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# The effect of group counseling based on positive psychology on the WhatsApp social media platform on the severity of premenstrual syndrome symptoms: a randomized clinical trial

Parvin Mohebbi<sup>1,2</sup>, Azam Maleki<sup>1</sup>, Loghman Ebrahimi<sup>3</sup> and Hamideh Mirzaeyan<sup>2,4\*</sup>

#### **Abstract**

**Background** Premenstrual syndrome (PMS) is a prevalent health issue impacting women, significantly impacting their well-being and fostering a negative attitude of femininity and menstruation. We investigated the effect of group counseling based on positive psychology on the severity of PMS symptoms.

**Methods** Participants in the intervention group engaged in six online sessions of group counseling focused on positive psychology via WhatsApp. Data were collected using the Premenstrual Symptoms Screening Questionnaire (PSST) before, immediately, and two months post-intervention. Analytical assessments were performed using SPSS 16 software using Chi-square, independent t-tests, and repeated measures analysis of variance (ANOVA). Comparative analyses were carried out using the Bonferroni post hoc test with a 95% confidence level.

**Results** The mean intensity of PMS symptoms in the intervention group significantly decreased from 21.60 (2.50) to 13.35 (4.727) and 14.750 (5.963) immediately and two months after the intervention; however, the difference was not significant in the control group. The results of repeated measures ANOVA showed that the effect of the intervention over time and the interaction between time and group were significant. The Eta effect size was about 0.20 and 16%, respectively (p = 0.001). According to Bonferroni post hoc test results, the difference in the mean scores of the severity of PMS symptoms before the intervention was statistically significant compared to both follow-up periods ( $p \le 0.007$ ). However, the difference in mean scores immediately after the intervention compared to two months after the intervention was not statistically significant (p = 0.42).

**Conclusion** Using a positive counseling approach demonstrates efficacy in alleviating the severity of PMS symptoms in the short term. While all women can benefit from such interventions, targeting adolescents is particularly strategic, as early interventions can foster positive attitudes toward menstruation. Additionally, social media platforms like WhatsApp provide a feasible and engaging medium for adolescent health interventions. Integrating this approach

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into adolescent health promotion package appears to be a viable measure worthy of consideration by relevant policymakers.

Trial registration Current Controlled Trials IRCT20201113049377N1, Date of Registration 2020, 12, 08.

**Keywords** Group counseling, Positive psychology, Premenstrual syndrome

### **Background**

Premenstrual syndrome (PMS) is a set of emotional, behavioral, and physical symptoms that typically emerge during the luteal phase and subside with the onset of the menstrual cycle [1, 2]. PMS is possibly caused by a combination of genetic, hormonal, psychological, dietary, and behavioral factors [3]. Over 200 symptoms have been documented, including headaches, breast tenderness, anxiety, and irritability [4]. These symptoms can significantly impact women's quality of life, impairing cognitive function, attention span, and self-esteem [5].

Estimating the prevalence of PMS is challenging due to the absence of standardized diagnostic criteria, variations in symptom interpretation, and differences among studied populations [6]. Globally, the prevalence of PMS has been reported at 47.8% [7]. while a meta-analysis estimated the prevalence in Iran at 70.8% [8].

Non-pharmacological interventions such as education, counseling, psychological support, exercise, lifestyle modifications, herbal supplements, vitamins, special diets, and physical activities are widely employed to manage PMS [9-12]. These approaches have gained attention due to their ease of application and the absence of adverse health effects [13].

Positive psychology, introduced by Seligman et al. plays a crucial role in mental health counseling [14]. The claim of positive psychology is that instead of solely focusing on treating mental health issues, it emphasizes the creation of positive resources that can help enhance individuals' well-being [15]. No studies have specifically examined the impact of positive psychology counseling on alleviating PMS symptoms.

Since PMS significantly diminishes a person's quality of life and places a considerable burden on their ability to perform daily responsibilities and activities [16]. and due to the lack of research in this field, this study investigated the impact of positive psychology-based counseling through WhatsApp on the severity of PMS symptoms among students.

# **Methods**

# The participants

This randomized controlled clinical trial was conducted in 2021 on students with mild to moderate PMS residing in dormitories affiliated with the Zanjan University of Medical Sciences. The severity of PMS symptoms was assessed using the Premenstrual Symptoms Screening Tool (PSST). Participants with PSST scores indicating severe PMS or premenstrual dysphoric disorder (PMDD) were excluded from the study and referred to appropriate psychiatric centers for specialized care, given their need for more advanced mental health services.

#### Sample size

The sample size was estimated to be 14 people per group, considering a 95% confidence level ( $Z_{1-\alpha/2}=1.96$ ), 80% test power (Z1- $\beta$ =0.84), and the mean and standard deviation (SD) of the severity of PMS in the intervention and control groups from the study by Eshaghi [17], using the Sample Size Formula for Two-Group Comparison with a Z-test. Considering a 20% attrition rate, the final sample size was increased to 20 participants per group.

Participants were selected by convenience sampling and assigned to the intervention and control groups with a block size of four so that two allocations to the intervention group and two allocations to the control group were considered, with a total of six randomizations. The blocks were selected so that the sample size reached 40 (Fig. 1). To conceal allocation, sealed opaque envelopes with a random sequence were used. A table of random numbers was used to generate the sequences. This study adheres to CONSORT (Consolidated Standards of Reporting Trials) guidelines to ensure transparency and completeness in reporting randomized controlled trials.

$$N = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left(S_1^2 + S_2^2\right)}{\left(\mu_1 - \mu_2\right)^2}$$

$$N = \frac{(1/96 + 1.28)^2 (5/3^2 + 8/10)^2}{(7/35)^2} = 14$$

#### Intervention

The research objectives were explained to the participants, and their written informed consent was obtained. The intervention group received six online positive-oriented group counseling sessions, each lasting 60 to 90 min, conducted once a week for six consecutive weeks. Counseling was delivered via WhatsApp using voice messages and slide-based materials to enhance flexibility and accessibility. Educational content was provided in multiple formats through the WhatsApp platform.

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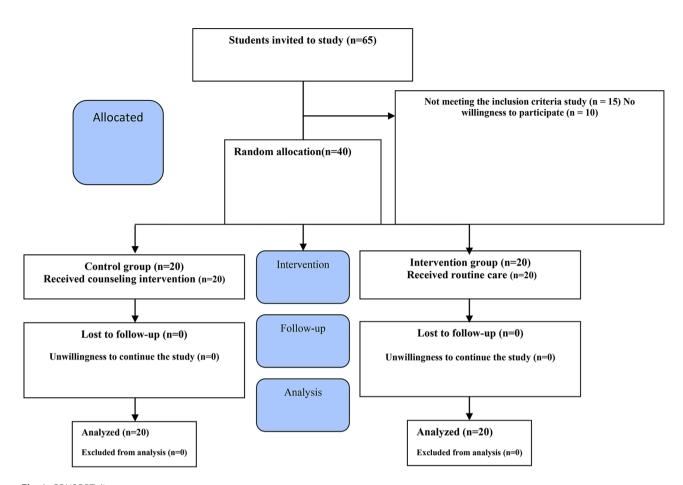


Fig. 1 CONSORT diagram

**Table 1** Description of positive counseling sessions in students with premenstrual syndrome

Session	Content
1	Introducing the participants and determining the rules of the sessions - explaining the study objectives - questions and answers about menstruation and premenstrual syndrome and its negative effects on life aspects, explanations about the physiology of menstruation and premenstrual syndrome - training how to use them in life - homework
2	Review of the previous topics - examining feelings and attitudes toward menstruation - acquainting people with positive emotions and its role in reducing premenstrual syndrome symptoms - homework
3	Review of the previous topics and homework and providing feedback - training on using the top 5 abilities to help others - presenting the task of giving the gift of time to others
4	Review of the previous topics and homework - teaching how to improve positive social relationships, happiness in life, active and constructive response techniques - providing homework on how to respond to events
5	Review of the previous topics - practicing the technique of gratitude in life, practicing gratitude in life - practicing the exercise of remembering three blessings in a day
6	Review of the previous topics – training how to enjoy activities - summary

Before each session, PowerPoint slides were converted into PDFs to ensure compatibility with mobile devices and were shared with participants ahead of time through WhatsApp. Participants were encouraged to review these materials prior to the session. During the session, the researcher summarized key points via voice messages and guided the group discussions.

Each session included questions and answers (Q&A), positive group counseling, group discussion (with 6–7 participants), and presentations of educational materials through slides. The structure of each session consisted of an introduction and Q&A (10–15 min) to address participants' questions from the previous session, positive group counseling (20–25 min) focused on strengths and positive emotions, group discussion (20–30 min) for sharing thoughts, experiences, and reflections on the session topics, and slide presentations (10–20 min) summarizing key points.

Assigned homework encouraged participants to apply positive psychology concepts in their everyday lives. After attending a workshop on Martin Seligman's positive psychotherapy protocol and obtaining certification, the researcher facilitated the counseling sessions. The content of the sessions is summarized in Table 1. The

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control group received an intensive three-session virtual training program after the study. In the present study, the control group received education on menstrual hygiene management, which included proper hygiene practices, understanding the menstrual cycle, and recognizing signs of menstrual disorders.

The subjects completed the PSST and the General Health Questionnaire (GHQ). Those with mild to moderate PMS and a score of less than 24 on the GHQ were included in the study.

The inclusion criteria were as follows: age≥18 years, residency in dormitories, mild to moderate PMS symptoms based on PSST, regular menstrual bleeding every 21–35 days lasting 2–7 days, a score of ≤24 on the GHQ, no special diet, and not having taken medications recently to treat PMS. Exclusion criteria included unwillingness to continue participating in the study, experiencing stressful events such as parental separation, divorce, financial crises, accidents, death of loved ones, and being absent from more than one counseling session.

#### Tools for data collection

The research tools included a demographic questionnaire, GHQ, and PSST, all completed in a self-reported manner. The demographic questionnaire included questions on age, educational background, occupation, marital status, family income, and menstrual cycle characteristics. The PSST consisted of two sections: physicalpsychological symptoms (14 questions) and the impact of symptoms on the individual's life (five questions). All items were answered on a four-point Likert scale ranging from "never=0" to "severe=3," with higher scores indicating the presence of PMS. Both total and domain- specific scores interpreted quantitatively and qualitatively [18, 19].

The diagnosis of moderate or severe PMS was made based on the presence of three following conditions on the PSST: (1) at least one item of moderate or severe from items 1 to 4, (2) In addition to number 1, at least four items of moderate or severe from questions 1 to 14, (3) at least one item of moderate or severe in the second part (the impact of symptoms on life). The participants were asked to complete the PSST twice: immediately and two months later, during the initial four days of their menstrual cycle. The translation and psychometrics of the Iranian version of this questionnaire were carried out by Hariri et al. in 2009 on students in Tehran. The reported Cronbach's alpha was 0.93, and the content validity for students at Tehran University was reported as 0.93, 0.8 respectively [20].

#### Outcome

The primary endpoints were significant changes in the mean severity of PMS symptoms in the

emotional-psychological domain, Physical domain and impact of symptoms on life after 6- session intervention.

#### Statistical analyses

SPSS 16 (SPSS Inc., Chicago, IL, USA) was employed for statistical analyses. The Kolmogorov-Smirnov test verified the normal distribution of variables. Continuous and qualitative variables were reported as mean (standard deviation) and frequency (percentage), respectively. Paired comparisons were made using the t-test (continuous variables) and Chi-square test (qualitative variables). Repeated measures of ANOVA and Bonferroni's post hoc test was used to compare the effect of intervention between the groups and the interaction between time and group. Statistical significance was set at p<0.05 for all analyses.

#### Results

The Chi-square test indicated no significant differences between the groups regarding age, field of study, marital status, and educational level, confirming their homogeneity (p>0.05). An independent t-test further showed no significant differences in mean age at menarche, cycle length, duration of menstrual bleeding, and PMS severity between the two groups (p>0.05). In the intervention group, the average intensity of PMS symptoms decreased from 21.60 (2.650) before counseling to 14.75 (5.96) two months after counseling, while the control group showed no significant change in this parameter (Table 2).

The repeated measures ANOVA was employed to assess the effects of the intervention on total score, over time, between groups, and the interaction of time and group (Wilks' Lambda=0.59, F=12.74, P<0.001, Eta=0.40). Mauchly's sphericity test indicated significance levels greater than 0.05, allowing the use of Huynh-Feldt values for interpretation. The results revealed a significant effect of the intervention over time (P=0.001), with an eta effect size of approximately 0.20, indicating that 20% of the variance in scores during the follow-up periods was attributed to positive psychology counseling. Additionally, the interaction effect between group and time was statistically significant, with an eta value showing that about 14% of the variance was due to the counseling intervention (P=0.003) (Table 3). The summary of changes in the severity scores of PMS symptoms is shown in Fig. 2.

A paired comparison of the intervention's effects on the severity of PMS symptoms was conducted at three time points: before, immediately after, and two months post-intervention, using the Bonferroni post-hoc test. The result of Bonferroni post-hoc test indicated a statistically significant difference in the mean scores of PMS symptoms between the pre-intervention period and both follow-up points (immediately after and two months

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**Table 2** Comparison of the frequency of demographic characteristics of students with premenstrual syndrome

Variable		Intervention group	Control group	<i>p</i> -value
		N (%)	N (%)	
Age (year)	18–20	5 (25)	4 (20)	0.075 *
	20–25	15 (75)	16 (80)	
Field of study	Midwifery	9 (45)	11 (55)	0.433 *
	Nursing	11 (55)	8 (40)	
	Others	0 (0)	1 (5)	
Occupation	Student	18 (90)	17 (85)	0.633 *
	Employed	2 (10)	3 (15)	
Marital status	Single	17 (85)	17 (85)	1 *
	Married	3 (15)	3 (15)	
Education level	Master's degree	2 (10)	3 (15)	0.633 *
	Bachelor's degree	18 (90)	17 (85)	
Age at menarche	Mean (SD)	13.7 (0.97)	13.5 (0.76)	0.47 **
Length of cycle intervals	Mean (SD)	26.9 (1.65)	27.15 (1.42)	0.61 **
Duration of menstrual bleeding	Mean (SD)	6.45 (0.87)	6.2 (0.95)	0.39 **
Severity of premenstrual syndrome symptoms	Before intervention	21.6 (2.5)	21.45 (2.64)	0.85 **
	Immediately after intervention	13.35 (4.72)	19.45 (7.47)	0.004 **
	Two months after the intervention	14.75 (5.96)	21.1 (8.4)	0.009 **

<sup>\*</sup>Chi-square test-\*\*Independent t-test

**Table 3** Effect of positive counseling on the severity of premenstrual syndrome symptoms

Effect	Sum of squares	Degree of freedom	Mean square	F	<i>p</i> -value*	Eta squared
Huynh-Feldt (time)	544.017	2	277.008	12.805	0.001	0.252
Huynh-Feldt (time*group)	271.25	2	135.625	6.27	0.003	0.142
Error correction (time)	1644.067	76	21.632			

<sup>\*</sup>Repeated measures ANOVA test

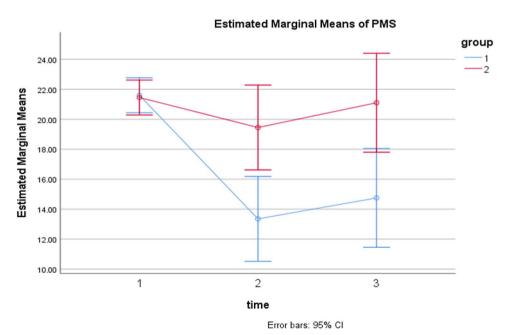


Fig. 2 Changes in premenstrual syndrome severity scores of students over time using Repeated measures ANOVA test

later) ( $p \le 0.007$ ). However, the comparison of mean differences between immediate post-intervention and two months post-intervention was not statistically significant (p=0.420) (Table 4).

# **Emotional-psychological domain**

The repeated measures ANOVA was conducted to examine the effect of the intervention on PMS domains, accounting for time, group, and their interaction (Wilks'

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**Table 4** A paired comparison of mean scores using the Bonferroni post-hoc test

Time	Time	Mean difference	Standard deviation	P-value*	95% confidence interval	
					Min	Max
Before intervention (1)	2	5.12	1.01	0.001	2.59	7.65
	3	3.6	1.09	0.007	0.85	6.34
Immediately after intervention (2)	1	-5.12	1.01	0.001	-7.65	-2.59
	3	-1.52	1.01	0.42	-4.05	1
Two months after intervention (3)	1	-3.6	1.09	0.007	-6.34	-0.85
	2	1.52	1.01	0.42	-1	4.05

<sup>\*</sup> Adjustment for multiple comparisons: Bonferroni post-hoc test

**Table 5** Comparison of the mean scores of components of premenstrual syndrome symptoms

Variable		Test result					
		Sum of squares	Degree of freedom	Mean square	F	P-value*	Eta squared
Psycho-emotional	Greenhouse-Geisser (time)	102.81	1.91	53.6	8.19	0.001	0.17
symptoms	Greenhouse-Geisser (time* group)	45.95	1.91	23.95	3.66	0.032	0.08
	Error correction (time)	476.56	72.88	6.53			
Physical symptoms	Huynh-Feldt (time)	56.11	2	28.05	7.49	0.001	0.16
	Huynh-Feldt (time* group)	40.01	2	20	5.34	0.007	0.12
	Error correction (time)	284.53	76	3.74			
The impact of symptoms on life	Huynh-Feldt (time)	46.51	2	23.25	6.12	0.003	0.13
	Huynh-Feldt (time* group)	11.71	2	5.85	1.54	0.22	0.03
	Error correction (time)	288.43	76	3.79			

<sup>\*</sup>Repeated measures ANOVA test

Lambda=0.73, F=6.69, P=0.003, Eta=0.26). Given that the significance level in Mauchly's sphericity test exceeded 0.05 and Greenhouse-Geisser correction values were below 0.75, the Greenhouse-Geisser correction was applied for interpretation. The analysis revealed a statistically significant effect of the intervention on the emotional-psychological domain over time (P=0.001), with an eta effect size of approximately 0.17. The interaction between group and time was also significant, although the eta size was small (P=0.032) (Table 5).

A paired comparison using the Bonferroni post-hoc test showed that the differences in the mean scores of the emotional-psychological domain between the preintervention period and both follow-up points (immediately and two months post-intervention) were statistically significant (P=0.008). However, the comparison of the mean difference immediately post-intervention with two months post-intervention was not statistically significant (Bonferroni test, P=1).

# Physical domain

The results for the physical domain showed Wilks' Lambda=0.70, F=7.72, P=0.002, and Eta=0.29. Mauchly's sphericity test indicated a significance level greater than 0.05, allowing the use of Huynh-Feldt values for interpreting the effects of time and the interaction

between group and time. The repeated measures ANOVA revealed that the intervention had a significant effect on the physical domain over time (P=0.001), with an eta effect size of approximately 0.16. Additionally, the interaction effect between group and time was statistically significant, with an eta effect size of 0.12 (P=0.007) (Table 5).

A two-by-two comparison using the Bonferroni posthoc test showed that the difference in the mean scores of the physical domain before the intervention compared to immediately after the intervention was significant (P=0.001). However, the comparison of the mean differences between the pre-intervention period and two months post-intervention, as well as between the immediate post-intervention period and two months postintervention, were not statistically significant (Bonferroni test, P>0.05).

#### Impact of symptoms on life

In the domain of the effect of symptoms on life, the results were Wilks' Lambda=0.75, F=5.95, P=0.006, and Eta=0.24. Mauchly's sphericity test showed a significance level greater than 0.05, and Greenhouse–Geisser correction values exceeded 0.75, leading to the use of Huynh-Feldt values for interpretation. The repeated measures ANOVA indicated that the intervention significantly

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affected the impact of symptoms on life over time (P=0.003), with an eta effect size of approximately 0.13. However, the interaction effect between group and time was not statistically significant (P=0.221) (Table 5).

A two-by-two comparison using the Bonferroni posthoc test showed that the difference in the mean scores for the impact of symptoms on life between the pre-intervention and immediately after the intervention was significant (P=0.004). However, the comparisons of mean differences between the pre-intervention period and two months post-intervention, as well as between the immediate post-intervention period and two months postintervention, were not statistically significant (Bonferroni test, P>0.05).

#### Discussion

The current research investigated the effect of positive counseling on the severity of PMS symptoms in students at Zanjan University of Medical Sciences. The results showed a significant decrease in both the severity and type of PMS symptoms in the intervention group. Several studies have supported these findings, indicating that psychological interventions can mitigate PMS symptoms effectively. For instance, Khodakarmi et al. (2017) highlighted that group counseling reduces PMS severity among high school girls, which was consistent with our findings [21]. Similarly, Kaur et al. (2016) reported that enhancing PMS awareness among Indian adolescents significantly reduced symptoms [22]. Since raising awareness was a goal of our intervention, achieving consistent results was expected. However, our study explored psycho-emotional dimensions in greater depth, focusing not only on awareness but also on fostering positive emotions and strengths through structured interventions. Kues et al. (2014) demonstrated the positive impact of Internet-based self-awareness programs on PMS symptoms in Germany, further supporting the role of psychological interventions in managing PMS [23]. Although the approaches of the two studies differed, the consistent findings suggest that remote psychological interventions are feasible and effective.

The emotional- psychological improvements observed in our study are consistent with the findings of Feizi et al. (2024), who reported that online group positive psychology intervention on the Skyroom platform was effective in reducing the psychological effects of the COVID-19 pandemic [24]. Additionally, Matvinko-Sikar et al. (2017) concluded in their study that interventions based on gratitude and mindfulness can be effective in reducing stress and cortisol levels in pregnant women [25]. The results of this study are consistent with our results despite the difference in the research population.

In the domain of physical symptoms, the reduction observed in our study aligns with the findings of Eshaghi et al. (2019), who reported that stress managementbased counseling reduced physical symptoms of PMS [17]. Similarly, Zou et al. (2023), in a systematic review, showed that the use of WeChat/WhatsApp in cancer management could improve both physical and psychosocial health outcomes among cancer patients [26]. However, Nourani Saadoldin et al. (2013) found no significant effect of life skills training on PMS physical symptoms [27], This discrepancy with the present study may be attributed to differences in the intervention methods, training content (e.g., effective communication, selfawareness, and managing negative emotions and stress), and the screening tools used to measure PMS symptoms (e.g., the daily PMS symptom registration forms). Maddineshat et al. (2016) investigated the effectiveness of group cognitive-behavioral therapy (CBT) on PMS symptoms and revealed its effectiveness in psychological symptoms of PMS in the intervention group. However, no significant effect on PMS physical symptoms was observed [28], which can be due to the difference in the used approach and the severity of the symptoms of the subjects because in the mentioned study, those with moderate to severe PMS were included and we examined samples with mild to moderate PMS.

In the present study, the intervention group showed a significant reduction in psycho-emotional symptoms compared to the control group. This aligns with the findings of Eshaghi et al. (2019), who demonstrated that stress management-based counseling reduced psychological symptoms of PMS [17]. Likewise, Zolfaghary et al. (2024) demonstrated that computer-based stress inoculation training (SIT) counseling significantly reduced the severity of PMS symptoms and related psychological factors among students [29].

Regarding the effect of PMS on life impact, we found a significant decrease in the intervention group compared to the control group. Eshaghi et al. (2019) also showed the positive effect of counseling sessions on the effect of PMS symptoms on people's lives [17]. These findings highlight those psychological interventions can enhance well-being by reducing the life disruption caused by PMS symptoms. Other studies examining positive psychology interventions further support the effectiveness of such approaches. For example, Tabatabii et al. (2021) found that positive mindfulness training improved social skills, emotional, and cognitive empathy in female students [30]. This aligns with our findings, as both studies suggest that positive-focused interventions foster personal growth and emotional regulation. Likewise, Ebrahimi et al. (2021) and Madani et al. (2019) reported improvements in self-efficacy following positive-thinking and resilience training, respectively [31, 32]. Although these studies were conducted on different populations (e.g., diabetic patients and adolescents), they reinforce the idea Mohebbi et al. BMC Women's Health (2024) 24:600 Page 8 of 9

that cultivating positive mindsets and skills can enhance well-being across various contexts, including PMS management.

Among the strengths of this study is its adherence to the principles of randomized-controlled clinical trial, including the use of random allocation. Furthermore, the psychometric properties of the questionnaires used have already been validated in Iran.

This study has several limitations that need to be acknowledged. First, the generalizability of the results may be limited by the sample size, which was relatively small and drawn from a single university. Future studies with larger and more diverse samples are recommended to strengthen external validity. Second, while the study assessed the short-term effects of positive counseling on PMS symptoms, the absence of long-term follow-up leaves the sustainability of these effects uncertain. Future research with long-term follow-up is needed to address this limitation. Third, the online nature of the intervention via WhatsApp may have influenced participant interaction and group dynamics compared to face-toface sessions. A comparative study exploring the impact of online and face-to-face interventions could provide further insights. The final limitation of this study is the narrow age range of participants, as it included only university students aged 18 to 25. This restricts the generalizability of the findings to other age groups. Future research should involve a more diverse age range to better capture PMS symptoms across different life stages, considering lifestyle differences as well.

#### Conclusion

The online delivery of the positive counseling sessions via a widely accessible platform like WhatsApp may offer a feasible option for reaching young women. however, further investigation is needed to determine its effectiveness across diverse populations and settings. With further validation, this approach could be considered by health policymakers for integration into broader health promotion programs to support the well-being of women affected by PMS.

# **Abbreviations**

Premenstrual syndrome **PMDD** Premenstrual dysphoric disorder

**PSST** Premenstrual Symptoms Screening Questionnaire

GHQ General Health Questionnaire **ANCOVA** Analysis of covariance

CONSORT Consolidated Standards of Reporting Trials

# **Supplementary Information**

The online version contains supplementary material available at https://doi.or g/10.1186/s12905-024-03437-w.

Supplementary Material 1

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#### **Author contributions**

study design, draft preparation, and supervising the interpretation of the results: P.M. data analysis supervision and initial editing: A.M. data collection, analysis, and interpretation: H.M. Preparation of the content of the sessions and supervision of their implementation: L.E.

#### **Funding**

#### Data availability

No datasets were generated or analysed during the current study.

## **Declarations**

#### Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of Zanian University of Medical Sciences based on the Declaration of Helsinki (Ethics Code: IR.ZUMS.REC.1399.287, Approval date 17 November 2020). It was also registered with the Iranian Registry of Clinical Trials (IRCT20201113049377N1) on 8 December 2020 (https://en.irct.ir/trial/52415: 08/12/2020). Written informed consent was obtained from all participants before their inclusion in the study.

#### Consent for publication

Not applicable.

#### **Competing interests**

The authors declare no competing interests.

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