Journal of Midwifery & Reproductive Health

JMRH.mums.ac.ir

The Effect of Cognitive-behavioral Group Therapy on Reducing Anxiety Levels among Perimenopausal Women: A Randomized Controlled Trial

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ARTICLE INFO

Article type:
Original article

Article History:
Received: 27-Nov-2023
Accepted: 06-Apr-2024

Key words:
Cognitive Behavioral Therapy
Perimenopause
Anxiety
Effectiveness

ABSTRACT

Background & aim: Perimenopause is a natural transition from reproductive years into menopause that women will experience if they reach middle age. Although most women go through this period without experiencing psychological problems, some may experience anxiety during this stage of life. Therefore, this study aimed to assess the cognitive-behavioral group therapy (CBGT) on anxiety levels among perimenopausal women.

Methods: A randomized clinical trial was conducted from August 23 to October 23, 2017, with 42 premenopausal women (aged 45 to 60 years). Participants were recruited from Imam Musa Kazem (AS) Health Center, Shahrood University of Medical Sciences, Iran, using convenience sampling and based on inclusion criteria. Participants were randomly assigned to either the CBGT or the control group (routine care) in a block design. The intervention group received seven weekly two-hour counseling sessions, with 8 to 10 participants in each group. The data were collected using the Hamilton Anxiety Rating Scale (HAM-A) and the Kupperman's menopausal symptom questionnaire. Both groups completed questionnaires immediately after the intervention. Both the independent t-test and paired t-test were employed to analyze the data. All statistical analysis was performed using SPSS version 24.

Results: There was no statistically significant difference between the two groups in the average total anxiety scores before the intervention (P=0.574). However, the total anxiety scores were significantly decreased in the intervention group after the intervention, as compared with the control group (P<0.001).

Conclusion: CBGT therapy could reduce the perimenopausal anxiety symptoms. Therefore, its use in clinical settings is recommended.

▶ Please cite this paper as:
Ameri B, Mohammadi S, Aghayan Sh, aliyari R, Keramat A , Motaghi Z. The Effect of Cognitive-behavioral Group Therapy on Reducing Anxiety Levels among Perimenopausal Women: A Randomized Controlled Trial. Journal of Midwifery and Reproductive Health. 2025; 13(4): 1-11. DOI: 10.22038/jmrh.2024.76491.2263

Introduction

The perimenopausal stage is the stage of life when the menstrual cycle becomes irregular and women experience fewer than 12 cases of menstrual cycles within 12 months (1). It is one of the most sensitive periods in women's life between the ages of 45 to 60. During this period, ovarian hormone depletion occurs within an average of 3 years (usually 2 to 8 years), and

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there is also an increase in pituitary gonadotropins, leading to the deregulation and the stop of the menstrual cycles (2).

Common symptoms of perimenopause include hot flashes, decreased libido, vaginal dryness, symptoms of anxiety (such as irritability, insomnia, memory weakness, and lack of energy that affect work, social activity, leisure time, temperament, concentration, etc.), physical signs, sexual activity, life satisfaction, nonspecific physical and mental symptoms (such as fatigue, irritability, insomnia, palpitations, memory problems, mood swings, and depression that affect overall quality of life) (2-3).

When a person becomes anxious, anxiety level affects a person's life in three different domains: physiological domain (increased heart rate, sweating, and muscle tension), behavioral domain (avoidance and trying to escape different situation), and cognitive domain (negative thoughts such as "I am fainting" and "I can't cope with the situation"(4).

Excessive anxiety, like other mental disorders, has harmful side effects or complications, most notably lack of self-confidence, isolation and loneliness, deprivation of a peaceful life, body exhaustion, deprivation of development and progress, and obsession (5). Rabiee et al.'s study (2012) showed that 9.2% of postmenopausal women suffered from depression, and also 4. 2% had anxiety (6).

Mohammad Zadeh et al. (2017) reported that 42.7% of postmenopausal women living in Babol suffered from severe hot flashes and 48% had severe anxiety (7). All of the above-mentioned studies have focused on the importance of care and support for these women and their role in the prevention of psychological disorders (5, 8). The protocol published by the Health Department of the Ministry of Health puts emphasis on the significance of changes in the lifestyle of middle-aged people (9).

Due to decreased estrogen levels, postmenopausal women can develop different disorders, like anxiety (10). The anxiety associated with menopause can be improved by estrogen replacement therapy (11). However, the long-term use of estrogen in postmenopausal women can increase the risk of endometriosis, breast cancer, and cardiovascular diseases. Nowadays, researchers are looking for an alternative treatment for estrogen, which not only has positive effects but also prevents the complications associated with the effects of synthetic estrogen. Therefore, counseling seems to be a necessary tool to help women adapt to changes and reduce related problems (12).

Cognitive behavioral therapy (CBT) is one of the most effective counseling approaches used in this area. CBT can help people think differently; as a result, the new way of thinking can help address healthier and better behaviors in the face of adverse events (13). CBT is one of the most effective treatment modalities in 50% of individuals suffering frompsychiatric and personality disorders, anxiety, and depression (14). According to the UK's Department of Health, CBT is very effective in facilitating and accelerating the treatment of people with mental disorders and reducing theirrecurrence (15).

Menopause not only can lead to a life-threatening challenge and its complications lead to illness and disability and have a detrimental effect on one's quality of life, but can also indirectly endanger family and community health. These problems can impose a double pressure on the health care system; therefore, any effort to maintain and promote the health of postmenopausal women can have a significant impact on reducing the overall burden of health care costs (10, 16). Hormonal therapies for per menopause complications are associated with some side effects, while CBT is an appropriate way to deal with psychological complications caused by menopause (14).

This study was conducted for several reasons. First, the previous studies evaluated the effect of the CBT on the treatment of anxiety, while the present study assessed the effect of the CBT on the prevention of anxiety. Second, the previous studies showed that the effectiveness of the CBT for anxiety varies in different groups. So, the present study was performed on a specific group of perimenopausal women.

This study aimed to assess the cognitive-behavioral group therapy (CBGT) on anxiety levels among perimenopausal women in Shahroud city, Iran.

Materials and Methods

This was a randomized controlled trial (RCT) which was registered under code of IRCT20170826035896N2 in the Iranian clinical

trial database. This study was conducted from August 23 to October 23, 2017.

The study population consisted of all perimenopausal women who referred to the health care centers of Shahroud city in Semnan Province, Iran. Sampling was conducted at one Comprehensive Health Service Center.

The study inclusion criteria were as follows: women aged 45-6, willingness to participate in the study, and having at least a middle school diploma (taking the active and collaborative nature of CBT into consideration). The study exclusion criteria included refusal to continue the treatment at any stage, the induction of artificial menopause through medication or surgery, presence of chronic medical conditions (e.g., uncontrolled diabetes, cardiovascular disease, cancer, or renal failure), unresolved thyroid issues, and taking hormonal or other drugs that influence the function of glands,having a history of psychiatric disorders (e.g., major depressive disorder, generalized anxiety disorder, bipolar disorder, or schizophrenia)or psychological treatment during the study, substance abuse within the past six months, participation in any other psychological or counseling treatment during the study period, and experiencing major stressful life events (e.g., death of a spouse or close family member, divorce, job loss, or serious accident) within the previous six months.

To compare the average anxiety scores between the two groups, based on the study by Hassan et al. (2011) (17), considering 5% error, power= 80%, s1=5.98, s2=6.98, d=6, and 10% attrition, a sample size of 30 people per group was determined (n=60 in total) (Fig. 1).

After calculating the sample size, the study subjects were selected using convenience sampling from the Imam Musa Kazem (AS) Health Center affiliated with Shahrood University of Medical Sciences. The participants were randomly assigned to the control or intervention groups using the blocks (Block of 4). R software and the Block Round package were used to design the randomization list. The sequence allocation and preparation of opaque envelopes were done by a statistician who was not involved in sampling or data collection. Neither the researcher (the first author) who conducted the intervention nor the participants were blinded to group allocation. However, the second research assistant, who collected completed questionnaires, was blinded to the allocation. Since the questionnaires and groups were coded, entering the data into SPSS software and the subsequent data analysis performed by the researcher did not affect the blinding of outcome evaluation.

In this study, the data were collected by the following instruments:

Demographic and obstetric form: This scale contains 20 items to collect descriptive data about basic demographic and obstetric variables, such as age, education level, occupation, ethnicity, place of residence, current and previous pregnancy status, a history of illness/surgery, a history of taking certain medications, and history of high-risk behaviors (smoking, alcohol). The Form was developed based on a thorough review of established scientific literature. Content validity was assessed through a formal evaluation by 10 expert faculty members from the School of Nursing and Midwifery at Shahroud University of Medical Sciences. Feedback was systematically collected, and appropriate revisions were made to improve the clarity, relevance, and comprehensiveness of the items. Content validity was thereby confirmed through expert consensus, ensuring the instrument's suitability for the intended research context.

Hamilton anxiety rating scale (HAM-A): This scale was developed by Max Hamilton between 1960 and 1967, and was also considered as one of the clinical scales used to assess the severity of anxiety. Currently, the HAM-A is one of the most well-known anxiety tests. It contains 14 items, each rated in 5 scale, ranging from 0 to 4, depending on the severity of the symptoms. Zero indicates the absence of the symptom, and 4 represents the highest severity of the same symptom in the patient. This scale is scored by an interviewer. The HAM-A can be used to obtain the information needed to complete the questionnaire through interviews, assessing history, collecting data from relatives, and observations. This scale covers a wide range of symptoms that are commonly diagnosed as symptoms of an anxiety disorder. The symptoms include anxiety, tension, fear, insomnia, difficulty concentrating, depression, muscle tension (tick

or tremor), general physical status, cardiovascular symptoms, respiratory symptoms, gastrointestinal symptoms, symptoms related to the genitourinary tract, other physical symptoms (dry mouth, sweating), and the patient's behavior during the interview. Based on this scale, each item is scored using a 5-point scale. The overall test score indicates the severity of anxiety. The maximum score in each item is 4, and the maximum overall score is 56 (18). The validity and reliability of this tool have been proven by the previous Iranian studies (19-20).

Table 1. Content of CBGT sessions

First session
• Welcoming • Elaborating group rules • Emphasizing constant presence in the classroom and observing the rules • Appointing a disciplinary representative • Familiarizing the participants with each other • Emphasizing the confidentiality of counseling sessions • Teaching the principles of cognitive behavioral counseling and the structure of counseling sessions (number of sessions, venue, time of each session and session logisticsEvaluating participants' information • Training menopause and related misconceptions • Explaining the general course of group sessions • Teaching the principles of cognitive behavioral therapy and presenting the counseling rationale
Second session
• Evaluating anxiety problems • Preparing a list of current problems of each participant • Identifying the domain of concern
Third session
• Introducing the cognitive triangle • The influence of thoughts on behavioral emotions • Evaluation of factors and causes of worry and distinguishing concerns from reality
Fourth session
• Training muscle relaxation • Evaluating and identifying negative thoughts • Examining evidence for and against negative thoughts
Fifth session
• Training people to extend relaxation practices to different situations • Introducing problem-solving and self-adaptation skills
Sixth session
• Introducing errors and cognitive distortions
Seventh session
• Understanding self-efficacy and improving cognitive distortions • Promoting the skills to enjoy time • Completing the Hamilton anxiety questionnaire and Cooperman menopausal symptoms questionnaire

Kupperman's menopausal symptom questionnaire: This scale was developed and adjusted by Kupperman et al. (1953). It is a modified version of the Suzuki and Abbi method that has been used repeatedly in various studies to measure menopausal symptoms and diagnose and treat gynecological diseases. Kupperman Index includes 11 items that are used to assess menopausal symptoms in three domains, including physical domain (such as hot flashes, night sweats, and palpitations), psychological domain (such as insomnia, anger, depression, dizziness, weakness or fatigue, feeling of insect movement on the skin, headache, burning sensation, and genitourinary itch), and urinary and genital domain (such as decreased sexual desire, decreased marital satisfaction, urinary incontinence, urinary difficulty, vaginal dryness,

vaginal burning) (21). This questionnaire has been used by previous studies evaluating menopausal symptoms, and its reliability and validity have also been confirmed (21-22).

After random assignment of samples to control and intervention groups, the subjects were contacted and asked to attend counseling sessions held at Health Center. In accordance with the standards of CBT, the participants received seven counseling sessions for two hours each week. Group counseling sessions were held in group for 45-60 minutes. Each group consisted of 8-10 individua . Counseling sessions were conducted in a suitable place in terms of sufficient lighting, no noise, and no visits from different people, with enough seats and educational equipments. The validity of the counseling sessions content was evaluated by 10 academic staff members of Shahroud University of Medical Sciences including reproductive health specialist and clinical psychologist.

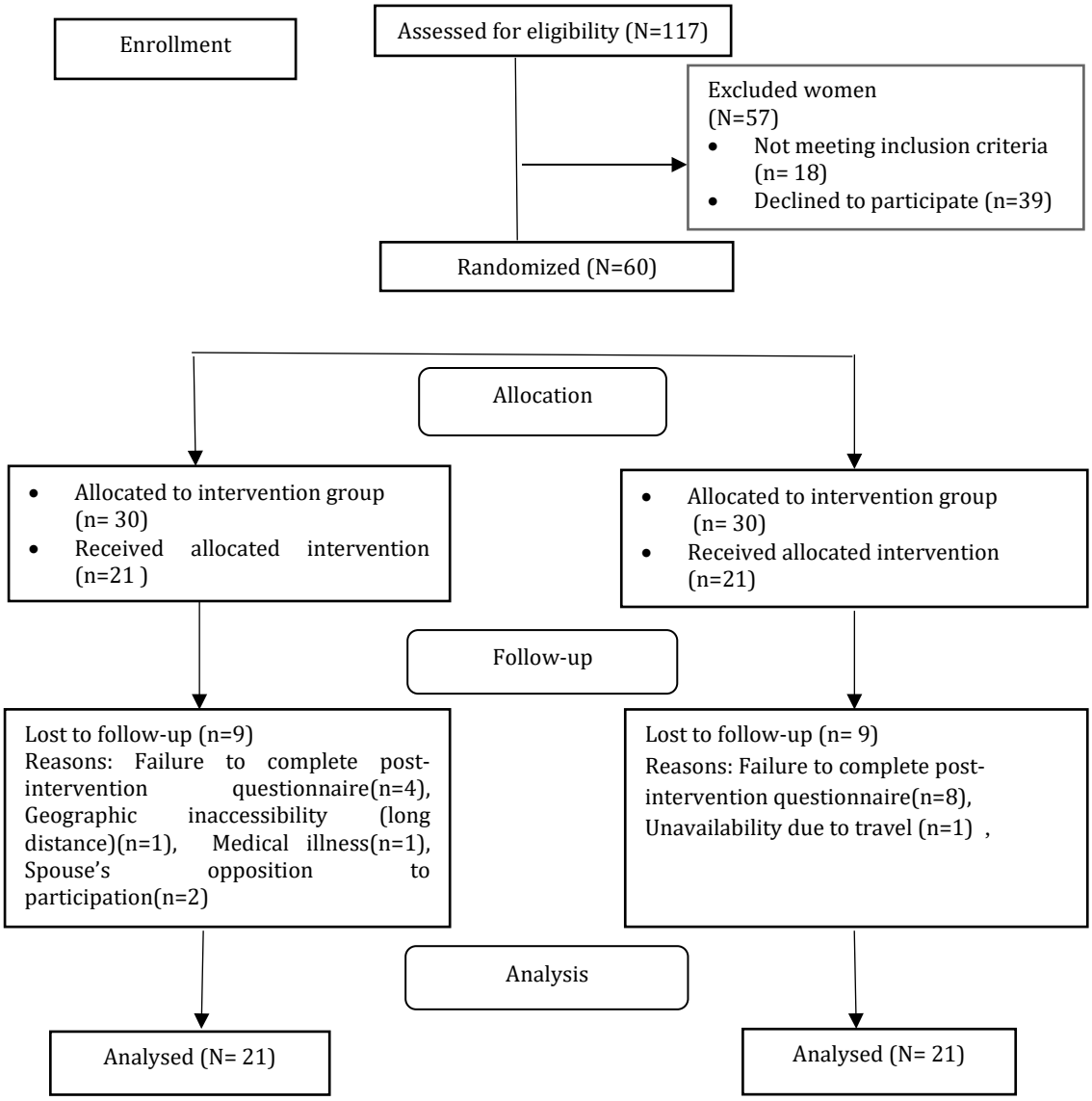

Figure 1. CONSORT Flowchart of the study

The counseling sessions were held by the first author (who was a master's student with 10 years of midwifery experience) under the supervision of a master's degree in clinical psychology. The content of each session is presented in Table 1.

The control group did not receive any intervention and only received routine care according to the middle-aged services defined at SIB system (Local integrated health record system in Iran)). This care included periodic health check-ups, initial counseling about menopausal symptoms, lifestyle advice (such as nutrition and physical activity), and referral to a specialist if needed.

In both the intervention and control groups, a pre-test was conducted by completing the research tools. Immediately after the intervention, questionnaires were completed again by the two groups. The questionnaires were self-administered, with an estimated completion time of 25–35 minutes in total, depending on individual reading speed and comprehension. Nine dropouts were observed in either group until the end of the intervention (Figure 1).

The data was analyzed using both descriptive and inferential statistical methods. Descriptive statistics involves calculating central indices like the mean and dispersion indices like the standard deviation. Additionally, tables and graphs were created to visually represent the data. To test the desired hypotheses, the normality of the data was determined using the Kolmogorov-Smirnov test. Furthermore, both the independent t-test and paired t-test were employed to analyze the data. All statistical analysis was conducted using SPSS version 24.

Results

In this clinical trial, 42 women aged 45-60 were allocated to two groups. The mean age of perimenopausal women was 53.09 ±4.03 years. Table 2 presents the demographic characteristics of intervention and control groups.

As presented in Table 3, no significant difference was observed between the two groups in terms of anxiety levels before the intervention, and also, they were homogeneous. The paired t-test results showed that a significant difference was observed in the intervention group in terms of the mean anxiety scores before and after the intervention ($P< 0.001$), so the mean anxiety score in this group decreased from 21.2 to 12.2. The mean anxiety score before and after the intervention also showed a significant difference in the control group ($P< 0.001$), but this difference was reversed in the control group, and the results showed an increase in anxiety levels in this group after the intervention. In addition, the independent t-test results showed a significant difference between the two groups in terms of the mean anxiety scores; it also showed a significant difference in the intervention group with respect to the mean anxiety scores before and after the intervention ($P< 0.001$). According to the covariance analysis, we concluded that the anxiety scores after adjusting for the confounding effect of the pre-test anxiety score showed a statistically significan.

Before the intervention, the two groups were homogeneous in terms of the physical domain. The paired t-test results demonstrated no significant difference between the mean scores of the physical domain before and after the intervention ($P>0.05$). Based on the results of the independent t-test, the changes after the intervention, compared to before the intervention, in the intervention group were 12.4±3.12, and in the control group were 11.5±2.94, with a significant difference between the two groups ($P= 0.315$) (Table 3).

Before the intervention, the two groups were homogeneous in terms of the psychological domain. The results of the paired t-test showed a significant difference between the mean scores of the psychological domain before and after the intervention ($P<0.01$). However, this difference was not significant in the control group. In addition, the independent t-test results showed a significant difference between both groups in terms of mean scores of the psychological domain before and after the intervention ($P<0.01$) (Table 3).

No significant difference was observed between the two groups in terms of the urinary and genital domain before the intervention, and they were homogeneous. The results of the paired t-test showed no significant difference between the mean scores of the urinary and genital domains before and after the intervention ($P>0.05$).

Table 2. Demographic characteristics of intervention and control groups a

Variable	Intervention Group N(%)	Control Group N(%)	Test Result
Maternal education level			
12 years or less	13(61.09)	10(46.7)	X2=0.865
More than 12 years	8(38.1)	11(52.4)	P=0/352 chi-square
Mother's occupation			
Housewife	15(71.4)	18(85.7)	X2=1.27
Employee	6(28.6)	3(14.3)	P=0/259 Fisher's exact
Marital status			
Married	17(81)	20(95.2)	X2=5.24
Other marital status	4(19)	1(4.8)	P=0/073 Fisher's exact
Mode of delivery			
Vaginal delivery	17(81)	13(61.9)	X2=2.35
C/S delivery	4(19)	8(18.1)	P=0/309 Fisher's exact
Abortion history			
Yes	5(28.3)	3(14.3)	X2=6.18
NO	16(76.2)	18(85.7)	P=0/432 Fisher's exact
Smoking			
Yes	0(0)	1(1)	X2=1.024
No	21(100)	20(0/99)	P=0/311 Fisher's exact
Mother's age (Mean ± SD)	53.52±4.85	52.66±3.42	T=0/661 P=0.512 T-test
Age at first menstruation mean	13.23±1.7	12.9±1.94	T=0/591 P=0.558 T-test
Duration of marriage means	32.4±8.04	28.7±8.87	T=1.4 P=0.168 T-test

[a] Values are presented as Mean ± SD or No. (%)

Table 3. Comparison between mean scores and standard deviation of sources of anxiety and menopausal symptoms of the participants in both groups before and after intervention

Variable	Before, Mean ± SD	After, Mean ± SD	Changes, Mean ± SD	Paired Samples T-Test (Before-After)
Anxiety				
Intervention Group [a]	21.2±7.45	12.2±6.85	9±4.72	P= 0.001
Control Group [a]	22.5±7.24	24.1±7.35	-1.61±1.35	P= 0.001
Independent samples t-test	P=0.580	P= 0.001	P= 0.001	
Physical domain of menopausal symptoms				
Intervention Group [a]	12.5±3.07	12.4±3.12	0.047±0.384	P= 0.576
Control Group [a]	11.6±3.11	11.5±2.94	0.142±0.358	P= 0.083

Variable	Before, Mean ± SD	After, Mean ± SD	Changes, Mean ± SD	Paired Samples T-Test (Before-After)
Independent samples t-test	P= 0.375	P= 0.315	P= 0.411	
Psychological domain of menopausal symptoms				
Intervention Group [a]	13.8± 2.71	8.95±2.31	1.79±4.85	P= 0.001
Control Group [a]	13.7±2.36	13.6±3.27	0.095±1.94	P= 0.825
Independent samples t-test	P= 0.952	P= 0.001	P= 0.001	
Urinary and genital domain of menopausal symptoms				
Intervention Group [a]	13.1±2.76	13.3±2.74	-0.19±0.872	P= 0.329
Control Group [a]	12.2±2.93	12.7±2.94	1.43± -0.476	P= 0.144
Independent samples t-test	P= 0.309	P= 0.449	P= 0.44	

[a] Values are presented as Mean±SD

Furthermore, the results of an independent t-test showed no significant difference between both groups of the mean of scores of the urinary and genital domain before and after the intervention (P>0.05) (Table 4)..

Table 4. Results of covariance analysis for anxiety variable

Source of changes	Sum of squares	df	Mean square	F	P- Value	The square of η
group	1215.6	1	1215.6	108.09	0.000	0.735
Error	438.6	39	11.2			
Total	17482	42				

Discussion

The present study aimed to evaluate the effect of CBGT on reducing anxiety levels and menopausal symptoms in perimenopausal women. The results of this study showed that CBGT could have a significant effect on anxiety levels and symptoms of the psychological domain in perimenopausal women; however, it had no significant effect on the symptoms in the urinary and genital domain.

It is important to note that anxiety levels were significantly increased in the control group after the intervention. Studies have shown that hormonal fluctuations during perimenopause could increase anxiety symptoms during perimenopausal and menopausal periods, as compared with earlier times (23, 24). In the present study, increased anxiety levels in the control group might be due to the hormonal fluctuations in perimenopausal women. In the intervention group, CBGT could help the subjects control their emotions and behavior, but the subjects who received only routine care did not have the necessary efficacy to control the above symptoms.

Binfa et al. (2004) conducted a study and investigated the effect of CBGT on the reduced symptoms of anxiety in schizophrenic patients, and showed that it had a significant positive effect in the intervention group, but there was no change in the symptoms and signs of anxiety in the control group (25). In line with our study, the study of Charmchi et al. (2016) showed that CBGT might be a successful method to reduce anxiety and increase mental resilience in postmenopausal women (26). Khatibian et al. (2014) and Shakerian showed that CBGT significantly reduced depression, anxiety, and tension levels in women with breast cancer (27).

As a general reason, this finding might be attributed to the beneficial effects of group therapy, as compared with individual therapy. Group therapy helps individuals to learn effective social skills and then test their learn lessons on other members. They feel self-confidence and ease when observing others' problems that are similar or perhaps even more severe than their problems (28).

In this method, it is also assumed that there is a relationship between thoughts, feelings, and behavior so that negative automatic thoughts cause emotional arousal and disturb the performance. Therefore, informing individuals and helping them through cognitive reconstruction can help them control their thoughts and prevent emotional and behavioral problems (29). Through increasing self-esteem in people who suffer from anxiety and

empowering them to accept themselves, this type of treatment allows patients to focus less on their mistakes and to experience fewer negative emotions in the face of adverse performance under such circumstances.

Concerning the behavioral aspects of the present technique, planning activities were very helpful. Since perimenopausal women are sensitive to the smallest cases of failure and reinforce their perceptions of self-negativity, planning activities help patients minimize the likelihood of failure in fulfilling a daily schedule. Patients are encouraged to value any increase in daily activity and to enhance their positive thinking. The other aspect is the poor interpersonal relationships within these people; often these individuals have many problems in their interpersonal relationships and have poor communication styles (often aggressive or passive), leading to lead to rejection by others and social isolation. Therefore, the objectives of the therapy sessions are to teach correct, courageous, and unrestrained styles of communication in these individuals and to encourage people to build good and supportive social relationships (30-31). As another possible explanation for the above finding, it could be said that by reducing the levels of anxiety and depression in these individuals, their focus on the cycles (perimenopause) and their attention toward symptoms may be reduced. As one more possible explanation, cognitive behavioral therapy simultaneously reduces anxiety, depression, and perimenopausal symptoms, which may indicate an interrelationship between psychological symptoms and somatic symptoms.

Another possible explanation is that one of the important factors contributing to the severity of menopausal symptoms is the attitude of women in menopause (32). The results of study by Mohammad Zadeh et al. (2017) showed that the anxiety level in Iranian postmenopausal women were higher than that in those living in other countries (7).

The results of studies showed that this might be due to two reasons. First, childbearing is very important for Iranian women and menopause is considered the end of childbearing.Second, menopause is considered the equivalent of aging and loss of freshness and beauty, so it causes anxiety in them. Due to their attitude towards menopause that causes their anxiety at this age, which has a cognitive aspect, they need psychological interventions to prevent it, especially the CBT (32-33).

However, the findings of the present study and other research showed that CBT could reduce the symptoms of perimenopause and consequently lead to an improvement in symptoms of depression and anxiety, which in turn decreases the severity of symptoms during this period. This study has several methodological and practical strengths. It utilized a RCT design, ensuring high internal validity and enabling causal inference about the efficacy of CBGT in reducing anxiety in perimenopausal women. The intervention was structured, time-limited, and grounded in established CBT principles, enhancing its reproducibility and potential for integration into primary care. Furthermore, the use of validated tools such as the HAM-A and the Kupperman Index supports the reliability and accuracy of the outcomes. The present study also had some limitations. It was performed only on perimenopausal women in Shahroud. Therefore, it is necessary to be cautious when generalizing the results to other communities and groups. As another limitation, some of the perimenopausal women were unwilling to participate and did not cooperate, and refused to complete the questionnaires and attend treatment sessions. Finally, in the present study, there was no follow-up due to the lack of access to the subjects. It is therefore recommended that further research be conducted to evaluate the effect of CBT on other psychological characteristics of perimenopausal women. Also, future research should investigate long-term efficacy, cross-cultural applicability, and synergies with complementary approaches such as lifestyle modification and a mindfulness based interventions.

Conclusion

From a clinical and public health perspective CBGT represents a valuable non-pharmacological intervention for perimenopausal women, particularly those reluctant to use psychotropic medications or at risk of polypharmacy. Given the high burden of anxiety during this transition and persistent gaps in mental health service access, CBGT offers a cost-effective, scalable, and culturally adaptable model. Integration within primary care

settings—such as urban health centers demonstrates high feasibility, especially within existing frameworks like Iran's SIB system, where midwives and trained providers can deliver the intervention with minimal infrastructure.

Declarations

Acknowledgements

This paper is extracted from a master thesis in Shahroud University of Medical Sciences. The authors would like to express their sincere gratitude to o the University for its financial support provided for the research project No.258.

Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

The ethical considerations that were taken into account involved informing the participants about the research process and its timing, the nature of the intervention, obtaining written consent, maintaining the confidentiality of the sessions, and allowing the participants to withdraw from the study at any point during the research.

Code of Ethics

The Ethics Committee of Shahroud University of Medical Sciences approved the study protocol (ethical code IR.SHMU.REC.1396.61.

Use of Artificial Intelligence (AI)

We acknowledge that no AI tools or technologies have been used to prepare this manuscript.

Funding

This study was supported financially by Shahrood University of Medical Sciences.

Authors' contribution

BA Data collection, contribution to the drafting of the initial manuscript.
SM Contribution to the initial draft, critical revision of the manuscript for important intellectual content, and preparation of the final report.
SA, RA and AK Scientific consultation and project supervision.
ZM Conceptualization of the research idea, study design, overall supervision and guidance of the project, and critical review of both initial and final versions of the manuscript. All authors read and approved the final manuscript.

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