http://www.ijwhr.net
doi 10.15296/ijwhr.2023.45
Open Access Original Article
IJWHR
International Journal of Women's Health and Reproduction Sciences
Vol. x, No. x, xx 2023, x–x
ISSN 2330-4456

Effects of Acupuncture on Menopausal Hot Flashes and Sleep Quality in Women With Natural Menopause: A Single Arm Clinical Trial

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Abstract

Objectives: Hot flush (HF) is a common menopausal symptom and can cause dysfunction in different aspects of living. Due to the concerns about hormonal treatment, non-medical methods, including acupuncture, are suggested for managing HFs. This study aimed to assess the effect of acupuncture on HF episodes and sleep quality in menopausal women.

Materials and Methods: This single-arm clinical trial was performed on 26 menopausal women who were referred to the gynecologic clinic of a tertiary hospital in Mashhad, Iran between December 2018 and December 2019. The menopausal state was documented based on hormonal tests. Participants underwent acupuncture 3 times a week (7 acupuncture points based on traditional Korean medicine) for 4 weeks. The duration of each session was 20 min. Pittsburgh Sleep Quality Index (PSQI) was filled for each participant at baseline, at the end of the intervention, and after 6 and 12 weeks of follow-up.

Results: The mean age of participants was 51.96 ± 3.53. Moderate and low knowledge about menopause were reported in 50% and 34.6% of the participants, respectively. Reduced spousal interest was reported by 15.4% of the participants. Acupuncture significantly improved HFs, sleep disorders and sleep quality, and sleep latency subscales of PSQI ($P<0.05$).

Conclusions: Acupuncture could reduce HFs and improve sleep quality in menopausal women. The effects of acupuncture with medical interventions should be evaluated in future studies.

Keywords: Acupuncture, Menopause, Hot flushes

Introduction

Hot flush (HF) is the most common complaint in perimenopausal women (1). The severity of HF, differs largely between individuals and may range from minimal symptoms to annoying HF episodes, which can cause dysfunction in performing daily tasks, reduced social function, dysfunction in social activities, sleep disorders, and finally, disorders in the perception of general health (2-4). HF episodes during sleep increase with the severity and frequency of HFs and may disturb sleep quality (5). Sleep disorders are seen in 40%-60% of perimenopausal women with forms of HF. The complications of sleep disorder can predispose women to various conditions, including anxiety, depression, hypertension, and diabetes (6). Nocturnal HF can be experienced frequently at night and result in sleep disorder by elongating the fourth stage of sleep, shortening the early rapid eye movement, and elongating the late phase of rapid eye movement. These changes reduce sleep quality. The main reason for these changes is the alterations in the temperature regulating center in the hypothalamus (7). Regarding the recent increase in life expectancy and the increased focus on all aspects of the quality of life, improving the quality of life of menopausal women has become a necessity.

On the other hand, the desire to use non-medical approaches, including acupuncture, has increased recently in the general population. Minimal side effects and high efficacy has made acupuncture a common complementary treatment method. Studies have shown that acupuncture had high efficacy in managing HF in normal menopause, menopause due to surgery or treatment-induced menopause (8,9). The use of complementary therapies has gained public acceptance due to the concerns regarding the effects of current hormonal treatments in managing HFs and the increased risk of breast and ovarian cancers (10,11).

Acupuncture is among the complementary treatments previously used in the treatment of low back pain, migraine, and weight loss (12-16). Various mechanisms have been proposed for the effects of acupuncture, but the main mechanism is central and peripheral nervous system stimulation that interferes with pain, appetite, or satiety perceptions (16,17). As acupuncture was shown to be effective in managing bodily pains and adverse feelings, it is hypothesized that it might be effective managing of menopausal symptoms and sleep quality in menopause.

Received 12 July 2021, **Accepted** 16 February 2022, **Available online** 13 January 2023

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Key Messages

- Acupuncture is among the non-pharmacological treatments for menopausal symptoms.
- This study evaluated the effectiveness of acupuncture on menopausal symptoms.
- Acupuncture improved hut flushes, sleep disorder, sleep quality, and sleep latency in menopause women.

Regarding the acceptability of alternative medicine in the population, acupuncture can be practiced by menopausal women if its effects on menopausal symptoms and sleep quality are documented.

Acupuncture is a new method in Iran; therefore, this study aimed to evaluate the effects of acupuncture with medication in reducing menstrual symptoms, especially HF episodes, and sleep quality improvement in menopause women.

Materials and Methods

Study Design and Participants

This single arm before-after clinical trial was conducted on 26 menopausal women who referred to the gynecology clinic of Imam Reza hospital, Mashhad, Iran, between December 2018 and December 2019 with the complaint of HFs. The study included a 4-week acupuncture intervention period and 6 and 12 weeks follow-up evaluations (Figure 1).

The menopausal state was confirmed using laboratory testing based on the following cut-off values; Estradiol <18 pg/mL and follicular stimulating factor ≥30-110 IU/L. The inclusion criteria were lack of menstruation in the past 12 months, natural menopause, experiencing at least 4 HFs during the day, and not using any over-the-counter herbal medicine for HFs. The exclusion criteria were positive history of ovarian surgery, thyroid disorders, diabetes, migraine, chronic infections, heart disease, arrhythmia, epilepsy, and medication for any medical disorder. Sampling was based on convenience sampling.

Interventions

Participants received acupuncture 3 times a week for 4 weeks. Each acupuncture session lasted 20 minutes. A total of 7 acupuncture points, including ST36, SP6, L14, PC6, HT7, HT8, and a point at the bottom of the CV4 abdomen, were determined based on traditional Korean medicine to reduce HFs. The procedures were performed using 40 mm metal disposable needles in the mentioned points for 20 minutes. Needles were inserted 3-15 mm deep in the designated points. Participants were followed for 12 weeks.

Outcomes and Data Collection

Data was collected using a demographic data questionnaire, Pittsburgh Sleep Quality Index (PSQI) questionnaire, and a questionnaire to evaluate the frequency and severity of nocturnal HFs. The PSQI questionnaire is a self-report tool for measuring the quality of sleep in seven components, including subjective sleep quality, sleep latency, and sleep duration, and habitual sleep efficiency, sleep disturbances, consuming sleeping medication, and daytime dysfunction. The components are evaluated in the past one month. The scores of the seven components are summed up to form the total PSQI score (18). The PSQI

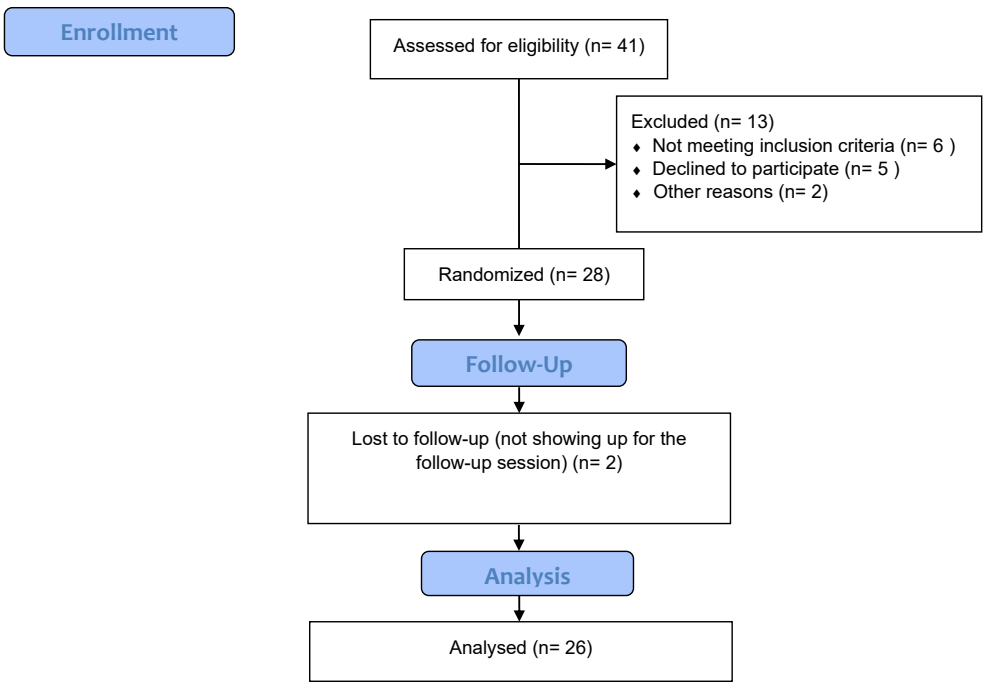

Figure 1. Consort Flow Diagram of the Study.

was reported reliable and valid in the Iranian population (Cronbach's alpha coefficient of 0.77 for all components) (19). The severity of menopausal symptoms, including HF, palpitation, sleep disorders, muscular pain, feeling of sorrow, nervousness, anxiety, amnesia, reduced libido, urinary incontinence, and vaginal pain, were assessed and scored on a 5-point Likert scale ranging from zero (no) to 4 (very severe). Assessments were performed at baseline and the end of intervention period (4th week) and at 6th and 12th weeks follow up in all participants.

Sample Size

The sample size was calculated based on the findings of a similar study that reported reduced incidence of HFs by -3.2 ± 2.5 in the acupuncture group and by considering type 1 and 2 errors of 5% and 20%, respectively (20). The calculated sample size was 20 participants. Considering 25% dropout, the minimum sample size was 25 participants.

Data Analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) software (IBM Inc, Chicago, IL, USA) version 16. The normality of continuous data was assessed using the Kolmogorov-Smirnov test. Mean and standard deviation (SD) were used for normally distributed data, and median and interquartile range were used for non-normally distributed data. Categorical data were presented using frequency and percentage. Continuous data was compared using the repeated measures analysis of variance (ANOVA) or Friedman test. Pairwise comparison of the continuous variables was performed using the Wilcoxon test as post hoc test. Comparison of categorical data was performed using the chi-square, Monte Carlo, or Fisher exact test. Levels of statistical significance were considered as 0.05.

Results

A total of 26 menopausal women participated in this study. The baseline characteristics of the participants are presented in Table 1.

Changes in menopausal symptoms in the study participants are presented in Table 2. Based on the Friedman test results, there was a significant difference in HFs, sleep disorder, feeling of sorrow, nervousness, anxiety, reduced libido and vaginal pain between time points.

Changes in the PSQI domain scores in the study participants are presented in Table 3. There was a significant change in subjective sleep quality, sleep latency, and total PSQI score between time points (Table 3).

Table 1. Baseline Characteristics of Study Participants

Variables	Mean ± SD
Age (y)	51.96 ± 3.53
Menarche age (y)	13.88 ± 1.51
Menopausal age (y)	41.48 ± 40.24
Marital age (y)	20.76 ± 7.50
	Median (IQR)
Gravida	3.00 (2.25)
Parity	2.00 (1.00)
Family size	2.00 (1.00)
	Frequency (%)
Education	
Illiterate	2 (7.7%)
Below diploma	5 (19.2%)
Above diploma	19 (73.1%)
Occupation	
Housewife	19 (73.1%)
Employee	6 (23.1%)
Number of marriages	
One	24 (92.3%)
More than one	1 (3.8%)
Spousal relationship	
Moderate	4 (15.4%)
Good	7 (26.9%)
Very good	11 (42.3%)
Hormonal treatment	2 (7.7%)
Knowledge on menopause	
Very low	9 (34.6%)
Low	2 (7.7%)
Moderate	13 (50.0%)
Good	2 (7.7%)
Change in spousal interest	
Reduced	4 (15.4%)
No change	17 (65.4%)
Presence of medical conditions	11 (42.3%)

SD: standard deviation, IQR: Interquartile range.

Discussion

This study assessed whether acupuncture can improve menopausal symptoms, including HF and sleep quality. The findings of this study revealed that acupuncture reduced some menopausal symptoms, including HF, sleep quality, feeling of sorrow, nervousness, anxiety, libido, and vaginal pain.

A meta-analysis showed that acupuncture could significantly reduce menopausal vasomotor dysfunctions, including HF and night sweats, compared to participants who did not undergo acupuncture (21). Similarly, a systematic review revealed that acupuncture effectively reduced HF based on 6 trials (22). The findings of another meta-analysis were also similar to our study (23).

Another finding of our study was the effect of acupuncture on muscular pain ($P=0.153$). To the best of our knowledge, no study assessed the effects of acupuncture on muscular pain. Our study findings showed that acupuncture did not reduce amnesia. An animal study showed that acupuncture could reduce scopolamine-induced amnesia (24). Due to the complexities in inducing amnesia in animals, there is a need for further studies in this regard. A meta-analysis reported that acupuncture could reduce mild cognitive dysfunction (25). Although cognitive function was not assessed in our study, it can

Table 2. Changes in Menopausal Symptoms in the Study Participants

Variables	Baseline	End of Treatment	1st Follow up	2nd follow up	*P* Value[#]
Hot flush	3.00 (1.00)[abc]	1.00 (1.00) [a]	1.00 (1.75)[b]	1.00 (1.00)[c]	<0.001*
Palpitation	0.00 (1.00)	0.00 (1.00)	0.00 (0.75)	0.00 (1.00)	0.260
Sleep disorder	2.00 (1.00)[def]	1.50 (2.00)[d]	1.00 (1.75)[e]	1.00 (1.00)[f]	<0.001*
Muscular pain	1.00 (2.00)	1.00 (2.00)	0.00 (2.00)	0.00 (2.00)	0.153
Feeling of sorrow	1.00 (1.00)[g]	0.00 (0.25)[g]	0.00 (0.75)	0.00 (1.00)	0.028*
Nervousness	1.00 (2.00)[hij]	0.00 (1.00) [h]	0.00 (1.00)[i]	0.00 (1.00)[i]	0.001*
Anxiety	1.00 (2.00)[klm]	1.00 (2.00)[k]	0.00 (1.00)[l]	0.00 (1.00)[m]	0.001*
Amnesia	1.00 (2.00)	1.00 (2.00)	0.50 (1.00)	0.00 (1.00)	0.060
Reduced libido	2.00 (3.00)[no]	2.00 (3.00)[n]	1.00 (1.75)	1.00 (2.00)[o]	0.013*
Urinary incontinence	0.00 (1.00)	0.00 (1.00)	0.00 (1.00)	0.00 (1.00)	0.522
Vaginal pain	0.00 (3.00)[p]	0.00 (3.00)[p]	0.00 (2.00)	1.00 (1.50)	0.029*

[#] Data presented as median (interquartile range) and the Friedman test was used for the comparison.
The Wilcoxon test was used for pairwise comparison between assessments. Values with similar superscript were significantly different and the p value for the difference in presented using the same superscript in the footnote. [a] $P=0.001$, [b] $P=0.006$, [c] $P=0.001$, [d] $P=0.012$, [e] $P=0.003$, [f] $P=0.001$, [g] $P=0.005$, [h] $P=0.023$, [i] $P=0.016$, [l] $P=0.014$, [k] $P=0.003$, [l] $P=0.018$, [m] $P=0.009$, [n] $P=0.015$, [o] $P=0.038$, [p] $P=0.007$
* Significant difference.

Table 3. Changes in PSQI Domain Scores in the Study Participants

Variable	Baseline	End of Treatment	1st Follow up	2nd Follow up	*P* Value[#]
Subjective sleep quality	2.00 (1.00)[abc]	2.00 (0.50)[a]	2.00 (1.00)[b]	2.00 (1.00)[c]	0.025*
Sleep latency	2.00 (2.00)[def]	0.50 (2.00)[d]	1.00 (2.00)[e]	1.00 (2.00)[f]	0.004*
Sleep duration	2.00 (2.00)	1.00 (3.00)	1.00 (3.00)	1.00 (2.00)	0.345
Habitual sleep efficiency	0.00 (0.00)	1.00 (1.00)	0.00 (0.00)	1.00 (1.00)	0.112
Sleep disturbances	1.00 (0.00)	1.00 (1.00)	1.00 (0.00)	1.00 (1.00)	0.074
Sleeping medication	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.194
Daytime dysfunction	1.00 (1.00)	0.00 (1.00)	0.00 (0.75)	0.00 (1.00)	0.392
Total score	1.00 (0.00)[ghj]	0.00 (1.00)[g]	1.00 (1.00)[h]	1.00 (1.00)[i]	0.011*

[#] Data presented as median (interquartile range) and the Friedman test was used for the comparison.
The Wilcoxon test was used for pairwise comparison between assessments. Values with similar superscript were significantly different and the p value for the difference in presented using the same superscript in the footnote. [a] $P=0.030$, [b] $P=0.021$, [c] $P=0.020$, [d] $P=0.005$, [e] $P=0.018$, [f] $P=0.010$, [g] $P=0.003$, [h] $P=0.020$, $P=0.046$
* Significant difference.

be estimated that the patients of the current study did not have moderate to severe cognitive dysfunction as the participants filled the questionnaires by themselves. Therefore, the findings of the mentioned study could be in congruence with the findings of our study. Based on another study findings, the mechanism of effect for acupuncture on psychological symptoms of menopause is due to the increase in serotonin (26). Therefore, most the clinical trials have reported positive effects of acupuncture on psychological symptoms of menopause.

The current study showed that psychological menopausal symptoms, including the feeling of sorrow, nervousness, and anxiety, were significantly reduced after acupuncture. A previous study showed that acupuncture significantly reduced agitation and depression scores ($P<0.05$) (27). Similarly, a meta-analysis showed that depressive symptom reduction by acupuncture was significantly different compared to medical treatment ($P=0.001$) (28).

Another finding of the current study was the significant changes in libido due to acupuncture ($P=0.013$). A systematic review of 23 studies reported that acupuncture could improve libido and sexual function in menopause women. The systematic review reported that acupuncture had its effects through regulating sex hormones (29). Our findings also indicated that acupuncture significantly reduced vaginal pain ($P=0.029$). A previous study showed that vaginal symptoms significantly reduced 3-week after acupuncture compared to the control group ($P=0.032$) (30). These findings may indicate that reduced vaginal pain might be the mechanism of action for acupuncture in improving libido.

The current study's findings showed no significant change in urinary problems due to menopause after performing acupuncture ($P=0.522$). It was previously shown that urinary complications of menopause are age-related (31). The incidence of menopausal-related urinary problems increases from 25% at the initiation of menopause to 75% in middle age (31). It was previously shown that menopausal-related urinary problems

decreased significantly after acupuncture (31). The average age of the participants in our study was 51.96 ± 3.53 years. Based on the mean age of menopause in Iran (49 years), participants in our study were mainly in the initial phases of menopause. In contrast, the mean participants in the mentioned study was 58.8 years, which was approximately 7 years higher compared to the median age of the participants in the current study (31).

The findings of our study showed that some PSQI domains significantly improved after acupuncture. A previous study showed that the total PSQI score significantly improved after 10 sessions of acupuncture ($P < 0.001$) (32). A systematic review of 79 studies showed that all acupuncture methods significantly improved sleep quality in menopause women (33).

Findings of the current study showed that acupuncture did not reduce palpitation. On the other hand, one of the complications stated by the participants in our study was palpitation ($P = 0.260$). To the best of our knowledge, previous studies have assessed the overall effects of acupuncture on vasomotor dysfunction in menopause and did not indicate the effects of acupuncture on palpitation (22,34,35). A previous study reported that acupuncture could increase heart rate immediately after the procedure, but this effect resolved quickly, and no significant difference was observed between the study participants (34).

One of the strengths of our study was its multidimensional assessment of the changes in bothersome menopausal symptoms, including vasomotor symptoms, and sleep quality after acupuncture. Furthermore, to the best of our knowledge, this study was the first conducted by Mashhad University of Medical Sciences by acupuncture, gynecology, and reproductive health specialists. One of the limitations of the current study was the small sample size. It should be noted that a small sample size is the limitation of the majority of trials on acupuncture. Furthermore, participants in the current study might have a negative attitude towards acupuncture, as a holistic approach to treatment is not followed in Iran. Acupuncture has been practiced in Iran for approximately 10 years and can be considered a new treatment option for menopausal symptoms.

Conclusions

The findings of this study showed that four weeks of acupuncture improved some menopausal symptoms and sleep quality in women in a menopausal period, which lasted for 12 weeks.

Authors' Contribution

LPA, TFN and HA designed the study, LPA and conducted the research. SD and TFN monitored, evaluated, and analyzed the result of the study. Further, TFN, HA and SD reviewed the article. All authors approved the final manuscript and take responsibility for the integrity of the data.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

The study was approved by the Ethical Committee of Mashhad University of Medical Sciences, Mashhad, Iran (Code: IR.MUMS.REC.1393.44). The study was approved by the Iranian Registry of Clinical Trials (Code: IRCT20171104037220N2). All participants gave a written informed consent before participating in this study. Participants were ensured that they could leave the study at any point. Participants were given a unique code, and data analysis was performed based on the codes without disclosing the names of the subjects. All forms that included the names and contact number of the participants were kept in a safe place during the study period and were archived based on the university's ethics guidelines with a specific focus on preserving the identity of the participants. The contact number of the primary investigator was provided to participants to report any complications or side effects.

Financial Support

The study was funded by the Mashhad University of Medical Sciences.

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