Journal of Midwifery & Reproductive Health

JMRH.mums.ac.ir

The Effect of Acupressure and Fluoxetine on Premenstrual Syndrome: A Randomized Clinical Trial

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ARTICLE INFO

Article type:
Original article

Article History:
Received: 14-Jul-2022
Accepted: 02-Oct-2023

Key words:
Premenstrual Syndrome
Acupressure
Fluoxetine
TENS (Transcutaneous Electrical Nerve Stimulation)

ABSTRACT

Background & aim: Premenstrual syndrome (PMS) is a common disorder in women that can affect normal aspects of their life. We conducted the present study to compare the effect of acupressure and fluoxetine on PMS.

Methods: This randomized clinical trial included 90 Iranian female students at Qazvin University of Medical Sciences with moderate to severe premenstrual syndrome. After convenient sampling, individuals were randomly assigned to three groups (30 acupressure, 30 fluoxetine, and 30 control) using block randomization. The tools used include the Beck Depression Inventory (BDI), and the Daily Record of Severity of Problems form (DRSP). The intervention was performed in three consecutive menstrual periods and was followed up three months later. The acupressure group applied acupressure to 4 points (LIV3, SP9, LI11, LI4) every other day, 14 days before menstruation, using the TENS device (6 sessions during the second half of the menstrual cycle). The fluoxetine group received oral fluoxetine 20 mg daily for 14 days prior to menstruation. The control group received no intervention. Data were analyzed using R software Version 4.1.1.

Results: There was a significant difference between the acupressure and fluoxetine groups with the control group in DRSP score ($P<0.001$) after the intervention. However, no significant difference in DRSP score was observed between the two intervention groups during the intervention ($P>0.05$), but the difference between the two groups became significant during the time of follow-up ($P=0.033$).

Conclusion: Acupressure can be recommended as a useful complementary method to selective serotonin reuptake inhibitors in women with PMS.

► *Please cite this paper as*:
Jourabchi Z, Ranjkesh F, Habibi M, Alizadeh A, Zarabadypour Z. The Effect of Acupressure and Fluoxetine on Premenstrual Syndrome: A Randomized Clinical Trial. Journal of Midwifery and Reproductive Health. 2024; 12(4): 4424-4433. DOI: 10.22038/JMRH.2023.66739.1947

Introduction

The term "premenstrual syndrome (PMS)" is defined as a set of physical, psychological, and behavioral symptoms occurring in the luteal phase of menstrual cycle, and resolves with menstruation. These symptoms occur when the underlying mental disorders are not present (1). Epidemiological studies show that up to 85% of women experience PMS (2-4), and about 3-8%

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of them experience the severe form (4). The severity of the symptoms is determined by affecting the individual's daily activities and performance with regard to her personal, social, and professional life (5, 6). Moderate and severe forms of PMS appear to be associated with increased unpleasant educational and social consequences and reduced quality of life (7), and by reducing work productivity and increasing absence from work, it is considered a potential economic burden (8).

The etiology of PMS is still unknown, yet researchers suggest that periodic changes in estrogen and progesterone levels during the luteal phase, and their effect on opioid neurotransmitter systems, serotonin and gamma-aminobutyric acid levels may be the main causes of this syndrome (9, 10). On the one hand, there is ample evidence to highlight the importance of serotonin levels in the pathogenesis of PMS (10, 11). Treatments that increase serotonin function improve PMS irritability and mood swings rapidly, suggesting that the action mechanism is different from depression treatment (12). A systematic review of 31 studies revealed that Selective Serotonin Reuptake Inhibitors (SSRIs) are effective for treatment of the PMS symptoms in women with moderate-to-severe PMS, but SSRIs have many side effects that can lead to discontinuation of treatment (13).

Research indicated that 80% of women suffering from this syndrome are willing to use complementary and alternative medicine treatments (14). In Traditional Chinese Medicine (TCM), the pathogenesis of PMS can be explained as stagnation of energy in the liver and pathological changes in energy level Qi affecting other body organs. Mind and mood are regulated by regulating the liver function. Therefore, when the liver Qi is stagnated and cannot move easily, it leads to disturbing the mind and mood and appeating psychological and emotional signs (15, 16). Acupressure is a branch of TCM that helps balance the energy flow and the heat and cold distribution by applying pressure on the acupuncture points. Pressure is applied to these points, muscle spasm is eliminated, blood circulation and vital energy of the body are improved, and the patient is relaxed (17).

Since the prevalence of PMS in Iran is high (18) and to date, no research has compared the effect of fluoxetine and acupressure in PMS treatment (19), therefore, We conducted the present study to compare the effects of acupressure and fluoxetine on PMS.

Materials and Methods

This randomized clinical trial was performed on 90 female students of Qazvin University of Medical Sciences from May 2018 to May 2020. Sampling was done through a convenience method and then, the participants were randomly assigned to three groups using the block randomization method (the block size of three, six, and twelve with a 1:1:1 allocation ratio. A was the acupressure group, B was fluoxetine and C was the control group. The first block, a block of 6 (BBCAAC), the second block, a block of 6 (CBACBA), the third block, a block of three (ACB), the fourth block, a block of three (ABC), the fifth block, a block of twelve (CABACCABBCAB) was considered. In order to hide the random allocation, after preparing the allocation sequence, the sequence was written down on paper and placed inside the envelope, and the envelopes were numbered sequentially. Questionnaires were also coded in the same order. In this case, the questionnaire was completed with the same code for the person who received the code 1 intervention. Allocation and concealment sequence was done by someone outside the research team.

According to the study of Yonkers et al. (20) and PASS software at a significance level of 5% and 90% power, the sample size was determined 24 samples in each group. However, considering the 20% dropout, 30 samples were considered for each group.

Inclusion criteria were: age of 18-35 years, normal body mass index (BMI) (18.5-25 kg/m^2), regular menstrual cycles (24-35 days) with normal bleeding volume and menstrual period of 3-10 days, and experiencing moderate-to-severe PMS symptoms based on the Daily Record of Severity of Problems (DRSP). Exclusion criteria were: known mental illnesses (self-reported), use of tobacco, drugs and psychiatric medications (self-reported), use of medications (e.g., antidepressants, sedatives, hormonal drugs, vitamin supplements, and drugs that are known to interact with

fluoxetine), the existence of skin lesions on acupressure points, and a traumatic event occurring within the past six months such as parental separation, death of first-degree relatives.

The data collection tool included:

1-Questionnaire for the temporary diagnosis of premenstrual syndrome.For the initial diagnosis, a temporary PMS diagnosis questionnaire was used, which is completed based on the symptoms of the previous menstrual cycle. A person who has at least 5 symptoms and one of these 5 symptoms is part of the first 4 symptoms is diagnosed with PMS. This form is only used for the initial diagnosis of PMS(1) The validity of this questionnaire was confirmed in 2012 in a study by Shakri et al.(20) The reliability of this questionnaire has been confirmed in Noorani et al.'s study in 2012 with Cronbach's alpha of 0.82(21).

2- the Beck Depression Inventory, in order to exclude the participants with underlying depression, they were asked to complete the Beck Depression Inventory (BDI) between the end of menstruation and the beginning of the luteal phase. Individuals, who were non-depressed based on the BDI, were included in the study and were asked to sign the written consent form. They were also ensured that they could leave the study at any stage of the research. Beck et al. (2000) have reported the internal consistency of Beck's depression tool from 0.73 to 0.92 with an average of 0.86 and an alpha coefficient of 0.86 for the patient group and 0.81 for the non-patient group(22).

3- Daily Record of Severity of Problems :

Then, people who were not depressed according to the Beck questionnaire, were asked to record their symptoms daily for 2 months using the DRSP. The DRSP comprises 30 items describing the PMS symptoms based on DSM-V criteria. This form contains 5 subscales including: anxiety symptoms, depression symptoms, emotional symptoms, retention symptoms, and somatic symptoms (23). Individuals, who have the symptoms during two cycles from 7 days before the first day of menstruation and up to the first 4 days of menstruation, are known to have PMS (24). The research units scored the severity of their daily symptoms on a scale of 0 (none) to 3 (severe). A score of 0-33 is considered mild symptoms, a score of 33-66 moderate symptoms, and a score higher than 66 severe symptoms (25). The reliability of this form has been confirmed in the study of Ozgoli et al. by Cronbach's alpha of 80% (26).

4- Demographic questionnaire: it includes two sections of demographic information and menstrual cycle information, and the demographic section contains questions about age, weight, height, major and degree, occupation of mother and father, marital status, if married, spouse's occupation, number Delivery and contraceptive methods were asked.

The questions related to menstrual history were related to the age of the person at menarche, the length of the menstrual cycle, the intensity of bleeding in the menstrual cycle, the intervals between two cycles, and the history of first-degree infections. that the content validity of the checklist was done using the opinions of 10 professors of the Faculty of Nursing and Midwifery of Qazvin University of Medical Sciences.

Participants in the acupressure intervention group received acupressure induced by the KWD-808 TENS machine for 15 minutes during the second half of the menstrual cycle for 12 days every other day (6 sessions in three consecutive cycles). Acupressure was applied to 4 points (LIV3, SP9, LI11, LI4) by the researcher using a TENS machine (pulse trains of 4-100 Hz, the current intensity of 0.5 amps, and the voltage of 5). Research shows that the frequency of 4 Hz releases endorphins and cortisol, and frequencies of 50 to 200 Hz release serotonin. In the TENS machine with pulse trains (instead of continuous pulses), each group has waves with a frequency of 200 Hz, and the repetition frequency of the groups is 4 Hz. In this way, both endorphins are released at a frequency of 4 Hz and serotonin at a frequency of 100 Hz (23).

In the fluoxetine intervention group, participants received 10 mg (24) of fluoxetine capsules (made by Tehran Daroo Company) under the supervision of a physician during the luteal phase every 12 hours for three consecutive cycles. They were given an envelope containing 28 fluoxetine capsules (for one month) and the DRSP form. They were asked to take one fluoxetine capsule every 12 hours for

two weeks after the onset of menstrual bleeding and to complete the form. The next follow-up started with the re-start of menstrual bleeding, and they were given the next envelope and the DRSP form. Their vital signs (blood pressure, pulse rate, respiration rate) were monitored, and the side effects of the drug were asked. No intervention was performed in the control group. The outcome of the intervention was the severity of clinical symptoms of PMS based on the DRSP. All participants in the study were asked asked to complete the DRSP every month during the intervention (which was three months) and three months after its end.

Finally, the collected data were entered in Excel and analyzed using R Version4.1.1 software and Mixed effect model tests descriptive (including frequency, mean, and standard deviation) and inferential statistics of mixed effect model, one-way analysis of variance and Chi-square test. P<0.05 was considered statistically significant.

Results

In this study, 5 participants in the acupressure group, 10 in the fluoxetine group, and 9 in the control group were excluded at the beginning of the research due to the longitudinal type of the research and their unwillingness to continue the study. In addition, 3 participants in the acupressure group dropped out after the first month of intervention due to the absence of more than 3 sessions in the first month. In the fluoxetine group, 2 participants were excluded from the study before the end of the first month of the intervention due to the drug's side effects (fatigue and drowsiness) and severe stomach pain, and 1 participant was excluded after the end of the first month due to abnormal bleeding and irregular menstrual cycle (Figure1).

The three groups were homogeneous regarding demographic variables (P>0.05) (Table 1). Examining the group-by-time interaction showed that there was a significant difference between the intervention and control groups in the DRSP total score (P<0.001) (Table 2).

Based on the post hoc tests of mixed models, no statistically significant difference was observed between the three groups regarding the mean score of the severity of PMS symptoms before the intervention (P>0.05).

However, after the intervention, there was a significant difference between the intervention groups (acupressure and fluoxetine) and the control group during the first, second, and third months of the intervention and the three months after the intervention (follow-up) (P<0.05).

Table 1. Demographic characteristics of the study groups

Variables	Overall	Group			P-value
		Acupressure	Fluoxetine	Control	
Age (year)					
M±SD	23.15±3.421	23.28±3.273	23.67±3.162	22.47±3.893	0.559 *
BMI (kg/m²)					
M±SD	21.29±3.934	21.00±2.502	21.81±2.994	21.22±5.927	0.817 *
Marital status					
single	55(85.94%)	22(88%)	16(88.89%)	17(80.95%)	0.735 **
married	9(14.06%)	3(12%)	2(11.11%)	4(19.05%)	
Father's education					
illiterate or primary school	9(14.29%)	7(28%)	1(5.88%)	1(4.76%)	
Middle school	8(12.7%)	3(12%)	1(5.88%)	4(19.05%)	0.065**
diploma or university	46(73.02%)	15(60%)	15(88.23%)	16(76.19%)	
Mother's education					
illiterate or primary school	10(15.67%)	5(20%)	3(16.67%)	2(9.52%)	
Middle school	11(17.19%)	6(24%)	0(0%)	5(23.81%)	0.179**
diploma or university	43(67.18%)	14(56%)	15(83.33%)	14(66.67%)	
Father's job					
Retired	8(13.33%)	3(12.5%)	2(12.5%)	3(15%)	
Freelance	25(41.67%)	11(45.83%)	3(18.75%)	11(55%)	0.217 **
Worker	2(3.33%)	2(8.33%)	0(0%)	0(0%)	
Employee	23(38.33%)	7(29.17%)	10(62.5%)	6(30%)	

Variables	Overall	Group			P-value
		Acupressure	Fluoxetine	Control	
Tteacher	2(3.33%)	1(4.17%)	1(6.25%)	0(0%)	
Mother's job					
Housewife	53(82.81%)	23(92%)	12(66.67%)	18(85.71%)	0.412 **
Freelance	1(1.56%)	0(0%)	1(5.56%)	0(0%)	
employee	4(6.25%)	1(4%)	2(11.11%)	1(4.76%)	
teacher	6(9.38%)	1(4%)	3(16.67%)	2(9.52%)	
Economic status					
Poor	2(3.17%)	1(4%)	1(5.56%)	0(0%)	0.079 **
Average	35(55.56%)	18(72%)	6(33.33%)	11(55%)	
Good	25(39.68%)	6(24%)	11(61.11%)	8(40%)	
Excellent	1(1.59%)	0(0%)	0(0%)	1(5%)	
Family history of PMS					
Yes	22(36.07%)	14(58.33%)	1(6.25%)	8(38.1%)	0.003 **
No	38(62.3%)	10(41.67%)	15(93.75%)	13(61.9%)	

Abbreviations: y: year, M: Mean, SD: Standard Deviation, kg: kilogram * ANOVA ** χ 2 test

Table 2. The interaction effect of time and intervention groups on the total score of Daily Record of Severity of Problems (DRSP**)**

Variables	Chisq	Df	Pr(>Chisq)
(Intercept)	38.152	1	0
Family history of PMS	2.41	1	0.121
Age	0.438	1	0.508
BMI	0.447	1	0.504
Maternal education	4.368	3	0.224
Time	999.474	4	0
Group	9.897	2	0.007
Time: Group	449.627	8	0

No significant difference was found between the two intervention groups during the first, second, and third month of the intervention (P>0.05); however, three months after the intervention (during follow-up), the difference between the mean score of the severity of PMS symptoms between the two groups became significant (P=0.033) (Table 3). In terms of side effects, no complications were reported in the acupressure group. In the fluoxetine group, two cases of nausea and two cases of appetite loss, one case of headache, one case of severe stomachache, one case of drowsiness, and one case of extreme fatigue were reported.

Table 3. Mean score of PMS symptoms before and during the intervention by the study groups

Group	Estimate	SE	df	t.ratio	P-Value
Before the intervention					
Acupressure - Fluoxetine	-0.26	0.09	55.29	-2.84	0.017
Acupressure - Control	-0.17	0.07	65.71	-2.45	0.044
Fluoxetine - Control	0.08	0.09	60.40	0.96	0.605
The 1st month of intervention					
Acupressure - Fluoxetine	-0.19	0.09	55.29	-2.14	0.092
Acupressure - Control	-0.52	0.07	65.71	-7.41	0.000
Fluoxetine - Control	-0.33	0.09	60.40	-3.77	0.001
The 2nd month of intervention					
Acupressure -Fluoxetine	-0.26	0.09	58.07	-2.86	0.016
Acupressure - Control	-0.94	0.07	67.83	-13.24	0.000
Fluoxetine - Control	-0.68	0.09	62.46	-7.70	0.000

The 3rd month of intervention					
Acupressure - Fluoxetine	-0.25	0.09	58.07	-2.70	0.024
Acupressure - Control	-1.17	0.07	67.83	-16.42	0.000
Fluoxetine - Control	-0.92	0.09	62.46	-10.43	0.000
3 months after the intervention					
Acupressure - Fluoxetine	-0.31	0.09	58.07	-3.34	0.004
Acupressure - Control	-0.64	0.07	67.83	-8.93	0.000
Fluoxetine - Control	-0.33	0.09	62.46	-3.72	0.001

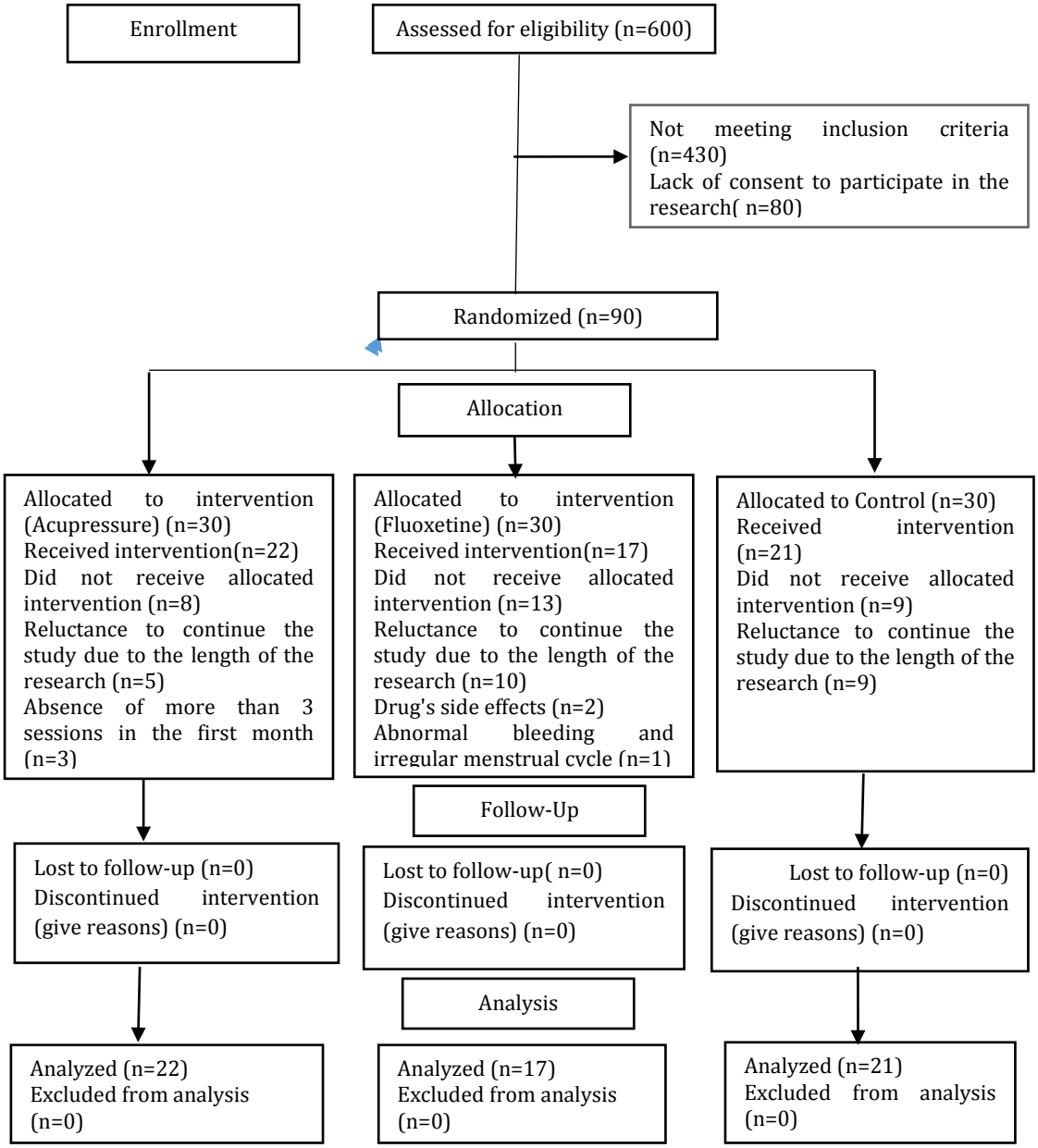

Figure 1. The CONSORT flow diagram of intervention in three groups

Discussion

The aim of the research was to compare the effect of acupressure and fluoxetine in premenstrual syndrome. In terms of the comparison of the acupressure and fluoxetine groups, no significant difference was found between the two groups in the total scores of PMS after the intervention; however, significant difference was observed between the two groups during the follow-up.

Significant improvement in PMS in the acupressure and fluoxetine groups can be explained by various mechanisms. The results show that low levels of estrogen during the luteal phase lead to a decrease in blood serotonin levels, which reduces the concentration of serotonin at the brain synapse or decreases the serotonin function in the brain. A decrease in estrogen induces an increase in serotonin metabolism, which in turn leads to a decrease in serotonin function in the nervous system, which in turn increases low mood, such as stress-anxiety and fatigue (9). Therefore, fluoxetine can increase serotonin (13). Some studies have suggested that treatments that increase serotonin function, such as fluoxetine, improve irritability and low mood during the luteal phase immediately after use, and neurosteroids, such as progesterone, may be responsible for the immediate action of fluoxetine (25). Side effects of fluoxetine have been reported in various studies (5, 13). In the current study, significant difference was found between the side effects of acupressure and fluoxetine. Side effects including headache, nausea, and loss of appetite were reported by 15% of participants in the fluoxetine group, while no side effect was observed in the acupressure group. Marjoribanks et al. (2013) found that SSRIs were effective in treating PMS. However, adverse effects, such as nausea, diarrhea, anxiety, decreased libido, etc., were relatively frequent (13). Similar results were reported by Yonkers et al.) which showed that fluoxetine had more therapeutic benefits for PMS than calcium. They also reported several side effects of fluoxetine such as constipation, nausea, etc. (26). In TCM, the main function of the liver is to balance energy and store blood (15). The pathogenesis of PMS can be explained as stagnation of energy in the liver and pathological changes in energy level Qi (16). Acupressure can be effective in treating PMS by helping to restore Qi energy function and return 80% lactic acid to the liver and recycle it as glycogen or energy (27). Alteration in the response to prostaglandins can be addressed as one of the mechanisms in the occurrence of PMS (28), and acupressure can help improve the PMS symptoms by altering the blood flow to the uterus and modulating the level of prostaglandins and promoting relaxation, reducing neuromuscular irritability, increasing blood circulation and gate control theory (29, 30). Since the level of inflammatory markers is increased in women with PMS (31), acupressure can be useful in treating PMS by reversing the inflammatory process by releasing the adrenocorticotropic hormone (32). Considering that decrease in beta-endorphin levels changes in neurotransmitters and decrease in serotonin during the late luteal phase due to changes in sex hormones are among the causes of PMS (33), acupressure can help improve the psychological symptoms of PMS by stimulating the brain to release endogenous opioids such as β-endorphins and enkephalins and increasing serotonin levels (34, 35). The study by Bazarganipour et al. (2016) showed that applying acupressure to LIV3 and LI4 points could reduce the PMS symptoms (36). Abdahi Fard et al. (2013) reported that plantar reflexology, as a branch of acupressure, is effective on reducing the severity of PMS symptoms (35). In the present study, TENS machine was used to apply the equal pressure in 4 points. In another study, Shin et al. (2009) compared the effect of acupuncture and moxibustion therapy on six points including A5, A6, A8, A12, A16, F18, and showed that acupuncture and moxibustion therapy were useful in reducing PMS symptoms ($p<0.001$) (37).

One systematic review by Jang et al. (2014) showed that acupuncture and all herbal medicines can significantly reduce PMS symptoms (38).

Compared to the side effects of acupuncture, including pain and bleeding at the site of needle insertion, damage to internal organs, and an increased risk of infectious diseases (23), acupressure, even in the case of incomplete

performance, has no side effects and no harm. Acupressure is a non-invasive method that is easy to use and can be done by the individual (36).

The limitations of the present study included the small sample size, the same age group, conducting the study among medical students, the difficulty of coordinating acupressure sessions due to the closure of the university, and the absence of the students and holding their clinical courses in different wards. Applying acupressure to several points using electrical stimulation and following up with the participants is one of the strengths of the present study. It is recommended that further study be conducted with more samples and in other non-medical communities.

Conclusion

The results of the current research study significantly revealed that both acupressure with electrical stimulation and fluoxetine reduced the severity of PMS. Additionally, acupressure had fewer side effects than fluoxetine. So, it seems that acupressure, as a non-pharmacological method, is a suitable method for the treatment of PMS. In conclusion, acupressure can be used as a safe and non-invasive, cheap, and simple technique in treatment of PMS.

Declarations

Acknowledgements

The authors would like to thank all the participants in this research.

Conflicts of interest

Authors declared no conflicts of interest.

Funding

This study funded by the Research Vice-Chancellor of Qazvin University of Medical Sciences (Code of 14003739).

Ethical Considerations

This research was conducted with observing confidentiality and obtaining written permission and was registered in the Iranian Registry Clinical Trial cente with the code (IRCT20190430043433N1). Additionally, first researcher assured participants that their information would remain confidential and that they could withdraw from the study at any time. The Female studentsentered the study if they were willing to participate in the study and met the inclusion criteria and obtained written consent.

Ethical approval

The ethics committee of Qazvin University of Medical Sciences has approved this research with the code (IR.QUMS.REC.1398.014).

Authors' contributions

ZJ supervised the study; MH and ZZ participated in data collection and analysis, and AA helped with data interpretation. FR assisted in data analysis. All authors have read and approved the manuscript.

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