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Effect of Auricular Acupressure on Quality of Life in Postmenopausal Women: A Randomized Clinical Trial

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ABSTRACT

Background & aim: Menopause is associated with early and late complications that affect menopausal women's quality of life. Based on evidence, acupressure could increase the quality of life. This study investigated the effect of auricular acupressure on quality of life in postmenopausal women.

Methods: This single-blind three-arm randomized clinical trial was conducted on 107 postmenopausal women referred to an Acupuncture Center in Mashhad, Iran in 2020. The patients were randomly allocated to three groups. In the intervention group, participants received ear seeds attached to an adhesive material on specific points on both ears. In one control group, participants received ear adhesive without seed and acupressure, on the same points as the intervention group. For the other control group, routine care was given. After four weeks, the quality of life questionnaire for menopause (MENQOL) was completed. Data were analyzed with SPSS software version 16 using Kruskal-Wallis, Mann-Whitney, and Wilcoxon tests.

Results: The average quality of life in the three groups did not show any significant difference at the beginning of the study (p=0.798). After four weeks, the quality of life in the acupressure group was significantly improved (p=0.002) compared to the two control groups. The average quality of life changed from 92.48 ± 21.88 to 73.77 ± 16.74 (p<0.001). However, there were no changes in the ear adhesive without seed group (p=0.67) and group with routine care (p=0.059).

Conclusion: The auricular-acupressure technique can be applied as a simple, effective, and non-invasive alternative method for enhancing quality of life during postmenopausal period.

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Introduction

Menopause is a normal event in women's life, but it is not understood in the same way for everyone (1). About 80% of women experience complications during menopause. Nearly 40% of cases are severe and disrupt normal life, and they use pharmaceutical methods to treat it (2).

Menopausal women experience many early and late complications. Early complications include vasomotor symptoms (hot flashes, night sweats), physical symptoms (insomnia, heart palpitations, headache, decreased concentration, decreased libido, joint and muscle pain), and psychological problems (depression, sadness, mood changes, irritability, anxiety, and lethargy). Late complications include cardiovascular complications and osteoporosis (3-4). Blumel et al. (2000) stated that menopausal women are 10.6 times more susceptible to vasomotor disorders, 3.5 times psychosocial disorders, 5.7 times physical disorders, and 2.3 times more prone to sexual disorders than other women (5). In general,

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these complications reduce the quality of women's life (6).

Quality of life is known as an indicator to measure health status in medical research. It is used to plan and evaluate healthcare programs. Quality of menopausal life emphasizes the symptoms and complications of menopause in four areas of vasomotor, physical, psychological, and sexual health (7). In a descriptive study on 700 postmenopausal women, Abdi and Solhi (2013) stated that the quality of their life was not optimal, and it is necessary to design appropriate interventions to improve it (8).

Hormone therapy is a well-known and standard method for the treatment of menopause complications, but due to the known potential risks and side effects, many women cannot or do not want to use hormone therapy (9, 10). In general, menopause does not require medical treatment, because it is a natural biological process (1). Among alternative and non-hormonal treatments, auriculotherapy has a special place and is recommended for the treatment of menopause symptoms (9). Treatment through external ear reflexology is called auriculotherapy. This method was originally developed in France by neurologist Paul Nogier (1957) about 65 years ago (11). The World Health Organization has stated that auriculotherapy is a type of treatment that can affect the whole body (12). The external ear (auricle) is like an upside-down fetus, which is a view of the internal organs of the body. As a result, stimulating any part of the ear can affect certain parts of the body. Auriculotherapy directs the signals resulting from ear stimulation from the brain to different parts of the body through cranial nerves (11, 13). In auriculotherapy, sensory points may be touched with needles (Acupuncture), seed vacaria or magnetic beads, probes or fingers (Acupressure), electric units connected to an ear needle (electrical nerve stimulation), or directly to the skin (neurocutaneous electrical stimulation) or laser. All these are forms of auriculotherapy (14).

Ear acupressure is one of the forms of auriculotherapy. Various studies have been conducted regarding ear acupressure in the treatment of menopause complications. Kurebayashi et al. (2012) showed in a study that the effect of Seed in acupressure is similar to the effect of needles used in acupuncture (13). Zhou et al.'s study (2011) stated that (Shen Man, AH6a, adrenal glands, subcortical, endocrine, kidney, heart, and liver) points had a positive effect in improving the symptoms of hot flashes, but this study was a combination of ear acupressure and acupuncture and does not show the real effects of acupressure alone (9). Kuo et al. (2012) in their study used (Shen Men and subcortical) points to reduce menopausal anxiety. Despite the reduction of anxiety within 4 weeks, there was no significant difference between the intervention and control groups (15). Yeh et al. (2014) used (Shen Man, subcortical) points on the ear with acupressure to reduce chronic back pain (16). Kang et al. (2011) acknowledged ear acupressure could increase the duration and quality of sleep in women after menopause (17).

The conflicting results of previous studies, led the researcher to conduct a study on auricular acupressure. Due to the public interest in acupressure, many studies have been conducted in the world and Iran, but no studies have been conducted on the quality of life by auricular acupressure (18). Considering the inadequacy of controlled clinical studies in this field, the increase in life expectancy and population of menopausal women, and the simplicity of the application of acupressure by patients with simple training, this study was conducted to determine the effect of ear acupressure on the quality of life of postmenopausal women.

Materials and Methods

This study is a three group's randomized clinical trial with single-blind design, which was conducted to investigate the effect of auricular acupressure on the quality of life of postmenopausal women in 2020. It should be noted that the article was written based on the criteria mentioned by Consort. This study was registered in the Iranian Registry of Clinical Trials under the code of (IRCT20160731029134N2) following obtaining permission from the ethics committee of Mashhad University of Medical Sciences (Ethical code: IR.MUMS.REC.1396.23).

In our initial search, no similar article was found. So, Cohen's table was used to determine the sample size. The number of 35 people in

each group with 95% confidence and 80% power can have an effect size of at least 70%, which is sufficient for the study. Considering a 15% chance of attrition, the sample size was 40 people in each group (19).

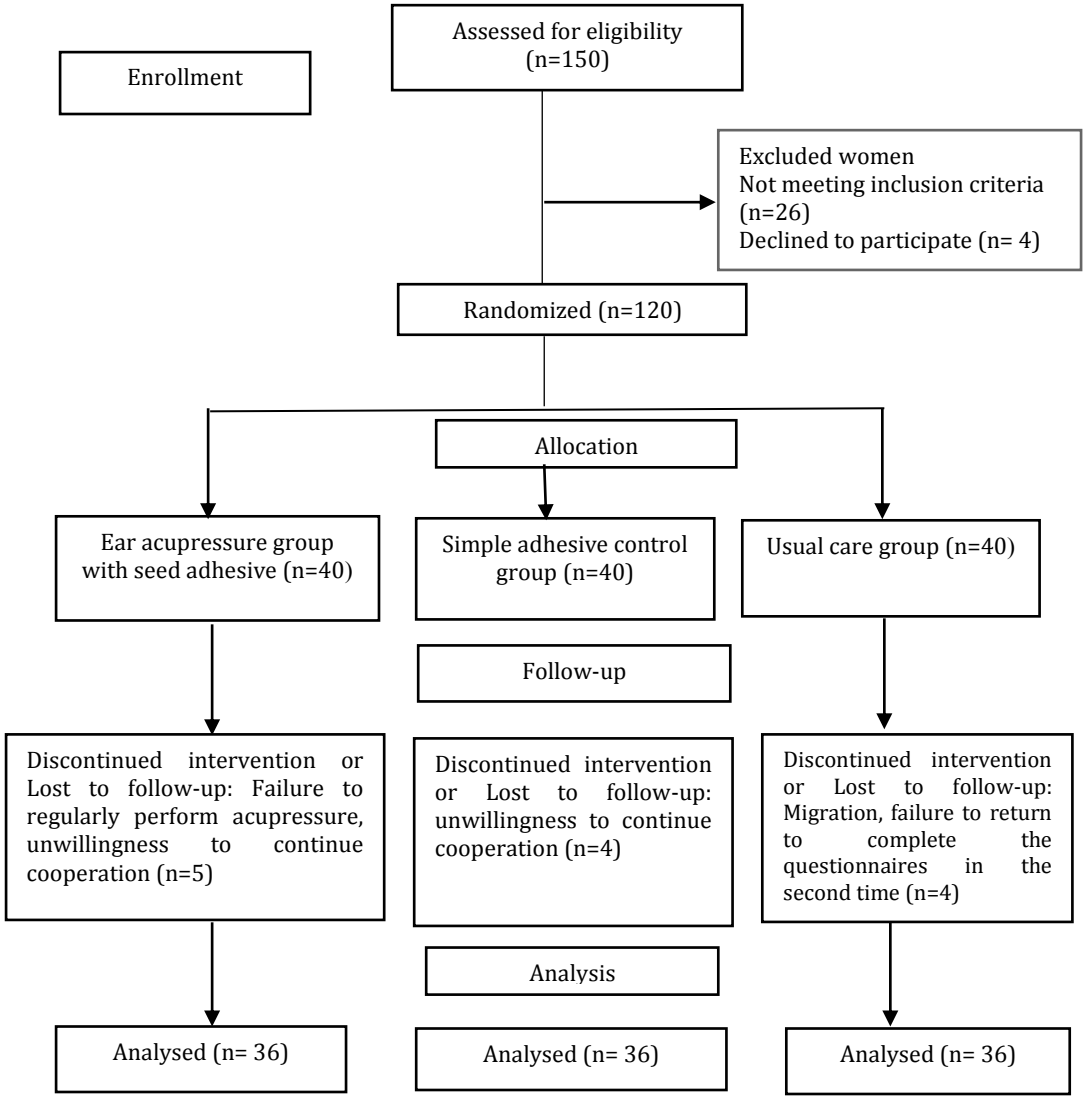

Figure 1. The CONSORT flow diagram of intervention in the three groups

After obtaining permission from Mashhad University of Medical Sciences and presenting it to the women's clinic and acupuncture center, data collection started. Also, confidentiality and the purpose of the study were explained to the women who were at the age of menopause (45-60), and had inclusion criteria. A written consent form was signed by all women who were entered into our study.

Inclusion criteria included living in Mashhad, age of 45-60 years, non-smoking, physiological cessation of menstruation for at least 12 months, experiencing menopause less than 10 years, no history of ovarian surgery, no hormonal, not taking non-hormonal and herbal

medicines in last six month to alleviate the complications of menopause, not having thyroid, cardiovascular and diabetes melitus, not having a history of abnormal vaginal bleeding, and not using of complementary and alternative medicine. Exclusion criteria included unwillingness to continue cooperation and doing acupressure less than two days a week.

The demographic and Menopause Quality of Life Questionnaire (MENQOL) were completed at the beginning of the study. The menopause quality of life questionnaire included 29 questions about menopause symptoms and complications in four areas: vasomotor (3 questions), psycho-social (7 questions), physical (16 questions), and sexual (3 questions). It was measured based on the Likert scale (point 1 for minimum intensity and point 6 for maximum intensity). The score was calculated for each separate dimension and in total. A higher score in each area indicates a worse and a lower score indicates a better quality of life (7). This questionnaire is a valid tool for measuring the quality of life that was designed and validated by Hilditch et al. (1996) at the University of Toronto, Canada. The validity of this tool has been confirmed in the study of Abedzadeh et al. (2012). Its reliability has been calculated with a correlation of 0.95 (19). Also, the reliability of this questionnaire was confirmed in the present study with Cronbach's alpha of 0.94. Then the study subjects were randomly (using a table of random numbers) assigned to intervention (ear acupressure with seed adhesive), control group one (adhesive without seed), and control group two (usual care). Seeds were very small. The size of these seeds allows them to be placed on the desired point and acupressure to be done more correctly (20). The study subjects of the intervention group were taught how, when, and how long to do acupressure. Then, after their ears were cleaned with alcohol, participants received ear adhesive tape with seed on the ear sympathetic (AH6a), shenmen (TF4), kidney (CO10), heart (CO15), endocrine CO18, liver CO12 and subcortex (AT4) points for both ears**.** The patients were asked to press points by themselves four times a day (after three meals and once before going to bed) for a 3 minutes duration each time (about 20 seconds at each point) for 4 weeks. It was noted that the strength of pressure should make the ear hot, numb and achy. We warned the control group not to touch the adhesives and to use the possible psychological effects of the adhesives, the people were told that these adhesives have the property of improving symptoms. The adhesives were changed once a week and we noticed that these adhesives are not removed by going to the bathroom and doing normal activities. However, if the adhesives were removed earlier than the end of a week, or if they were forced to remove the adhesives for some reason, they came back to get new adhesives.

All three groups received usual self-care including recommendations for exercising and walking, following a proper diet and taking calcium and vitamin D supplements, being exposed to sunlight, and not smoking. In addition, solutions to reduce the discomfort of hot flashes, solutions to improve sleep, use of lubricant ointment to reduce vaginal dryness during intercourse, advice to maintain regular sexual relations, and strategies to reduce anxiety were suggested.

After four weeks, subjects were asked to complete the menopause quality of life questionnaire for the second time.

T data were analyzed using SPSS 16 software. Normality was checked by the Kolmogorov-Smirnov test. Descriptive statistics (number, percentage, median, mean and standard deviation) were used to describe the demographic characteristics of the participants. To examine the homogeneity of the groups in relation to the categorical variables, chi-square test and for quantitative dependent variables, one-way analysis of variance was used. Kruskal-Wallis non-parametric test was used to compare the three groups in terms of quantitative variables without normal distribution. Due to the significant difference between the groups, Mann-Whitney test was used to compare the groups. To compare the differences before and after in each group, Wilcoxon test was used. The level of significance was considered as $\alpha=0.05$.

Results

Out of 120 postmenopausal women who were included in the study, some were excluded from the study due to the reasons of not performing

acupressure regularly, unwillingness to continue cooperation, immigration, and not returning complete questionnaires. Finally, 107 people were included in the study (Figure 1).

There was no significant statistical difference between the three groups in personal characteristics such as age, age of menarche, duration of menopause, education, and occupation. Quantitative variables are reported as median, mean and standard deviation, and qualitative variables are reported as frequency and percentage (Table 1).

Table1. Demographic characteristics of intervention and control groups

Variables	Intervention group Mean± SD	Simple adhesive (control group 1) Mean ±SD	Usual care (control group 2) Mean ±SD	P-Value
Age	52.8±4.6	51.7±4.6	53.1±4.7	0.400
Median	53	51	53	
Menopause duration (years)	4.0±2.6	3.7±2.5	3.7±3.2	0.316
Median	4.5	3	2	
Age at onset of menstruation (years)	12.5±1.5	11.9±1.2	13.0±1.9	0.849
Median	12	12	13	
Education				
High school	13 (37.2)	11 (30.6)	14 (38.9)	0.445
Diploma	11 (31.4)	15 (41.7)	11 (30.6)	
University	11 (31.4)	10 (27.7)	11 (30.6)	
Occupation				
Housewife	28 (80)	28 (77.8)	31 (86.1)	0.644
Employed	7 (20)	8 (22.2)	5 (13.9)	

The average quality of life was compared in three groups. The Kruskal-Wallis test did not show a significant difference between the quality of life in the three groups before the intervention (p=0.798), while this difference was significant after the intervention (p=0.002) (Table 2).

Table 2. Comparison of mean and standard deviation of quality of life in three groups before and after intervention

Quality of life	Intervention group Mean ±SD	Simple adhesive (control group 1) Mean ±SD	Usual care (control group 2) Mean ±SD	Result of Kruskal-Wallis test
Before intervention	92.4±21.8	92.94± 22.33	97.33± 35.7	X^2=0.452 df=2 p=0.798
After intervention	73.5± 16.7	90.75±20.68	95.0±34.9	X^2=12.4 df=2 p=0.002
Comparing before and after intervention (Intergroup)	p<0.001	p=0.054	p=0.067	

The results of two-by-two comparisons in the groups showed that there was a significant difference in the post intervention quality of life between the usual care and the intervention group (p=0.013), Also, there was a significant difference between the intervention and simple adhesive control group (p<0.001), but there was no significant difference between the two control groups (p=0.884). The result of comparing the differences between before and after in each group by the Wilcoxon test is shown in Table 2. The results of before and after changes in each dimension of quality of life in the ear acupressure group with seed adhesive are shown in Table 3.

Table 3. Mean and standard deviation of quality of life dimensions in the ear acupressure with seed adhesive group

Quality of life	Intervention group Mean ±SD	Result of the Kruskal-Wallis test
Vasomotor		
Before intervention	10.45± 3.6	Z= -4.961
After intervention	7.17± 3.14	p<0.001
psycho-social		
Before intervention	21.6± 6.7	Z= -0.702
After intervention	21.0± 6.7	p=0.483
Physical		
Before intervention	50.05±12.2	Z= -5.004
After intervention	38.34± 10.84	p<0.001
sexual		
Before intervention	10.37± 3.7	Z= -4.297
After intervention	7.0± 2.5	p<0.001

The reported side effects were redness and pain in the earlobe, which were seen in two subjects in the intervention group and one subject in the simple adhesive group, which could be due to allergy to the adhesive.

Discussion

In the present study, to determine the effect of ear acupressure on the quality of life of postmenopausal women, the groups were the same and homogeneous in terms of background variables. Regarding the main aim of the study, a significant difference was observed in the average scores of the components and the total score of the quality of life of postmenopausal women in the intervention group, compared to the two control groups. Therefore, based on the results of this research, ear acupressure can play an important role in the management of menopause complications.

In line with the results of the present study, Kuo et al. (2012) stated that performing ear acupressure on the shenmen and subcortex points with adhesives with magnetic beads on both ears improves the quality of life. Despite the consistency of the results, there are differences between their study and our study. In study by Kuo et al. (2012) the specific quality of life during menopause was not measured and only the general quality of life was measured by Short Form Health Survey (SF-36).

Also, in line with the aim of their study, which was to reduce anxiety, only two points were used (15).

The findings of the present study showed that although the quality of life improved in general, this was not significant in the psycho-social dimension. The reason for this can be explained by the fact that the changes in the psycho-social dimension probably require psychological counseling sessions and will not be improved by ear acupressure alone. In the secondary findings of study by Kuo et al. (2012), was also stated that physical performance had positive changes in the intervention group, but social performance, role limitations due to physical problems, role limitations due to emotional problems, mental health, and overall perception of health were not different between the control and intervention groups (15).

In the present study, ear acupressure could improve the quality of life of postmenopausal women. The findings showed an improvement in the physical dimension of quality of life, which is the main dimension in menopause problems. In line with the results of the current study, the study of Ryu & Choi (2020) showed that performing ear acupressure on the sympathetic nerve, occiput, central rim, and endocrine points of the ear, which are somewhat similar to the points of our study, has been able to increase the depth of sleep, serotonin level, and sleep duration, as well as reduce the cortisol level and the level of fatigue and improve the quality of sleep in general (21). In this regard, Kung et al. (2011) also acknowledged that auricular acupressure could increase the duration and quality of women's sleep after menopause (17). In addition, in line

with the physical dimension, the study by Yeh et al. (2014) showed that ear acupressure on (Shen Man, subcortical) points, reduced 46% of severe pain and more than 50% of moderate back pain. In addition, it has improved the overall intensity of pain and the interference of pain with daily activities. 62.5% of people also reported less use of painkillers (16). A systematic review study (2010) also showed that ear acupressure could reduce the intensity of pain in chronic and acute pain (14).

The findings showed that the average vasomotor scores before and after the intervention had significant changes. In the study of Zhou et al. (2011), which is consistent with the results of the present study, the findings indicated a significant effect of ear medicine on the severity and frequency of cramps during menopause. In this study, it was stated that the combination of auricular acupressure and acupuncture was able to reduce menopausal cramps as much as hormone therapy and even affected the laboratory values of LH, FSH, and E2 hormones (9). Rahmanian et al. (2022) in a systematic review also found that auriculotherapy could reduce anxiety, intensity, and frequency of hot flashes, sleep disorders, and quality of life in menopausal women (22).

The results of the present study showed that ear acupressure could be effective on the sexual dimension of the quality of life of postmenopausal women. In this regard, the results of study by Ahmadabadi et al. (2022) showed that performing ear acupressure during breastfeeding could change sexual performance and satisfaction. They admitted that one month after the intervention, the two groups of intervention and control had a significant difference in the average score of the quality of sexual life (23). In general, the studies conducted on the sexual aspect and auricular acupressure were limited, which can be a basis for future studies.

The present study shows this new finding that the use of the ear acupressure technique is an easy, cheap, and non-invasive method to reduce the complications of menopause. Based on having no side effects and ease of use by the medical staff and even the individual herself, it causes Improving the quality of a woman's life. Despite the importance of our results, several limitations must be noted. Performing acupressure by the objects themselves is one of our limitations. Because there was a possibility of forgetting and not doing it correctly, researchers tried to partly moderate this problem with follow-up and continuous training on each visit to change the adhesives. Another limitation of the study is that acupressure was measured after 4 weeks and cannot show the long-term effect.

Conclusion

Ear acupressure with seed can be used as an effective, simple and non-invasive complementary method to improve vasomotor, physical and sexual complications in the postmenopausal period.

Healthcare providers can suggest and train auricular acupressure in their clinical practice when caring for postmenopausal women.

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Conflicts of interest

Authors declared no conflicts of interest.

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