

ORIGINAL RESEARCH ORJİNAL ARAŞTIRMA

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Evaluation of the Effect of Acupuncture Therapy on Vasomotor Symptoms and Insomnia in Menopause: Randomized Controlled Trial

Menopozda Akupunktur Tedavisinin Vazomotor Semptomlar ve Uykusuzluk Üzerine Etkisinin Değerlendirilmesi: Randomize Kontrollü Çalışma

¹ Meryem BETOS KOÇAK^a, ² Yasemin ÇAYIR^a, ³ Emsal Pınar TOPDAĞI YILMAZ^b

^aAtatürk University Faculty of Medicine, Department of Family Medicine, Erzurum, Türkiye

^bAtatürk University Faculty of Medicine, Department of Gynecology and Obstetrics, Erzurum, Türkiye

ABSTRACT Objective: To examine how acupuncture influences post-menopausal vasomotor symptoms, sleep disturbance and quality of life in post-menopausal women. **Material and Methods:** This randomized-controlled trial was carried out with 80 postmenopausal women. Participants were randomly assigned to the acupuncture group and control group. Control group underwent usual care, while acupuncture group underwent acupuncture treatment for a total of 10 sessions in addition to usual care. The primary outcome measures were the mean change in Menopause Rating Scale, and Pittsburgh Sleep Quality Index at the week 5. The secondary outcome measures included the mean change of Menopause Specific Quality of Life scores and the number of hot flushes from baseline to endpoints. **Results:** Acupuncture group reported a statistically significant decrease in mean Menopause Rating Scale and Menopause Specific Quality of Life scores from pre-treatment to post-treatment ($p=0.000$). Pittsburgh Sleep Quality Index score was 10.1 ± 3.2 at baseline while it decreased to 5.6 ± 2.4 after acupuncture in acupuncture group; the baseline Pittsburgh Sleep Quality Index score was 10.4 ± 3.2 in control group, it was 10.6 ± 3.4 at the end of the study ($p=0.000$). In the baseline evaluation, daily hot flush frequency was 11.2 ± 7.1 in acupuncture group and 10.8 ± 6.5 in control group ($p=0.798$). It was decreased to 3.8 ± 3.2 in acupuncture group, while it was 11.0 ± 6.1 in control group ($p=0.000$) at 5 week. **Conclusion:** We demonstrated that 10 sessions of acupuncture treatment has positive effect on post-menopausal symptoms and sleep problems. Additionally, acupuncture practice improved menopause-related quality of life.

ÖZET Amaç: Bu çalışmanın amacı, akupunkturun menopoz sonrası kadınlarda vazomotor semptomlar, uyku bozuklukları ve yaşam kalitesi üzerindeki etkisini incelemektir. **Gereç ve Yöntemler:** Bu randomize kontrollü çalışma, 80 postmenopozal kadınla gerçekleştirildi. Katılımcılar, rastgele akupunktur grubu ve kontrol grubuna atandı. Kontrol grubu, normal bakıma tabi tutulurken; akupunktur grubu, normal bakıma ek olarak toplam 10 seans akupunktur tedavisi aldı. Birincil sonuç ölçütleri, 5. haftada Menopoz Derecelendirme Ölçeği'ndeki ve Pittsburgh Uyku Kalitesi İndeksi'ndeki ortalama değişim idi. İkincil sonuç ölçütleri, Menopoz Özgü Yaşam Kalitesi Ölçeği puanlarındaki ortalama değişim idi. Sıcak basmalarının günlük sayıları kayıt altına alındı. **Bulgular:** Akupunktur grubunda, tedavi öncesinden tedavi sonrasına ortalama Menopoz Derecelendirme Ölçeği'ndeki ve Menopoz Özgü Yaşam Kalitesi Ölçeği skorlarında istatistiksel olarak anlamlı düzeyde bir azalma bildirildi ($p=0.000$). Başlangıçta Pittsburgh Uyku Kalitesi İndeksi skoru $10,1\pm3,2$ iken, akupunktur grubunda akupunktur işleminden sonra $5,6\pm2,4$ 'e düştü; kontrol grubunda başlangıç Pittsburgh Uyku Kalitesi İndeksi skoru $10,4\pm3,2$ iken, çalışma sonunda $10,6\pm3,4$ 'tü ($p=0,000$). Başlangıç değerlendirmesinde, günlük sıcak basması sıklığı akupunktur grubunda $11,2\pm7,1$ iken; kontrol grubunda $10,8\pm6,5$ idi ($p=0,798$). Beşinci haftada akupunktur grubunda $3,8\pm3,2$ 'ye düşerken, kontrol grubunda $11,0\pm6,1$ idi ($p=0,000$). **Sonuç:** Çalışmamızda, 10 seans akupunktur tedavisinin menopoz sonrası semptomlar ve uyku sorunları üzerinde olumlu etkisi olduğunu gösterdik. Ek olarak akupunktur uygulaması, menopozla ilişkili yaşam kalitesini artırdı.

Keywords: Acupuncture; menopause; sleep initiation and maintenance disorders

Anahtar Kelimeler: Akupunktur; menopoz; uyku başlatma ve sürdürme bozuklukları

Correspondence: Meryem BETOS KOÇAK

Balıkesir Atatürk City Hospital, Clinic of Traditional Medicine, Balıkesir, Türkiye

E-mail: meryembetokocak@gmail.com

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Menopause refers to the permanent cessation of ovarian function and marks the end of a woman's reproductive lifespan. The postmenopausal phase is frequently accompanied by a variety of physical and psychosocial manifestations. Among these, vasomotor symptoms (VMS) and sleep disturbances are the most prevalent complaints.¹ VMS, which may manifest as hot flashes, nocturnal or cold sweats, and heart palpitations, affect approximately 60 to 80% of women undergoing the menopausal transition, with prevalence rates differing among racial and ethnic groups. VMS are closely linked to a range of sleep disturbances, such as problems with sleep onset, sleep maintenance, and premature awakening.² Evidence from a longitudinal and extensive study indicates that VMS peaks in the early postmenopausal years.³

VMSs and sleep disturbances adversely affect women's mental health and overall well-being. These symptoms have been well-documented to have a detrimental effect on the quality of life in postmenopausal women.⁴⁻⁶ VMS and sleep disturbance can be linked indirectly to mood and cognitive functions in postmenopausal women. Many of the postmenopausal women with VMS experience depression and anxiety disorders. VMS may also cause mood problems by disrupting sleep. Sleep disturbance is also accepted as an important risk factor for depressive mood.⁷

Various pharmacological and non-pharmacological therapeutic approaches are available for the management of VMSs and sleep disturbances in postmenopausal women. Non-pharmacological treatment begins with lifestyle changes such as avoiding hot environments, avoiding alcohol, regularly exercising, and to be in a healthy weight. Pharmacological treatments contain hormonal or non-hormonal medications. Hormonal medication includes estrogen and progestin, while non-hormonal medication contain antidepressants or gabapentin.^{8,9} Currently, millions of postmenopausal women use estrogen and progestin as hormonal therapy in the world. Hormonal therapy should be used at the lowest possible doses to treat VMS. Hormonal therapy may control intensity of VMS and it has positive efficacy on sleep disturbances. However hormonal therapy may have various potential side effects such as cardiovascular

disease and cancer. Some patients are unwilling to use hormonal therapy due to these adverse effects. Besides there are known uncertainties related to long time use of these hormones.¹⁰ Consequently, an increasing number of postmenopausal women are seeking effective non-pharmacological interventions to manage VMS and sleep disturbances.

Acupuncture, a core component of Traditional Chinese Medicine, has been employed for thousands of years in the management of symptoms and the treatment of a wide range of medical conditions.⁹ Currently, acupuncture is broadly adopted in various countries as an adjunctive approach within complementary and integrative medicine. Postmenopausal VMS and sleep disturbances are one of the health situations in which acupuncture is commonly recommended to use. A number of randomized-controlled trials and meta-analysis have shown that acupuncture can be effective for reducing VMS.^{11,12} However, a meta-analysis concluded ineffectiveness of acupuncture on hot flushes when they compared acupuncture with sham acupuncture.¹³ To our best knowledge, there is no sufficient evidence about the effectiveness or ineffectiveness of acupuncture on postmenopausal symptoms. On the other hand, existing studies have primarily concentrated on how acupuncture affects VMS or sleep disturbances in postmenopausal women.^{14,15} There is a relative paucity of data directly comparing the influence of acupuncture on VMS and sleep disturbances, as well as its influence on quality of life in postmenopausal women.

In light of this, we conducted a randomized controlled trial to evaluate the effects of acupuncture on VMS, sleep disturbances, and overall quality of life among postmenopausal women

MATERIAL AND METHODS

STUDY DESIGN

This randomized controlled trial employed a prospective, single-site, parallel-group design was conducted between May-July 2019 at the Research and Practice Center for Acupuncture and Complementary Therapies at Atatürk University and the Department of Obstetrics and Gynecology, Faculty of Medicine, Atatürk University, Erzurum, Türkiye. The study pro-

cedures complied in accordance with the ethical guidelines set forth by the Declaration of Helsinki, which provides ethical guidelines for clinical research. No significant modifications to the methodology were made after the trial commenced. Reporting of the acupuncture intervention adhered to the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines. Written informed consent was secured from every participant before their inclusion in the study, prior to their inclusion in the study and all published data have been fully anonymized to ensure confidentiality. The study protocol received approval from the Atatürk University Faculty of Medicine Ethics Review Board (date: February 13, 2019; no: B.30.2.ATA.0.01.00/115).

Participants

In our study, hot flushes and palpitations were evaluated as VMSs. In May 2019, a total of 120 postmenopausal women experiencing VMS and sleep disturbances presented to the Obstetrics and Gynecology Outpatient Department at Atatürk University. Eligibility for inclusion required a diagnosis with menopause for at least 1 year, not receiving any medicine or herbal treatment for symptoms, not taking hormonal treatment. Participants who had undergone hysterectomy and/or bilaterally oophorectomy, who were taking herbal estrogen or food supplement for symptom control, individuals who had undergone acupuncture for any reason within the preceding year, those who declined to provide informed consent for acupuncture treatment, and those with a fear of needles were excluded from the study. Additionally, patients with any known chronic disease were not included in the study. Elimination criteria were failure to adhere to the treatment protocol or refusal to continue treatment after inclusion.

Sample Size and Randomization

The sample size was determined based on a similar study by Nedeljkovic et al., which utilized the Menopause Rating Scale (MRS) as an outcome measure.¹⁶ An effect size of $d=0.93$ was anticipated. Using G*Power[®] version 3.1 software (Institute for Experimental Psychology, University of Düsseldorf, Düsseldorf, Germany), it was calculated that en-

rolling 20 participants per group would achieve 80% statistical power to identify a significant difference in MRS scores at a 5% significance threshold. To account for the potential use of nonparametric tests and possible participant dropout, the sample size was increased. Consequently, a total of 80 participants (40 per group) were planned for inclusion.

Following an initial assessment by a gynecologist, 80 eligible patients were enrolled in the study. The secretary of obstetrics and gynecology outpatient department utilized a computer-generated randomization tool (www.randomizer.org) to create an allocation sequence for assigning patients to the different study groups. Each patient who fulfilled the inclusion criteria was assigned an identification number for random allocation to one of the groups. A total of 80 participants were randomly assigned in equal proportions (1:1) to the acupuncture group (AG) or the control group (CG). The CG received standard care alone, while the AG underwent 10 acupuncture treatment sessions in addition to the usual care. All participants were monitored for a duration of 5 weeks. Adherence to the CONSORT guidelines was maintained throughout the study, and the flowchart of participant progression is depicted in Figure 1.

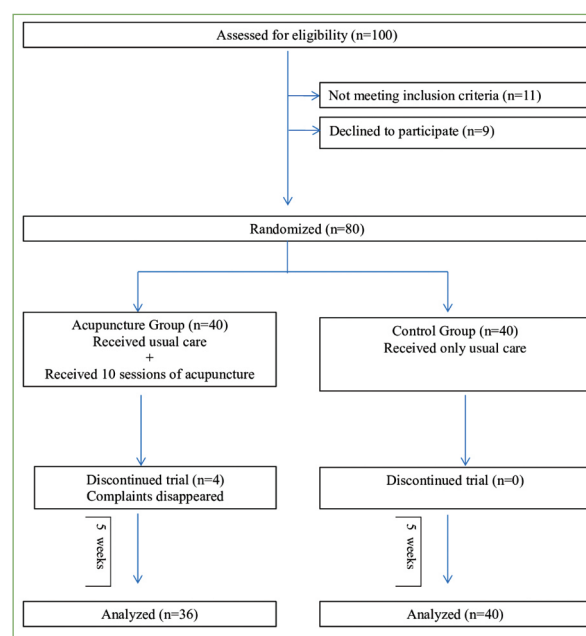


FIGURE 1: Flow chart of the participants

Intervention

Participants assigned to AG received 10 acupuncture sessions by an acupuncturist licensed by the Turkish Ministry of Health as an acupuncture practitioner. Acupuncture treatment was designed as 2 sessions in a week. All acupuncture points were selected and identified according to the World Health Organization's Standardized Acupuncture Point Locations and principles of Western Medical Acupuncture.¹⁷ The acupuncture points of bilateral LI-4, LI-11, ST-36, SP-6, KI-3, KI-7, LR-3, EX-CA-1 (Zigong) and EX-HN-3 (Yintang), GV-20, CV-3, CV-4 were selected. The selected acupuncture points are the acupuncture points previously determined in the literature and used for the treatment of menopause and menopause-related symptoms.¹¹⁻¹³ Acupuncture was performed using single-use sterile stainless steel needles measuring 0.25×25 mm, which were inserted 10 mm deep and retained for 30 minutes without further stimulation. Monitoring for adverse events occurred during each session.

Outcome Measurement

MRS questionnaire and the Pittsburgh Sleep Quality Index (PSQI) at week 5 were determined to be the main outcome measures.

MRS is a Likert type scale which contains 11 items including menopausal complaints and 3 sub-dimensions (psychological, somato-vegetative, urogenital). It is a highly valued scale used for the assessment of menopausal complaints. Each item represents the severity of a symptom from 0 (none) to 4 (very severe). The overall score of the scale is determined based on the scores given for each item and varies between 0-44. The high total scores obtained from the scale indicate the severity of the menopausal complaints.¹⁸

PSQI is a self-administered questionnaire that assesses sleep quality and disturbances over the previous month. It comprises 24 items, of which 19 are completed by the participant and 5 by a co-sleeper, if available. The scale evaluates 7 components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Each component is rated on a scale from 0 to 3 based on the

frequency of symptoms, and the total PSQI score is the sum of these components. A global score greater than 5 reflects poor sleep quality.¹⁹

The secondary outcome measures included the mean change of Menopause Specific Quality of Life (MENQOL) questionnaire scores and the number of hot flushes in a day from baseline to endpoints.

MENQOL is a Likert type scale containing 29 questions. The questions consist of 4 sub-dimensions: vasomotor, psychosocial, physical and sexual. As the score increases, the severity of the menopausal symptoms also increase. The MENQOL has been validated in prior studies as an effective and sensitive measure for assessing health-related quality of life in postmenopausal individuals.²⁰

In addition, all participants were asked to document the total number of daily hot flushes during 5 weeks. All data were gathered both at baseline and at the 5-week follow-up.

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS software version 23.0 (IBM Corp., Armonk, NY, USA). Numerical variables were presented as mean±standard deviation, while categorical variables were expressed as frequencies and percentages. The normality of numerical data was assessed using skewness. Differences between groups for outcome measures were evaluated using the independent samples t-test and chi-square (χ^2) test. p values less than 0.05 were regarded as indicative of statistical significance.

RESULTS

Eighty eligible participants were randomized into the AG or CG. Four participants in the AG dropped out due to disappearance of their complaints. A total of 76 patients completed the study. No adverse event or incident were reported at any point in time.

The ages of the participants ranged between 53.9±3.4 years. The baseline characteristics in terms of age, education level, and occupation ($p>0.05$) were similar for both AG (n=36) and CG (n=40). Table 1 shows the baseline characteristics of the participants.

Figure 2 shows the comparison of the MRS total scores among pre-treatment and post-treatment as-

TABLE 1: Baseline characteristics of the participants in each group

Characteristics	AG (n=36)	CG (n=40)	p value
Age (year) ($\bar{X} \pm SD$)	54.7 \pm 4.1	53.2 \pm 3.4	0.201
Education level, n, (%)			
<8 years	11 (30.5)	10 (25)	0.582
8-12 years	5 (13.9)	4 (10)	
>12 years	20 (55.6)	26 (65)	
Occupation, n, (%)			
Housewife	17 (53.1)	15 (46.9)	0.915
Official worker	12 (41.3)	17 (58.7)	
Others	7 (46.6)	8 (53.4)	

AG: Acupuncture group; CG: Control group; SD: Standard deviation

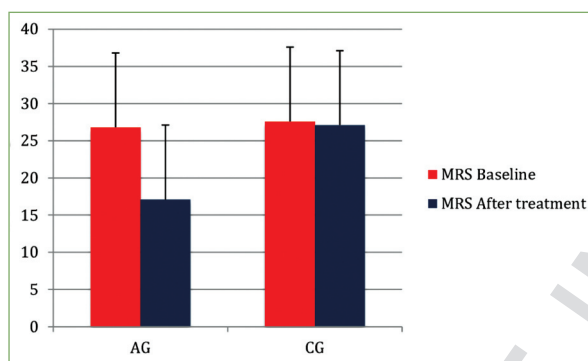


FIGURE 2: MRS total scores

AG: Acupuncture group; CG: Control group; MRS: Menopause Rating Scale

assessments for both groups. AG reported a statistically significant decrease in mean MRS total scores from pre-treatment to post-treatment ($p=0.000$). MRS total score decreased from 136.6 ± 39.5 to 102.5 ± 30.8 in AG; while it decreased from 144.6 ± 34.6 to 144.6 ± 34.5 in CG.

When data was analyzed in terms of sleep quality, it was seen that PSQI scores significantly improved after 10 sessions of acupuncture treatments (Figure 3). PSQI score was 10.1 ± 3.2 at baseline while it decreased to 5.6 ± 2.4 after acupuncture in AG; the baseline PSQI score was 10.4 ± 3.2 in CG, it was 10.6 ± 3.4 at the end of the study ($p=0.000$).

There were statistically significant differences between the groups as regards MENQOL scores at the end of the study (Figure 4). After 5 weeks mean MENQOL score decreased from 144.6 ± 34.5 to

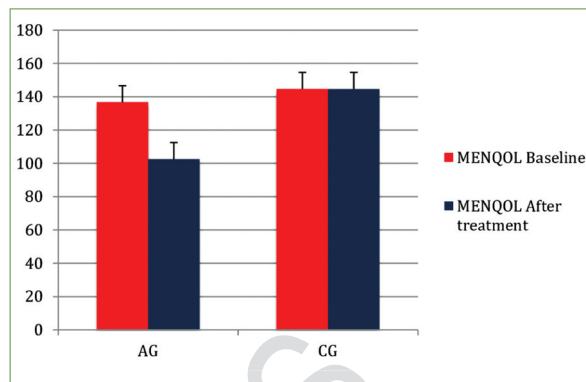


FIGURE 3: MENQOL scores

AG: Acupuncture group; CG: Control group; MENQOL: Menopause-specific Quality of Life Questionnaire

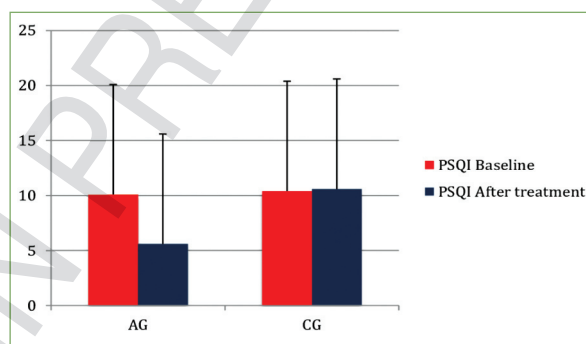


FIGURE 4: PSQI scores

AG: Acupuncture group; CG: Control group; PSQI: Pittsburg Sleep Quality Index

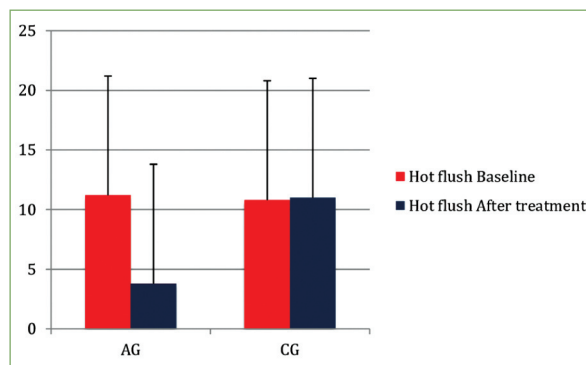


FIGURE 5: Hot flushes frequency

AG: Acupuncture group; CG: Control group

102.5 ± 30.8 in AG, while it decreased from 144.6 ± 34.6 to 136.6 ± 39.5 in CG ($p=0.000$).

The frequency of hot flushes was lower in AG than CG at the end of the study (Figure 5). In the baseline evaluation, the frequency daily hot flushes was 11.2 ± 7.1 in AG and 10.8 ± 6.5 in CG ($p=0.798$).

It decreased to 3.8 ± 3.2 in AG, while it was 11.0 ± 6.1 in CG ($p=0.000$) at the 5th week.

DISCUSSION

Our study was completed with 36 patients as a study group and 40 patients as a CG. Four patients who were excluded from the study did not come to acupuncture sessions, stating that their complaints had ended after a certain number of acupuncture sessions (after the 4th, 5th, 6th, 6th sessions, respectively). These 4 patients were excluded from the study because they did not complete the 10 session acupuncture treatment in the study plan. Through this randomized controlled design, it was shown that a 10 session acupuncture regimen have positive effect on menopausal symptoms and sleep problems of postmenopausal women. Additionally, acupuncture decreased hot flushes frequency, and increased the menopause related quality of life.

Following 10 sessions of acupuncture, the AG demonstrated significantly lower MRS scores compared to the CG, indicating a reduction in the severity of postmenopausal symptoms. The MRS assesses multiple domains of postmenopausal complaints, including psychological, somatic, and urogenital symptoms. In the subgroup evaluation, it was determined that there were improvements of varying degrees in all three subgroups. Hence postmenopausal symptoms do not contain only hormonal problems, it should be considered the other general problems related to menopausal period. A previously done meta-analysis of randomized-controlled trials on acupuncture reached the conclusion that all postmenopausal symptoms improved with acupuncture.²¹ Our results supported this conclusion via statistically differences on MRS between groups.

Acupuncture has gained widespread recognition not only in China but also in many Western countries, where it is frequently employed in the management of various symptoms that affect quality of life. Clinical studies have demonstrated that acupuncture is a safe and effective non-pharmacological treatment modality, with efficacy comparable to that of pharmacological interventions for several health conditions.²² The principles of Western Medical

Acupuncture and our clinical experiences guided the selection of the acupuncture points to be used in this trial. Some of these points influence the modulation of the neuroendocrine and endocrine systems, while others help regulate sleep and enhance blood flow to the uterus and ovaries.²³ As a result, we detected improving of VMS and sleep disturbances. A randomized-controlled trial demonstrated the effectiveness of 12 sessions of acupuncture on primary insomnia. According to the results of the study, acupuncture was more effective than sham acupuncture on quality of sleep without any side effect.²⁴ A meta-analysis conducted in 2021 examined 24 randomized controlled trials (approximately 1,500 participants) conducted on patients with sleep problems. The PSQI was used in these patients and significant decreases in PSQI scores were reported starting from the 3rd week of acupuncture application.²⁵ In a meta-analysis of 10 randomized controlled trials on patients with insomnia, medical acupuncture and sham acupuncture were compared and it was determined that medical acupuncture showed a significant improvement in PSQI scores when compared to sham acupuncture.²⁶ With reference, in accordance with the literature acupuncture can be suggested as a safely treatment for sleep problems. In our study, acupuncture improved the sleep quality while it was not changed in CG among postmenopausal women.

The menopausal transition can have a substantial impact on women's quality of life. During this period, clinicians should assess not only physical health but also psychological and social well-being. A comprehensive evaluation of quality of life in menopause should include instruments specifically designed to measure menopause-related health outcomes.²⁷ In our study, we assessed the menopause related health quality in the 4 sub-dimensions (vasomotor, psychosocial, physical and sexual) via a validated questionnaire. Acupuncture was found effective in reducing the scores of MENQOL which indicated the improving of menopause related health quality.

A Cochrane meta-analysis including 414 women and 8 studies showed that there the evidence to determine whether acupuncture treatment is effective or non-effective to manage VMS is limited. However, the analyses demonstrated the more benefit of

acupuncture compared acupuncture with no treatment, while acupuncture was seen to be less effective than hormonal therapy. Four studies in the same meta-analyses comparing acupuncture treatment against waiting list or no intervention indicated that the frequency of hot flushes significantly decreased from baseline and acupuncture was also significantly more effective in the reduction of hot flush severity.¹³ In the present study, although both groups exhibited similar frequencies of hot flushes at baseline, a significantly greater reduction was observed in the AG compared to the CG following the intervention. Moreover, no serious adverse effects were reported in association with the acupuncture treatment. Hormone therapy is recommended to treat hot flushes which are one of the most important symptoms related to menopause. On the other hand, it is well known that hormone therapy has some potential side effects. Therefore, many postmenopausal women do not consider to use.^{28,29} There are limited articles on the treatment of postmenopausal hot flashes with acupuncture. A 2016 study of 206 patients found that hot flashes were reduced by 35% and these benefits were maintained for 6 months after the end of treatment.³⁰ Another study found a difference of 9.64 in the 24-hour hot flash score, indicating that it is associated with significant clinical improvement.³¹ Given the side effects and expenses associated with current hormone therapies, the cost-effectiveness of acupuncture -both direct and indirect- the significance of acupuncture as a safe and non-pharmacological therapeutic option is also highlighted in this context.

Acupuncture is currently a widely utilized approach for managing postmenopausal symptoms. However, the underlying mechanisms by which acupuncture alleviates the severity of menopausal symptoms, enhances quality of life, and regulates sleep disturbances require further investigation. The findings of our study suggest that acupuncture effectively ameliorates key health issues associated with the menopausal transition. Our article supports the literature.

The potential limitations of this clinical trial include the following. 1- Each group had relatively small sample size, 2- The study did not have a sham AG. However, sham acupuncture can trigger near

acupuncture points. For this reason, some authors do not recommend the inclusion of a sham CG.³² Conversely, our study demonstrated that the acupuncture intervention employed effectively reduced menopausal symptoms and enhanced both sleep quality and overall quality of life in postmenopausal women. Further research is warranted to more comprehensively investigate the effects of acupuncture during the menopausal transition

CONCLUSION

This study underscores the potential role of acupuncture as a complementary approach in managing VMSs, sleep disturbances, hot flushes, and overall quality of life in postmenopausal women. To reinforce these findings, future research involving larger, multicenter randomized controlled trials with prolonged follow-up periods is recommended to further assess the efficacy of acupuncture and validate the current results.

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Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Meryem Betos Koçak, Yasemin Çayır, Emsal Pınar Topdağı Yılmaz; **Design:** Meryem Betos Koçak, Yasemin Çayır; **Control/Supervision:** Meryem Betos Koçak, Emsal Pınar Topdağı Yılmaz; **Data Collection and/or Processing:** Meryem Betos Koçak, Yasemin Çayır, Emsal Pınar Topdağı Yılmaz; **Analysis and/or Interpretation:** Meryem Betos Koçak, Emsal Pınar Topdağı Yılmaz; **Literature Review:** Meryem Betos Koçak, Yasemin Çayır; **Writing the Article:** Meryem Betos Koçak,

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