient despite the difference in its sample size compared to the present study. Besides, Harvey et al., (2016) explored patients with severe mental disorders and reported the effectiveness of transdiagnostic treatment on sleep disorders, sleep hours, and being awake despite the difference in its sample size compared to the present study. Moreover, the results of a study carried out by Zar et al., (2019) on addicted women indicated a negative significant relationship between PMS and sleep quality. Therefore, their results were consistent with the results of current study.

Based on the study done by Anatai et al., (2004), sleep disorder is one of the most prevalent symptoms that appear in premenstrual period. In addition, according to Pritchard (2010), sleep disorders as one of PMS symptoms can cause problems in sleep quality such as sleep time and wakening up at nights (Bastani et al., 2017). Various psychological treatments are employed to treat sleep disorders. One of the suggested treatments is transdiagnostic treatment in which identifying and treating sleep disorders and global sleep characteristics that are likely to influence individuals' welfare are highlighted (Harvey, 2009; Harvey et al., 2021; Harvey et al., 2016). Therefore, in order to explain this finding of the study, it can be said that sleep disorders are connected with different forms of psychopathology including interaction with emotion regulation, interaction with genetics, and function of serotonin and dopamine neurotransmitters (Harvey et al., 2011).

In addition, the results of the previous studies have indicated that mindfulness training is effective in sleep disorders (Heidenreich et al., 2006; Ong et al., 2008). Mindfulness emphasizes the teaching of the required skills for anxiety management, rumination, and distressing thoughts (Harvey et al., 2011). Based the points highlighted above and given that the focus on present time is emphasized in the third part of the transdiagnostic treatment, it is thus expected that transdiagnostic treatment via mindfulness training is effective in sleep quality of women with PMS. No study was found concerning the effects of transdiagnostic treatment on PMS symptoms. However, given that the focus of transdiagnostic treatment is on emotion regulation strategies, the present study has a positive significant relationship with the results of Azoulay et al., (2020) on women with PMS symptoms and premenstrual dysphoric disorder (PMDD) with respect to PMS and emotion regulation disorder. Therefore, the results of their study were consistent with the results of the present study (Azoulay et al., 2020).

The study on women with PMS symptoms and women without PMS showed that women with PMS remarkably employ inconsistent emotion regulation strategies (Eggert et al., 2016). Thus, their results were in line with the current study. Moreover, the results of research carried out by Petersen et al., (2016) on women with PMDD symptoms revealed that women with symptoms of PMDD experience more problems in emotion regulation. Therefore, the use of cognitive-behavioral strategies is likely to be helpful in regulating their emotions. Thus, the results is consistent with the findings of present study (Petersen et al., 2016). Up to the present time, emotion regulation processes have not been explored yet. However, the results of the previously-done studies indicate that biases in cognitive control or executive performance that are connected with inefficient emotion regulation in other mental disorders may exist in PMS (Joormann et al., 2014). This makes women with PMS focus on their physical feelings and reflects their response to negative experiences (Craner et al., 2015). Thus, it seems that this level of attention increase centered on the self is likely to lead to the inefficiency of emotion regulation strategies and an increase in PMS-related discomfort (Eggert et al., 2016). Hence, the use of psychological treatments for improving emotional symptoms in women with PMS is crucial.

Thus, since many women experience a lot of psychological symptoms in menstruation period, the use of psychological treatments focused on symptoms comorbidity is remarkably significant (Mansell et al., 2008; McHugh et al., 2009; Sahin et al., 2018). To this aim, Barlow et al., (2011) developed an integrative transdiagnostic protocol for emotional disorders. In this treatment, the main focus is on emotion regulation strategies, emotional components, and emotion-desire behaviors. Besides, this treatment emphasizes that the individual should be confronted with negative and positive emotions and not avoid unpleasant emotions (Barlow et al., 2010).

5. CONCLUSION

Therefore, to explain this finding of this study, it is noted that women with PMS experience mood and anxiety symptoms simultaneously. To improve these symptoms, the use of a treatment focused on emotional symptoms comorbidity can be more effective than specific treatments. It is thus expected that the transdiagnostic treatment focused on emotion regulation strategies is effective in improving women with PMS symptoms.

Limitation

The limitation of the study is the generalizability of these results. The present study investigated women with clinical PMS symptoms; the results thus need to be cautiously generalized to women without PMS. It is therefore suggested that further studies

need to explore the effects of transdiagnostic treatment on psychological symptoms of women without PMS. Moreover, given that issues of menstruation may be influenced by culture and ethnicity, it is suggested that future investigations be focused on other cultures and ethnic groups and their results be compared with the results of this study. Finally, it is suggested that gynecologists, clinics, and medical centers concerned with PMS and PMDD can use the results of present study as a practical and economic guide with respect to time and costs.

Authors' contributions
Nazanin Ahangari: wrote the manuscript with input from all authors; performed the measurements.
Maryam Bakhtiari: supervised the project and contributed to designing and directing the project; contributed to the writing of the manuscript.
Zahra Naeiji: contributed collecting the data; contributed to the writing of the manuscript

Ethical approval
The study was approved by the Medical Ethics Committee of Shahid Beheshti University of Medical Sciences (ethical approval code: IR.SBMU.MSP.REC.1398.668).

Conflicts of interest
The authors declare that there are no conflicts of interests.

Data and materials availability
All data associated with this study are present in the paper.

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