



The Comparative Effect of Biofeedback and Auriculotherapy on Alleviating Hot Flashes in Menopausal Women: A Pilot Study

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Objectives: Menopause is associated with a plethora of problems particularly hot flashes. This study aims to compare the effect of biofeedback and auriculotherapy on hot flashes in menopausal women in Kerman, Iran.

Methods: This study, a pilot clinical trial with a pretest–posttest control group design, was conducted on 39 postmenopausal women referring to the private offices of obstetricians and gynecologists in Kerman, Iran, in 2019. The participants were divided into 3 groups ($n = 13$ in each group) using simple random assignment. In the first and second intervention groups, the biofeedback program and auriculotherapy were conducted by the researcher 10 times in 45- and 30-min sessions twice a week, respectively. In the control group, routine care was provided. The participants completed the checklist of severity and frequency of hot flashes before, immediately, and 4 weeks postintervention.

Results: Immediate and 4-week postintervention biofeedback and auriculotherapy had a significant effect on reducing the severity and frequency of hot flashes ($P < 0.001$). However, the effect of auriculotherapy on mitigating the severity and frequency of hot flashes immediately and 4-week postintervention was more significant than that of biofeedback ($P < 0.001$).

Conclusions: Biofeedback and auriculotherapy may be effective in the treatment of hot flashes. Hence, they can be recommended as therapeutic methods for postmenopausal women.

Key Words: Auriculotherapy, Biofeedback, Hot flashes, Menopausal women

INTRODUCTION

Menopause marks a critical physiological period in women's life, the most palpable symptom of which is the cessation of menstruation for a year caused by the lack of ovarian follicle activity and estrogen depletion [1]. Symptoms exhibited by women during this period include night sweats, vaginal dryness, dyspareunia, moral fluctuations, joint pain and stiffness, palpitations, sleep disorders, restlessness, forgetfulness, urinary

symptoms, osteoporosis risk and hot flashes [2]. The World Health Organization (WHO) estimates that by 2030, 1.2 billion women will be over 50 years old [3]. In Iran, the population of menopausal women is estimated to exceed 5.8 million by 2021 [4].

With a prevalence of 70%, a hot flash is the most distressing symptoms associated with menopause [5].

Some women may experience it for about 1–2 years and it may last over 30 years [5]. Approximately, 80% of women experience hot flashes for three months after a

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normal or surgically-induced menopause [2].

Hot flash is the sudden onset of redness on the scalp, neck and chest with a strong sensation of heat in the body, which may result in excessive sweating. Its length varies from a few seconds to a couple of minutes and it rarely lasts more than an hour. As for frequency, it may occur rarely or frequently over several minutes [6].

The underlying physiological mechanisms governing hot flashes are not completely known [7]. However, the probable cause of hot flashes is the discontinuation of estrogen, which regulates body temperature. There are both pharmaceutical and non-pharmaceutical drugs for this complication [8].

Hormone therapy is one of the most effective treatment for vasomotor symptoms, but many women are either reluctant to seek this therapy or prohibited from using it [9]. Concerns about increased myocardial infarction, abnormal bleeding, breast tenderness, vascular thrombosis, arthralgia, headache, weight gain, edema, depression and biliary diseases as well as fear of breast cancer are the underlying reasons for discontinued hormonal screening [10,11].

Today, several solutions have been presented for menopausal complications, which can remarkably mitigate the severity of symptoms experienced by women [12]. In the study of Nikbakht et al. [13], 6.84% of participants had used at least one form of complementary medicine methods during their life time and 5.76% over the last year.

WHO suggests that complementary and alternative medicine may be effective in preventing menopausal symptoms and promoting women's long-term wellbeing in this period [14]. Complementary medicine is an alternative to pharmacotherapy that includes therapies such as herbal medicine, aroma therapy, massage therapy, vitamins, supplements, music therapy, relaxation, biofeedback, yoga and acupuncture [1].

Auriculotherapy is a branch of acupuncture that treats diseases by applying pressure to the ear area by means of a needle, electric current, laser, heat and seed (granular tags made of Vaccaria or metal). The method of application and necessary precautions of auriculotherapy differ from acupuncture. As a non-invasive, acceptable method, it could be helpful for doctors, midwives, nurses and even patients [15]. Many studies have used auriculotherapy to treat a wide range of ailments including menstrual irregularities, nausea and vomiting, labor pains, and anxiety [16-19]. Jokar et al. [5] showed that acupressure can be effective in mitigating hot

flashes in menopausal women.

Biofeedback is another therapy that can relieve the symptoms of hot flashes [20]. Opening a new path between a person and her physical and mental activities, biofeedback offers more control over psychological and physiological functions and promotes health and wellbeing [21]. The postmenopausal women's quality of life is a major health issue in different societies and one of the main goals of healthcare systems. Since menopausal symptoms such as hot flashes and night sweats may lead to psychological disorders such as anxiety and depression, these disorders could be treated by alleviating the symptoms of hot flashes, which in turn enhances the quality of life [22]. Biofeedback has been utilized extensively as a cure for many medical conditions such as anxiety and stress, dysmenorrhea and fecal incontinence, and improvement of the quality of life and emotion control [23-27].

Therefore, considering the high prevalence of hot flashes in postmenopausal women, the importance of developing a proper treatment and the paucity of studies on the effectiveness of biofeedback and auriculotherapy in alleviating hot flashes in postmenopausal women, the present study was undertaken to evaluate the comparative effect of biofeedback and auriculotherapy on mitigating hot flashes in postmenopausal women as an alternative for hormonal drugs.

MATERIALS AND METHODS

This pilot randomized clinical trial study was performed on 39 postmenopausal women referring to the private offices of gynecologists in Kerman, Iran, in 2019 (code of ethics: IR.KMU.REC.1398.202, clinical trial registration: IRCT20190728044351N1).

Inclusion criteria were at least one year elapsing since final menstrual period, hot flashes experienced at least twice a day, 45–60 years of age, no wounds or lesions on the ear, willingness to participate in the research and completion of the written consent form. The exclusion criteria were a history of hysterectomy and oophorectomy, hypertension and cardiovascular disease, thromboembolic, endocrine and thyroid, tobacco smoking or alcohol abuse, malignancy, abnormal vaginal bleeding, hormonal therapy and medications that affect vasomotor symptoms, itching or inflammation and ear infection.

There are 72 gynecological offices in 10 physician's office buildings across Kerman, of which 3 buildings

were randomly selected. From each of these buildings, 5 offices and from each office, 8 menopausal women were picked using simple random sampling method. The women were assigned to the intervention and control groups based on their day of referral (even or odd days). Accordingly, women referring on even days were assigned to the auriculotherapy group and those referring on odd days were assigned to the biofeedback group for a week and this sequence was reversed the following weeks. After selecting the intervention group's participants, the rest of visiting women were assigned to the control group in the following weeks. All subjects met the inclusion criteria and were willing to participate in the study. After explaining the study goals, a written informed consent was obtained for participation in the study before submitting questionnaires to the postmenopausal women. The subjects in the intervention and control groups had no communication with each other. After completing the questionnaires and prior to the intervention, the dates of auriculotherapy and biofeedback sessions were communicated to postmenopausal women in the intervention groups by messaging or phone calls.

In this study, demographic information questionnaire and daily recording of hot flashes and sweating questionnaire were used to obtain research data.

Demographic information questionnaire gathered data on age, level of education, marital status, monthly income, menopause status, body mass index, sports and physical activities, daily routine, and a history of physical illness or use of hormonal drugs, menopausal information, the amount of menopausal information and data source.

Daily hot flash and sweating questionnaire was also used to measure variables related to hot flashes. The tables in this questionnaire allow participants to specify the intensity and frequency of hot flashes during the day and in a weekly report. For each fit of hot flash, a signal is marked on a special column [4].

Daily hot flushes questionnaire records at least 16 hot flushes (from morning to nighttime sleep) and their characteristics (sensation of heat with/without sweating or ability/disability to continue activity). In this questionnaire, the severity of a hot flash was assessed based on the scale proposed by the U.S. Food and Drug Administration (FDA), which includes mild (feeling warm without sweating), moderate (sensing heat with sweating but able to continue activity) and severe (sensing heat and sweating that interrupts the activity)

which are equivalent to scores of 1, 2 and 3, respectively [28]. The final log of the frequency and severity of hot flashes included a summary report on weekly forms, which was filled out by the researcher for each participant separately. Thus, the average number of daily hot flashes was calculated by dividing the number of hot flashes over a week by 7, and the average daily hot flash intensity was calculated by dividing the intensity of hot flashes over a week by the frequency of hot flashes. This is a standard questionnaire used in many other studies [4]. A Cronbach's alpha coefficient of 0.9 was obtained in the data analysis [29]. Prior to the study, women were asked to fill out the hot flash questionnaire one week pre-intervention, which included the severity and frequency of hot flashes.

The auriculotherapy was conducted by the researcher in ten 30-min sessions twice a week as follows.

After disinfecting the ear with 70% alcohol, the endocrine, ovary, Shen Men, lung1 points in the left ear, the researcher stimulated the stress control, thalamus in the right ear for 5 to 10 seconds using Excel II (Thought Technology, Montreal, QC, Canada) (Fig. 1). Then, several labels including Vaccaria plant seeds (Seed), which can remain on the spot for three days, were installed in the marked places inside the ears. The subjects were taught that every two hours, press seeds on that spot with their finger for 1 min (it was emphasized that the pressure should be slightly until the patient had an aching pain, numbness, distention and a warm sensation). In line with ethical considerations, the contact number

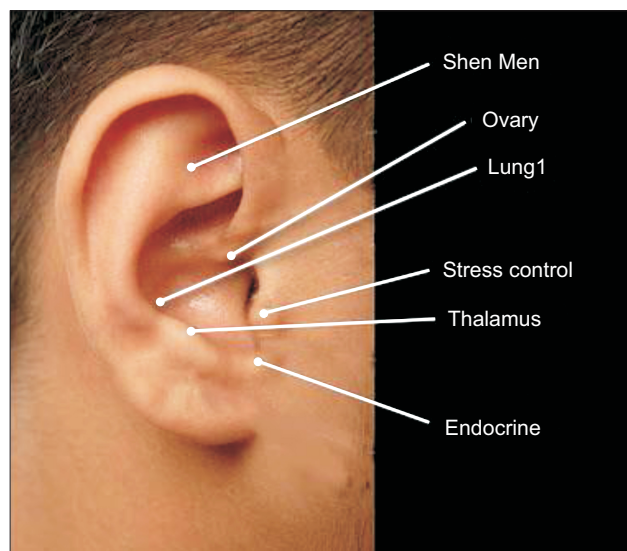


Fig. 1. Auricular points.

of the researcher was given to the research units to answer research questions. Moreover, they were asked to contact the researcher in case of any complications such as allergies, infections and itching.

In the biofeedback group, the Canadian biofeedback device, BioGraph Infiniti V4 Plus (Thought Technology) was used by the researcher for biofeedback. It was conducted by the researcher in 10 sessions of 45 minutes twice a week in the office under controlled conditions.

Respiratory biofeedback: In the respiratory biofeedback, relevant sensors are planted around the chest and changes in breathing pattern are observed in the monitor.

Biofeedback for heart rate: This type of biofeedback, used to monitor changes in the heart rate, allows a person to control his heart rate.

Skin temperature: The skin temperature tends to drop in stressful events. By monitoring skin temperature, people can learn when they are in stress and how to cope with it.

Routine care was provided in the control group.

At the end of intervention (5 weeks after the start of the intervention) and after 4 weeks of follow-up (9 weeks after the start of the intervention), the post-test questionnaires were distributed among the three groups. Auriculotherapy and biofeedback were pro-

vided to the control group.

The sample size ($n = 13$ in each group) was calculated as reported by Ramesh et al. [30] with a study power of 80% and an error level of 0.05.

$$\hat{n} = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (\sigma_1^2 + \sigma_2^2)}{d^2}$$

$$\alpha = 0.05 \quad 1 - \beta = 0.8 \quad \sigma_1 = 1.92 \quad \sigma_2 = 1.24 \quad d = 1.8$$

Thirty-nine subjects were divided into three groups with thirteen individuals in every group by using simple random assignment. The study design is shown in Figure 2.

Data analysis was performed by IBM SPSS Statistics 22 software (IBM, Armonk, NY, USA). Given the small sample size, non-parametric tests were used. Also, Fisher's exact was applied to test for nominal variables and Kruskal–Wallis with Bonferroni post hoc analysis to continuous variables. P value < 0.05 were considered significant.

RESULTS

Most of the subject were in the age group of 45–50 years in the control group and 51–55 years in the intervention groups. According to P value ($P = 0.36$),

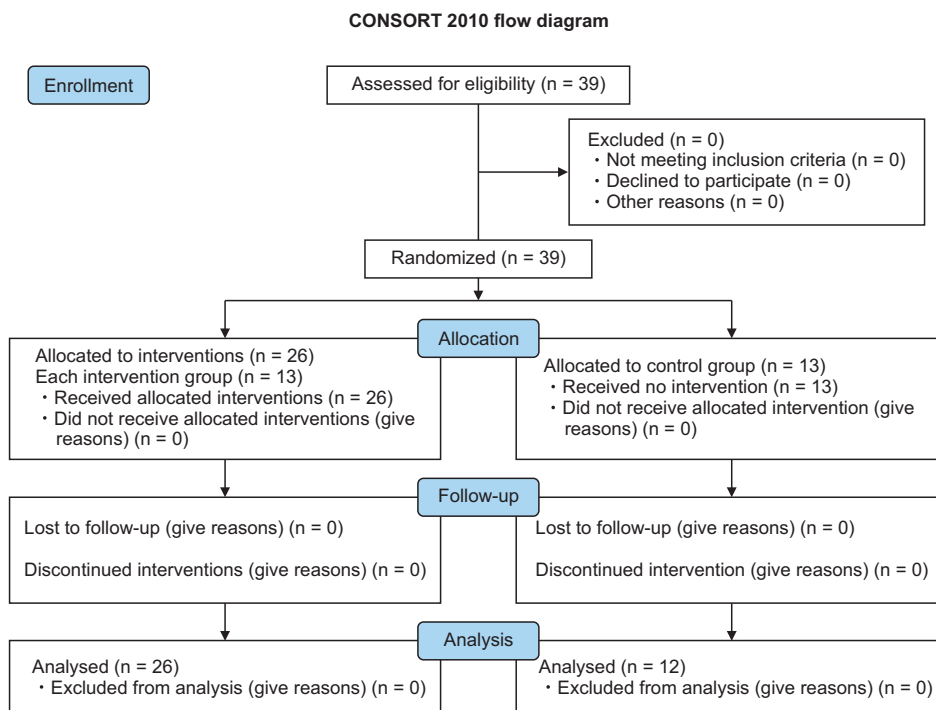


Fig. 2. CONSORT (Consolidated Standards of Reporting Trials) flow chart of study.

intervention and control groups were not significantly different in age and all three groups were homogeneous in this respect.

Regarding education, most people in the intervention and control groups had a high school diploma or a lower degree. There was also no statistically significant difference between intervention and control groups in terms of the level of education ($P > 0.99$). Most of participants in the intervention and control groups were married and no statistically significant difference was observed between the two groups in terms of marital status ($P = 0.85$).

According to the results, the demographic variables in all three groups were homogeneously distributed (Table 1).

The intensity and number of hot flashes at the times specified in the study were compared by Kruskal–Wallis test. According to this test, there was no difference in the severity hot flashes in groups before the intervention, but it was significant difference in number of hot flashes. Therefore, we used ANCOVA test between the three groups to compare immediately after the intervention and 4 weeks after the intervention. There was a significant difference ($P < 0.0001$) in the severity

Table 1. Frequency distribution of demographic variables in the control and intervention groups

Variable	Control group (n = 13)	Auriculotherapy group (n = 13)	Biofeedback group (n = 13)	P value	
Age group	45–50	6 (46.2)	4 (30.8)	0.36	
	51–55	3 (23.1)	5 (38.5)		
	56–60	4 (30.8)	4 (30.8)		
		51.23 ± 4.91	52.46 ± 4.90	53.92 ± 3.56	
Education	Diploma or a lower degree	8 (61.5)	8 (61.5)	9 (69.2)	> 0.99
	Above diploma	5 (38.5)	5 (38.5)	4 (30.8)	
Marital status	Married	11 (84.6)	10 (76.9)	12 (92.3)	0.85
	Single	2 (15.4)	3 (23.1)	1 (7.7)	
Income	Enough	12 (92.3)	9 (69.2)	10 (76.9)	0.47
	Insufficient	1 (7.7)	4 (30.8)	3 (23.1)	
Body mass index	Normal	4 (30.8)	5 (38.5)	5 (38.5)	0.12
	Overweight	8 (61.5)	2 (15.4)	5 (38.5)	
	Obese	1 (7.7)	6 (46.2)	3 (23.1)	
		25.61 ± 2.55	27.12 ± 5.90	26.22 ± 4.79	
Menopausal information	Yes	12 (92.3)	12 (92.3)	11 (84.6)	> 0.99
	No	1 (7.7)	1 (7.7)	2 (15.4)	
The amount of menopausal information	Low	6 (46.2)	7 (53.8)	2 (15.4)	0.12
	Medium	5 (38.5)	6 (46.2)	7 (53.8)	
	Much	2 (15.4)	0	4 (30.8)	
Data source	Medical staff	6 (46.2)	5 (38.5)	8 (61.5)	0.68
	Media	3 (23.1)	4 (30.8)	3 (23.1)	
	Friends and relatives	4 (30.8)	4 (30.8)	2 (15.4)	
Menopausal age (yr)	40–45	4 (30.8)	5 (38.5)	2 (15.4)	0.35
	45–49	6 (46.2)	2 (15.4)	5 (38.5)	
	50–54	3 (23.1)	6 (46.2)	6 (46.2)	
		46.76 ± 3.59	47.57 ± 4.53	48.61 ± 3.61	
Menopause duration (yr)	1–5	10 (76.9)	10 (76.9)	9 (69.2)	> 0.99
	6–10	3 (23.1)	3 (23.1)	4 (30.8)	
		1.23 ± 0.43	1.23 ± 0.43	1.30 ± 0.48	

Data are presented as number (%) or mean ± standard deviation.

and number of hot flashes in groups immediately after intervention and at 4-week follow.

The intensity and number of hot flashes at the times specified in the study were compared by Kruskal–Wallis test using Bonferroni correction. According to this test, there was no difference in the severity and number of hot flashes in the two intervention groups before the intervention, but a significant difference ($P < 0.0001$) in the number of hot flashes was observed immediately after intervention and at 4-week follow. Auriculotherapy was more efficacious than biofeedback immediately after intervention and at 4-week follow-up (Table 2).

Also, to evaluate the effectiveness of the interventions in each group, the severity and number of hot flashes before, immediately after and at 4-week follow-ups were compared. The results suggested that biofeedback reduced the severity and number of hot flashes (Table 2).

DISCUSSION

The present study was designed to compare the effect of auriculotherapy and biofeedback on hot flashes in postmenopausal women referring to the private office of gynecologists in Kerman. The results revealed that both auriculotherapy and biofeedback influenced the severity and frequency of hot flashes. The severity and frequency of hot flashes changed over time. Variations in the severity of hot flashes immediately after and at 4-week follow-ups were more noticeable in the biofeedback intervention.

Auriculotherapy, a type of acupuncture applied to specific areas of the ears, can improve the system function in these areas and expedite the healing process of patients. Specialists in this field have posited that different parts of the ear are linked to other body organs. The international organizations such as the WHO have approved and recognized this effective diagnostic and therapeutic approach. According to statistics

Table 2. Severity and number of hot flashes in postmenopausal women in groups

Variable	Group	Mean \pm SD	Comparison between three groups	Comparisons between two intervention groups
			<i>P</i> value	<i>P</i> value
Severity				
Before intervention	Auriculotherapy (n = 13)	1.74 \pm 0.24	0.55 ^a	0.29 ^b
	Biofeedback (n = 13)	1.65 \pm 0.24		
	Control (n = 13)	1.66 \pm 0.38		
Immediately after intervention	Auriculotherapy	0.27 \pm 0.76	< 0.0001 ^a	< 0.0001 ^b
	Biofeedback	1.14 \pm 0.16		
	Control	1.57 \pm 0.29		
4-week follow-up	Auriculotherapy	0.43 \pm 0.23	< 0.0001 ^a	< 0.0001 ^b
	Biofeedback	0.46 \pm 0.97		
	Control	1.46 \pm 1.18		
Number				
Before intervention	Auriculotherapy	9.92 \pm 4.17	0.002 ^a	0.21 ^b
	Biofeedback	10.92 \pm 2.78		
	Control	7.15 \pm 1.57		
Immediately after intervention	Auriculotherapy	0.23 \pm 0.83	< 0.0001 ^c	< 0.0001 ^b
	Biofeedback	3.07 \pm 1.65		
	Control	7.00 \pm 1.52		
4-week follow-up	Auriculotherapy	0.30 \pm 0.63	< 0.0001 ^c	< 0.0001 ^b
	Biofeedback	2.30 \pm 1.46		
	Control	7.07 \pm 1.70		

SD: standard deviation.

By ^aKruskal–Wallis; ^bKruskal–Wallis with Bonferroni; ^cANCOVA.

released by more than 100 countries, this method is widely used for the diagnosis and treatment of diseases. Biofeedback is a tool to control physical activity, boost relaxation, reduce pain, and ultimately promote health. Imaneh and Mahboubeh [31] conducted a single study on 18–35 years old patients, reporting that auriculotherapy is associated with a greater reduction in hirsutism compared to drug therapy. It is worth noting that acupuncture is effective in modulating endogenous systems such as the sympathetic nervous system and endocrine system. The exact mechanism of auriculotherapy is still unknown, but it is known to release neurotransmitters such as serotonin into the human body, which may affect mental health. In fact, this is a non-invasive, low cost and acceptable method for patients. It provides multiple benefits such as improved blood circulation throughout the body, deep relaxation, brain stimulation and enhanced immune system [32]. Kung et al. [33] administered menopausal medicine for 4 weeks to alleviate menopausal symptoms, especially hot flashes, sleep quality and heart rate fluctuations. Their results are aligned with the present study. In the same vein, Jokar et al. [5] found that acupressure is significantly effective in mitigating hot flashes. In this regard, it should be noted that auriculotherapy resembles reflexology (reflexology) of hands and feet. Ramesh et al. [30] also examined the effect of conflating cognitive-behavioral therapy and biofeedback on the treatment of patients with vaginismus. According to their results, this method not only influenced the treatment of vaginismus but also promoted their sexual status and other sexual functions, which is aligned with the present study. İlgün et al. [34] showed that biofeedback combined with pelvic floor muscle exercises significantly increased the quality of life in Turkish women, which is in agreement with the findings of this study. Mousavi et al. [18] performed auriculotherapy with a manual pointer to reduce post-cesarean anxiety. They concluded that auriculotherapy had no effect on mitigating anxiety after C-section up to 2 h postintervention, which is not aligned with the present study. The discrepancy of results could be attributed to different working methods and durations.

Black et al. [35] attempted to assess the effect of auriculotherapy on anxiety in patients withdrawing from psychotropic substances, concluding that auriculotherapy had no effect on the anxiety of these people, which is in conflict with the findings of this study.

In general, the results of this study suggest that auricu-

lotherapy and biofeedback are efficacious in mitigating hot flashes. They can be utilized as non-invasive methods without any side effects. One limitation of this research is that only a small number of factors associated with hot flashes were examined. Hence, it is essential to explore the role of other cultural, behavioral and emotional factors in symptoms. Further, further research with a larger sample size is required to accurately differentiate between the variables. Also, given the high prevalence of diseases such as hypertension, diabetes, depression, heart problems, etc. at this age, it is recommended to assess the effectiveness of these methods in women with chronic diseases along with other specialized medical groups.

In conclusion, auriculotherapy and biofeedback can alleviate menopause-related hot flashes in women, including the severity and frequency of hot flashes. This effect was more prominent in auriculotherapy than in biofeedback. These methods can be used as effective treatment for hot flashes in postmenopausal women.

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This article is based on academic theses.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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