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PII: S1876-3820(25)00023-X
DOI: <https://doi.org/10.1016/j.eujim.2025.102451>
Reference: EUJIM 102451



To appear in: *European Journal of Integrative Medicine*

Received date: 13 April 2024
Revised date: 14 February 2025
Accepted date: 28 March 2025

Please cite this article as: Zainab Alimoradi , Zohreh Hosseini Marznaki , Mohammad Hossein Hakimi , Terry Oleson , Mark D. Griffiths , The effect of auricular acupressure on sexual functioning among postmenopausal women: A randomized sham controlled trial, *European Journal of Integrative Medicine* (2025), doi: <https://doi.org/10.1016/j.eujim.2025.102451>

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Highlights

- Sexual dysfunction is one of the common complaints of postmenopausal women.
- Auricular acupressure was used to improve postmenopausal women's sexual functioning.
- Ear acupoints were Chinese and European genital, libido, ovarian, zero, Shen Men, and brain.
- Auricular acupressure significantly increased the sexual functioning.
- Auricular acupressure significantly decreased the sexual distress.

The effect of auricular acupressure on sexual functioning among postmenopausal women: A randomized sham controlled trial

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Abstract

Introduction: Sexual dysfunction is one of the common complaints of postmenopausal women. The present study investigated the effect of ear acupressure on sexual functioning (the primary outcome) and sexual distress (the secondary outcome) among postmenopausal women.

Methods: A randomized, sham-controlled triple-blinded trial was conducted from June 2022 to January 2023 among postmenopausal women recruited from urban comprehensive health centers in Qazvin, Iran. Ninety postmenopausal women were randomly assigned (1:1) to auricular acupressure or sham control group using a balanced block randomization method. The intervention was 10 sessions of ear acupressure (at four-day intervals) using adhesives containing vaccaria seeds. The sham intervention was identical except for the use of special non-latex adhesives but without the Vaccaria seeds. Female Sexual Function Index (FSFI), Arizona Sexual Experience Scale (ASEX), Female Sexual Distress Scale (FSDS) were assessed three times: before intervention, one month after intervention, and two months after intervention.

Results. Auricular acupressure significantly increased the mean score on the FSFI in the intervention group compared to the sham group (adjusted mean difference of 5.12 [95% CI: 3.39; 6.85] in first follow-up, and 10.17 [95% CI: 7.71; 12.63]) in second follow-up. There was a significant decrease in the mean score on the ASEX (decreased scores indicate better sexual experience) and FSD in the intervention group compared to the sham group in first and second follow-up. These changes were also clinically significant. No adverse events were reported during the intervention or the follow-ups.

Conclusion. Among postmenopausal women, auricular acupressure appears to be an effective intervention in improving sexual functioning, as well as reducing sexual distress.

Keywords: auricular acupressure, sexual functioning, sexual distress, postmenopausal women.

Trial registration: The trial was also registered prospectively in 2022-04-13 (code IRCT20180218038789N6) in the Clinical Trial Registration Center of Iran.

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Abbreviation:

ASEX: Arizona Sexual Experience Scale

BMI: Body Mass Index

CAM: Complementary and alternative medicine

FSDS-R: Female Sexual Distress Scale-Revised

FSFI: Female Sexual Function Index

FSH: Follicle-Stimulating Hormone

LH: Luteinizing Hormone

MCID: Minimal Clinically Important Difference

MD: Mean Difference

RM ANOVA-ANCOVA : Repeated Measurements Analysis of Variance–Covariance

SMD: Standardized Mean Difference

TCM: Traditional Chinese Medicine

WHO: World Health Organization

1 Introduction

Menopause is a natural physiological process that affects the life of women during middle age [1, 2]. The physiological mechanism responsible for menopause is the gradual loss of ovarian follicles and the final termination of the menstrual cycle and fertility [3, 4]. The average age of menopause is approximately 45-52 years, with lower age among women in developing countries compared to developed countries [5]. During this period, due to the natural reduction of reproductive hormones, the ovaries produce less estrogen and progesterone [6]. Estrogen deficiency symptoms specific to the menopause include physical symptoms, urinary-genital symptoms, and mood disorders. These symptoms are experienced by a considerable proportion of women during their transition to menopause and affects various aspects of women's health [3, 7]. Estrogen deficiency also causes a decrease in brain neurotransmitters such as dopamine, endorphins, and serotonin from the hypothalamus and an increase in noradrenaline [8]. Dopamine regulates emotions, immune system and sexuality; serotonin controls mood and behaviors related to sleep and wakefulness; and endorphins play a role in controlling memory function and feeling pain and mood swings [8]. Common negative consequences of the menopause include vasomotor symptoms such as hot flashes and night sweats, sleep disorders, physical problems, headaches, mood disorders, and urinary-genital and sexual dysfunction (4).

Sexual dysfunction is defined as a disorder in the sexual response cycle (including disturbance in desire, arousal, orgasm, and pain during intercourse) that prevents an individual or couple from engaging in satisfying sexual activity [9]. The prevalence of sexual dysfunction during menopause, varies between 38% and 82.5% [10] with different prevalence rates based on various types of sexual dysfunction including low sexual desire (40%–55%), poor lubrication (25%–30%), and dyspareunia (12%–45%) [11]. Sexual problems can lead to dissatisfaction in couples' relationships

and can have a negative effect on their quality of life as well as their physical, mental, social, and emotional health [12].

Although postmenopausal women seem to have less desire for sex, sexuality is still an important issue for middle-aged women which is often left unaddressed or ignored [13]. The global trend of an aging population and the subsequent increase in the numbers of postmenopausal women (an estimated 1.2 billion women worldwide will be menopausal or postmenopausal by the year 2030, with 47 million starting the menopause each year [14]) means that menopausal women's health and hygiene has become an increasingly important health issue [15]. As postmenopausal life consists of an average of one-third of women's life, it is necessary to try to control and reduce the symptoms of menopause, including improving sexual functioning during menopause in order to improve the quality of life among menopausal women [11].

Psychotherapy and drug therapy are the two main methods for treating female sexual dysfunction [16]. Estrogen, methyltestosterone [17], bupropion [18], transdermal testosterone [19], bremelanotide [20], dehydroepiandrosterone [21] and flibanserin [22] are all drugs used to enhance libido among postmenopausal women. However, the US Food and Drug Administration (FDA) does not recommend the use of drugs for the treatment of female sexual disorders, due to lack of established endpoints for phase 3 studies of female sexual dysfunction [23, 24]. Also significant side effects of these drugs and probable drug interactions with their routine drugs can limit the clinical and long-term use drug therapy for sexual dysfunction among postmenopausal women [25]. Consequently, the use of non-pharmacological treatments, such as the use of complementary medicine, is considered a potential alternative to drug treatment [14]. Complementary and alternative medicine (CAM) is an important part of healthcare. Moreover, the World Health Organization (WHO) has welcomed traditional and complementary medicine as an important

contributor in providing healthcare [26]. CAM is used by nearly 51% of women for their menopausal symptoms and more than 60% perceive it as an effective method to relieve their menopausal symptoms [14].

Auriculotherapy, a kind of complementary medicine originating from traditional Chinese medicine, has been scientifically studied since 1957. It views the external part of the ear (auricle) as an upside-down fetus with reflective points of all the organs and internal organs of the body [27]. This microsystem of ear acupoints can be used for ear acupressure (and also known as auricular acupressure) [28]. According to the principles of reflexology, each part of the body is connected to a specific part of the ear, which reflects the physiological or pathological state of the body [29]. Stimulation of these acupoints can be used to alleviate pathological conditions in related parts of the body [27]. The auricular acupressure can be performed by manual finger pressure, laser, electrical stimulation, different types of needles, magnetic beads or seeds [30]. Stimulating ear acupoints have physiological outcomes which helps to treat health problems [31], which remain for days and even weeks [32, 33].

Due efficacy of auricular acupressure in managing health disorders, the WHO has noted that auricular acupressure is a promising therapeutic approach [28]. The therapeutic effect of ear acupuncture for improving sexual dysfunction in the domains of desire, libido, and lubrication, as well as overall sexual functioning, was reported in a recent systematic review [34]. Similar to acupuncture, acupressure is complementary traditional Chinese medicine (TCM) method. Unlike acupuncture, acupressure is a non-invasive method which can be used in different acupoints [35]. The effect of auricular acupressure on sexual functioning has only been investigated in a few studies [36, 37] and further evidence is needed regarding its efficacy. Therefore, the present study

investigated the effect of ear acupressure on sexual functioning (the primary outcome) and sexual distress (the secondary outcome) among postmenopausal women.

2 Methods

2.1 Study design and setting

The present randomized, sham-controlled trial was conducted from June 2022 to January 2023 in Qazvin, Iran. The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA guideline)[38] was adhered to in preparing the report of this intervention.

Recruitment was conducted in urban comprehensive health centers. The 16 urban comprehensive health centers in Qazvin have a population coverage of nearly 90%. Midlife women receive age-appropriate healthcare provision, such as periodic assessment of blood pressure, annual checking of fasting blood sugar, level of plasma lipid, breast examinations, and mammography checkups. Consequently, comprehensive healthcare centers were selected for participant recruitment.

2.2 Participants

Post-menopausal women referred to the comprehensive health centers in Qazvin, were invited to participate in the study if they met eligibility criteria. The inclusion criteria were: (i) being willing to participate in the study, (ii) being menopausal (based on self-report of absence of menstruation in the past year), (iii) having a normal earlobe without lesions, (iv) being able to read and write, (v) currently living with husband, and (vi) availability during the study period (and being resident in Qazvin city). The exclusion criteria were (i) having a history of chronic mental and physical illness (self-reported or reported in their health records), (ii) having a history of substance abuse

(the woman and/or their spouse, (iii) having used acupuncture in the past three months, and (iv) having a history of stressful events in the past three months (such as a family bereavement).

2.3 Recruitment and randomization

Participant recruitment was carried out using convenience sampling. With the help of comprehensive health centers in Qazvin, a list of names and contact numbers of postmenopausal women was provided to the research team. After contacting these individuals, eligible participants were recruited. Random allocation of participants into two groups was performed using balanced block randomization method with a block size of four. To generate a random sequence list, each group was assigned a letter (A: auricular acupuncture group, B: sham control group). Then, the random sequence was generated using an online randomizer (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). The allocation sequence was written down on the paper and placed inside sealed envelopes in order to conceal the sequence. The random sequence was generated and concealed by an individual outside of the research team.

2.4 Sample size estimation

G-Power v3.1 software was used to estimate the sample size. According to a previous study by Rashidi Ahmad Abadi [37] the mean (SD) scores of total sexual functioning on the Female Sexual Functioning Index among women before and four weeks after auricular acupuncture were 51.6 (14.39) and 72.7 (8.35) in intervention, and 43.9 (15.85) and 61.0 ± 6.62 in placebo control group. Based on dppc-2 method introduced by Morris (2008), which is used to standardize the difference in pre/post change between intervention and control groups [39], the standardized mean difference observed in the present study was 0.27 equal to an F effect size of 0.14. Taking into account a type I error of $\alpha=0.05$ and a study power of 80%, the estimated total sample size was calculated to be

84 participants. Considering an approximate 10% dropout during the follow-up period, 90 participants (45 for each group) were invited to participate in the study.

2.5 Procedure

2.5.1 Ear acupoints selection

Chinese and European genital points, libido point, ovarian point, zero point, Shen Men point, and brain point were the selected ear acupoints chosen in present study (Figure 1). Ear acupoints were selected based on literature review [27, 40, 41] and the expert opinion of one of the research team members (TO). The *Chinese genital point* is found on the helix region that leaves the face [HX4 on the ear chart]. Stimulation of this point among women relieves low back pain, and facilitates sexual desire. The *European genital point* is located on the helix root area adjacent to the superior tragus [HX1 on the ear chart]. These points reflect the function of external genitalia (namely, the clitoris for women). The *libido point* known as sexual desire or the Bosch Point is located on the helix root as it joins the superior edge of tragus [HX1/TG5 in the ear chart]. The stimulation of this point can regulate the function of clitoris in women and increase their libido and enhances sexual arousal. The *ovarian point* related to function of internal genitals or sex glands is located on the concha wall near the intertragic notch toward the bottom of the auricle [CW1 in the ear chart]. This point is consistent with the Nogier location for the pituitary gonadal hormones follicle-stimulating hormone (FSH) and luteinizing hormone (LH). Stimulation of this point relieves sexual dysfunctions. The *Zero point* is located on the concha ridge [CR1/CR2 in the ear chart]. Stimulation of this acupoint balances dysfunctions throughout the body. The *Shen Men* point is located superior and central to the tip of the triangular fossa, between the junction of the superior crus and the inferior crus of the antihelix [TF2 in the ear chart]. Stimulation of this point alleviates

stress, pain, tension, anxiety, depression, insomnia, restlessness, and excessive sensitivity. Shen Men is utilized in almost all treatment plans. The *brain point* is located on the upper edge of the concha wall, behind the occiput on the antitragus [CW3 in the ear chart]. Stimulation of this point relieves pain, and improves sensory and limbic arousal functions [27, 42].

2.5.2 Auricular acupressure

First, both external earlobes were cleaned with 75% alcohol. Next, special non-latex adhesives containing Vaccaria seeds were attached on the aforementioned specified acupoints. There were 10 intervention sessions held at four-day intervals for each participant. Participants were instructed to keep the seeds on their ear for three days and press each point three times a day for twenty seconds. They were told that the pressure should be performed with steady, moderate stimulation with slightly firmer pressure until a tingling sensation and mild discomfort is felt. After three days, seeds should be removed from ear and rest for one day. The participants were reminded to press acupoints three times daily through SMS. There were also reminders for the next intervention session. Participants were instructed to contact with principal researcher if there were any problems when using this method.

2.5.3 Sham control

The same procedure, same acupoints, same treatment sessions, and same instructions were implemented for participants assigned to the sham control group. The only difference was using special non-latex adhesives but without the Vaccaria seeds. Using adhesive patches without the seeds on the same ear acupoints as the intervention group is a common sham control for auricular acupressure interventions [43].

2.5.4 Treatment fidelity

Adhesives with/without seeds were attached by a trained research team member. She had successfully passed an acupressure training course under the supervision of a traditional medicine specialist sponsored by the Iranian Scientific Association of Midwifery. After ensuring the accuracy of the implementation method, the intervention was performed with the participants.

2.5.5 Blinding

The control group received the sham intervention with same protocol as the intervention group unless adhesives without seeds were used. Because participants had no previous experience of auricular acupressure and were not informed what group they are in, they were blinded. Moreover, the outcomes were assessed using online surveys directly sent to the participants. In this regard, no-one was assigned as assessor in present study. All outcomes were assessed using online links completed by participants (as outcome assessors) which remained blind to their treatment group (as auricular or sham acupressure). Identification regarding the study group was not added to the online survey. To distinguish participant groups, two similar links were prepared (A for intervention group, B for sham group), but this was not identifiable to participants. After completing data collection, a person who was not a member of the research team, prepared the final dataset for analysis. The groups were coded as A and B. The data analyst was not informed what the 'A' or 'B' labels represented. After complete analysis, code labels relating to the study groups were revealed to the research team. Therefore, the outcome assessor was blinded. Also, the data analyst was blinded because the final dataset was blinded regarding participant groups. Consequently, the present study was triple-blinded.

2.6 Variables

Demographic and reproductive characteristics, sexual functioning (using two measures) and sexual distress (using one measure) were assessed (see next section). Sexual functioning was the primary outcome, and sexual distress and frequency of monthly coitus were the secondary outcomes.

2.6.1 Measures

Demographic and reproductive characteristics were asked about at the start of the survey. The information asked for included participants' age, their spouses' age, job, education, and chronic disease history. Participants were also asked questions regarding their menopause age, marriage duration, number of childbirths, whether they had regular health visits, addiction history, surgery history, and family economic status. Their weight and height were asked to calculate body mass index (BMI)

The Arizona Sexual Experience Scale (ASEX) [44] comprises five items and was used to assess sexual dysfunction related to sex drive, arousal, vaginal lubrication, ability to reach orgasm, and satisfaction from orgasm. Items (e.g., "*How easily are you sexually aroused [turned on]?*") are rated in six-point scale from 1 (*very easy*) to 6 (*never*). Possible total scores range from 5 to 30, with higher scores indicating greater sexual dysfunction. The psychometric properties of Persian version are robust [45]. The intraclass correlation coefficient (ICC) was 0.891 in present study, demonstrating very good internal consistency.

The Female Sexual Distress Scale-Revised (FSDS-R) [46] comprises 13 items and was used to examine various aspects of female sexual distress. Items (e.g., "*In the past 4 weeks, how often have you been anxious about your sex life?*") are rated in five-point scale from 0 (*never*) to 4 (*always*). Possible total scores range from 0 to 52, with higher scores indicating greater sexual

distress. The psychometric properties of Persian version are robust [47]. The intraclass correlation coefficient (ICC) was 0.886 in present study, demonstrating very good internal consistency.

The abridged Female Sexual Function Index (FSFI-6) [48] comprises six items and was used to assess women's sexual functioning in various aspects of desire, arousal, lubrication, orgasm, sexual satisfaction, and pain during intercourse [48]. Items (e.g., "*When you had sexual stimulation or intercourse, how often did you reach orgasm?*") are rated on a five-point scale from 1 (*Almost never or never*) to 5 (*Almost always or always*). Possible total scores range from 6 to 30 with higher scores indicating better sexual functioning [48]. The psychometric properties of Persian version are robust [49]. The intraclass correlation coefficient (ICC) was 0.895 in present study, demonstrating very good internal consistency.

Frequency of monthly coitus was assessed with a single item question (e.g., "*What was your frequency of coitus during the past month?*").

2.6.2 Measurement time points

Demographic and reproductive characteristics were assessed when participants were first recruited. Scores on the ASEX, FSFS-R and FSFI were assessed three times points: before intervention, one month after the completed intervention, and two months after the completed intervention. These time points were selected to be consistent with previous studies with interventions targeting female sexual function[37, 50]. All surveys were completed using an online platform (*Porsline*) via two separate links. Link A was sent to participants in the intervention group and link B was sent to participants in the sham control group. The link of the survey was sent to participants via a mobile phone text message and they were asked to complete the survey. Their phone number was used as their unique ID code to merge data of different time-points.

2.7 Ethical considerations

The study protocol was reviewed by the Qazvin University of medical Sciences Review Board and the Ethics Committee and approved (decree code: IR.QUMS.REC.1400.450). The trial was also registered prospectively on April 13, 2022 (code IRCT20180218038789N6) in the Clinical Trial Registration Center of Iran. Written informed consent was provided by all the participants after explaining study aims, their anonymity, confidentiality, and right to drop out if they wanted.

2.8 Statistical analysis

Data were analyzed using SPSS software version 24 (by IBM SPSS Corp, New York, USA). Continuous variables were described with means and standard deviations (SDs). Categorical variables were described using frequencies and percentages. Intergroup distribution of variables were compared using the method proposed by Imbens and Rubin, taking into account the standardized mean difference criteria of <0.25 for continuous quantitative variables and $<10\%$ difference for categorical variables (which are interpreted as inconsiderable intergroup difference)[51]. The normality of the study variables was examined and confirmed using the Shapiro-Wilks test, histogram diagram, indicators of central tendency, and dispersion.

Repeated measurements analysis of variance–covariance (RM ANOVA-ANCOVA) were used to assess the changes of study variables' mean scores (including FSFI, FSDS-R, ASEX and average frequency of monthly sexual coitus) between study groups at different measurement time points. All analysis was done with a crude model, an adjusted model for potential covariates with imbalanced distribution at baseline. Bonferroni corrections for multiple comparisons were also performed.

The mean difference (MD) and the standardized mean difference (SMD) based on Cohen's d and Partial eta squared (η^2) were calculated to assess measure of effect of intervention. A Cohen's d effect size of 0.2-0.5 was considered as small effect size; 0.5-0.8 was considered as medium effect size; and more than 0.8 was interpreted as large effect size [52]. Partial eta squared was the other effect size used to assess the measure of effect of the intervention in the present study. Partial eta squared (η^2) is interpreted as trivial when <0.010 ; small effect when between 0.010-0.059; medium effect when between 0.060-0.139; and large effect when ≥ 0.140 [53]. All analysis was adjusted for identified covariates as aforementioned. The significance level of all tests was $p<0.05$.

3 Results

In the study, 90 individuals were randomly assigned to study groups including auricular acupuncture (N=45) or sham control groups (N=45). All participants continued the study intervention and follow-up assessments. Figure 2 shows the CONSORT diagram for the study process. Table 1 present distribution of demographic and reproductive characteristics of participants based on study groups. Based on Imbens and Rubin's criteria of balanced distribution in trials [51], menopause age (years), spouse age (years), number of childbirths, and spouse chronic disease history appeared to have imbalanced distribution between study groups. Therefore, these variables were controlled as covariates in subsequent analyses.

3.1 Primary outcome: Sexual functioning (FSFI)

Table 2 and Figure 3A (in the supplementary materials) present the effect of the intervention on mean FSFI scores at measurement time points based on study groups. The mean FSFI score was not significantly different at baseline between the two groups. However, a significant increase in the mean FSFI score was observed at first and second follow-up in the intervention group

compared to the sham group (mean difference = 5.12 at first follow-up [95% CI: 3.39; 6.85]; and 10.17 at second follow-up [95% CI: 7.71; 12.63]).

3.2 Secondary outcomes: Sexual dysfunction (ASEX), sexual distress (FSDS-R), and frequency of monthly coitus

Table 3 presents the effect of the intervention on secondary outcomes at measurement time points based on study groups.

Sexual dysfunction. The mean score ASEX score was not balanced at baseline and it was entered in model as covariate. In the adjusted model for baseline scores and other covariates, a significant decrease in the mean ASEX score, where decreased scores indicate better sexual functioning, was observed at the first and second follow-up in the intervention group compared to the sham group (mean difference = -5.89 at first follow-up [95% CI: -7.34; -4.42]; and -9.07 at second follow-up [95% CI: -10.75; -7.39]). Changes in mean ASEX scores over time were significant for the intervention group (Figure 3B in the supplementary materials).

Sexual distress. The mean FSDS-R score was not significantly different at baseline between groups. In the adjusted model, a significant decrease in the mean FSDS-R score, where decreased scores indicate less sexual distress, was observed at the first and second follow-up in the intervention group compared to the sham group (mean difference = -13.60 at the first follow-up [95% CI: -15.71; -11.50]; and -23.53 at the second follow-up [95% CI: -26.34; -20.72]). Changes in mean FSDS-R scores over time were significant for the intervention group (Figure 3C in the supplementary materials).

Frequency of monthly coitus. The mean frequency of monthly coitus was not significantly different at baseline between groups. In the adjusted model, a significant increase in mean frequency of

monthly coitus was observed at the first and second follow-up in the intervention group compared to the sham group (mean difference =1.58 at the first follow-up [95% CI: 0.41; 2.75]; and 1.96 at the second follow-up [95% CI: 1.09; 2.82]). Over time, the mean frequency of monthly coitus increased in the intervention group and decreased in the sham group (Figure 3D in the supplementary materials).

3.3 Adverse events

No adverse events were reported during the intervention or the follow-ups.

4 Discussion

The present study was conducted to evaluate the efficacy of ear acupressure on sexual functioning among postmenopausal women. The findings showed that auricular acupressure improved the sexual lives of postmenopausal women by increasing sexual functioning, reducing sexual distress, and reducing problems concerning various aspects of sexual response.

The promising effect of auriculotherapy on various aspects of women's life during menopause has been reported in a number of studies including climacteric symptoms [54, 55], hot flushes [56], sleep quality [57], insomnia [58], and quality of life [36]. In a recent systematic review, the available evidence of the effect of auriculotherapy on climacteric syndrome, menopause, and old age was evaluated. The results of this systematic review study (four semi-experimental studies and 11 clinical trials) showed that among postmenopausal women, auriculotherapy (i) reduces anxiety, (ii) reduces intensity and frequency of hot flushes, (iii) improves the level of sex hormones, (iv) reduces sleep disorders, and (v) improves quality of life [59]. However, few studies have been conducted on the efficacy of ear acupressure on the sexual functioning among women. However, this limited evidence is consistent with the findings of the present study. The positive effect of

auriculotherapy on improving the sexual functioning of lactating women has been investigated and confirmed [60]. In another study, the positive effect of auriculotherapy in improving various aspects of quality of life among postmenopausal women, including sexual quality of life, have been reported [36].

Based on evidence in the extant literature, the physiological effects of ear acupressure point stimulation remain for days and even weeks [32, 33]. The same findings were observed in present study. Participants reported higher scores of sexual functioning and lower scores in ASEX and FDS-R scales at the second follow-up (two month after intervention) compared to first follow-up (one month after intervention).

The specific mechanism of how auriculotherapy works is still in progress [61], but some underlying mechanism have been proposed. First, the ear is one of few body structures comprising tissue from all primary embryonic tissues (e.g., ectoderm, mesoderm, and endoderm). Therefore, hypothetically this could be the reason of having reflective points related to all body systems in the auricle [62]. Second, the external ear or auricle is near to the sensory innervation of the vegetative nerve centers including auriculotemporal nerve, auricular branch of the vagus nerve, minor occipital nerve, and greater auricular nerve. Therefore, information can be received from the internal organs through alpha, beta, and gamma fibers [63]. This means that the auricle is potentially the best place for direct stimulation of the central nervous system [64, 65]. Due to this rich innervation, ear connections with the central nervous system are considerable and facilitate modulating endogenous systems, the sympathetic-parasympathetic nervous system, and the endocrine and neuroendocrine systems [64, 65]. Moreover, these nervous systems can transmit the signals received from sensitive perception from touch, pressure, temperature to different body systems through the posterior horn of the spinal cord [63]. Therefore, auricular acupressure can

produce health signals in response to ear stimulation, and direct them to the brain and different parts of the body [66].

Based on treatment protocol and selected acupoints [27], auricular acupressure might influence individuals' sexual functioning through affecting endocrine, psychological, and physiological mechanisms related to sexual functioning [67]. Stimulation of selected ear acupoints in the present study were proposed to be helpful in relieving pain especially low back pain, improving sensory and limbic arousal functions, facilitating sexual desire, increasing libido, enhancing sexual arousal, and alleviating sexual dysfunctions. Stimulation of two master points of Zero point and Shen Men help in balancing dysfunctions throughout the body and improving the psychological state of individuals [27, 42]. Consequently, the suggested set of ear acupoints selected in present study might influence endocrine, psychological, and physiological aspects responsible for sexual functioning.

The results indicated that there was no significant change in study variables for the control group, even for the frequency of monthly intercourse. To check the effect of time on each group, a group specific-repeated measure analysis was conducted. The effect of time for intervention group was significant for FSFI, ASEX and FSD (all p -values <0.001), and marginally significant for the frequency of monthly intercourse ($p=0.06$). The effect of time was not significant for any of the study outcomes in control group including: FSFI ($p=0.45$), ASEX ($p=0.48$), FSD ($p=0.64$) and frequency of monthly intercourse ($p=0.40$). The control group received placebo auriculotherapy but they did not show any changes that might have been expected due to the placebo effect. One reason might be due to their age. A review by Bingel et al. [68] noted that specific age-associated conditions can substantially impair the individuals' ability to produce placebo responses. Individuals with chronic conditions (such as postmenopausal women with sexual problems), tend

to accept their situation as being due to age-related changes and who view their condition as being untreatable because of irreversible anatomical and physiological changes [69].

Placebo responses are produced based on factors such as individuals' expectations, their prior experiences, and contextual factors (e.g., verbal suggestions and information provided by physician, patient-doctor relationship) [68, 70]. Such prior experiences can result in negative and frustrating experiences regarding treatment. Negative mood states among patients with chronic conditions can lead to negative treatment expectations. This negative treatment expectancy can modulate or completely nullify placebo effects [68].

The placebo effect can occur due to contextual factors including patients' beliefs and expectations, the quality of patient-practitioner interaction, and the intervention environment [71]. Based on a recent meta-analysis focused on contextual effects related to placebo responses in 186 trials comprising 16,655 patients, the effect of contextual factors was found to be higher for trials with blinded outcome assessors, concealed allocations, and older-aged participants [70]. The present study had a blinded outcome assessor, concealed allocation, and older-aged participants. Moreover, no verbal suggestions or information was provided to participants (e.g., advice on sexual functioning during the menopausal period, how it might be improved, probable mechanisms of auriculotherapy). All of these factors may provide reasons as to why there was no placebo effect in present study.

4.1 Limitations

The present study is among the first to investigate the effect of auricular acupressure on sexual functioning among postmenopausal women. However, the interpretation of the study results should consider the following limitations. First, all study variables were assessed using self-report

scales which are vulnerable to social desirability bias. Assessing objective biomarkers might provide a better understanding for underlying mechanism of how ear acupressure can influence different body systems. But the study did not receive financial support for this type of assessment. Second, the spouses' sexual-related factors were not assessed. Sexual functioning is something that centres on couples rather than individuals and it is better to take into account the marital relationship including the partner's sexual health if possible. Third, while randomization was carried out using the balanced block method, and the randomization sequence was concealed, some baseline characteristics had imbalanced distribution between groups. However, the authors tried to control for this limitation when estimating the sample size by considering four possible covariates and conducting adjusted statistical analysis to control baseline scores of variables of interest, as well as imbalanced distributed baseline characteristics.

5 Conclusion

The results of the present study suggest that auricular acupressure was an effective intervention in improving postmenopausal women's sexual functioning, reducing their sexual distress, and reducing sexual dysfunction. Auricular acupressure can be discussed by healthcare providers with postmenopausal women to improve their sexual functioning, due to its simplicity, cheapness, safety, and acceptability for patients.

Funding sources: No financial support was received.

Declaration of generative AI and AI-assisted technologies in the writing process: No AI technologies was used in the writing process.

Data availability: The raw data is available via Mandalay data repository with access link of <https://data.mendeley.com/datasets/3bz87ws4xn/1> with DOI: 10.17632/3bz87ws4xn.1.

Acknowledgments: We would like to thank all the participants for their participation in the study.

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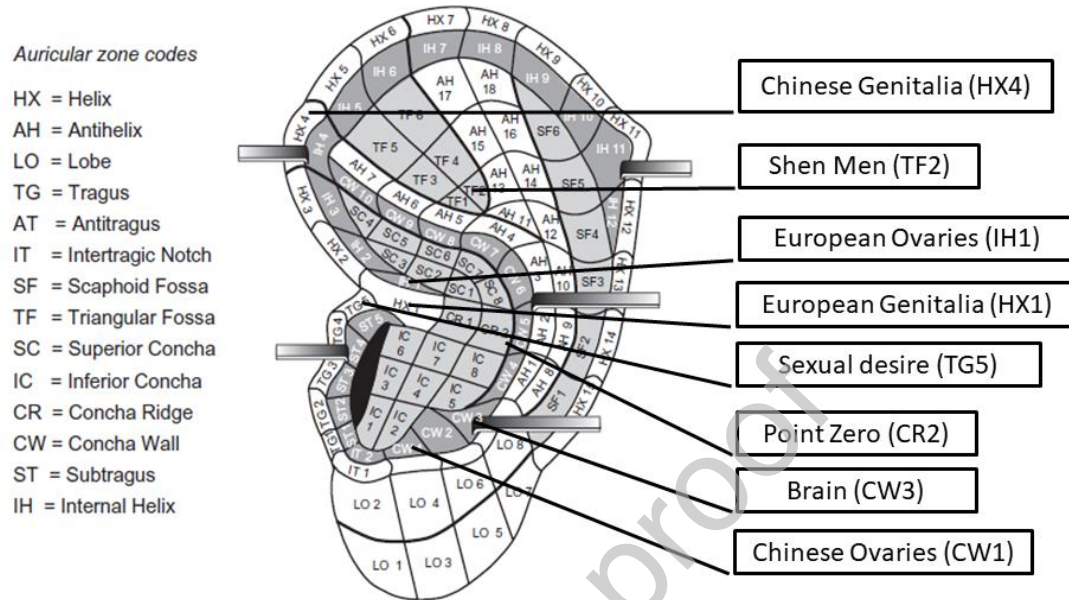


Figure 1- Ear acupoints used in present study

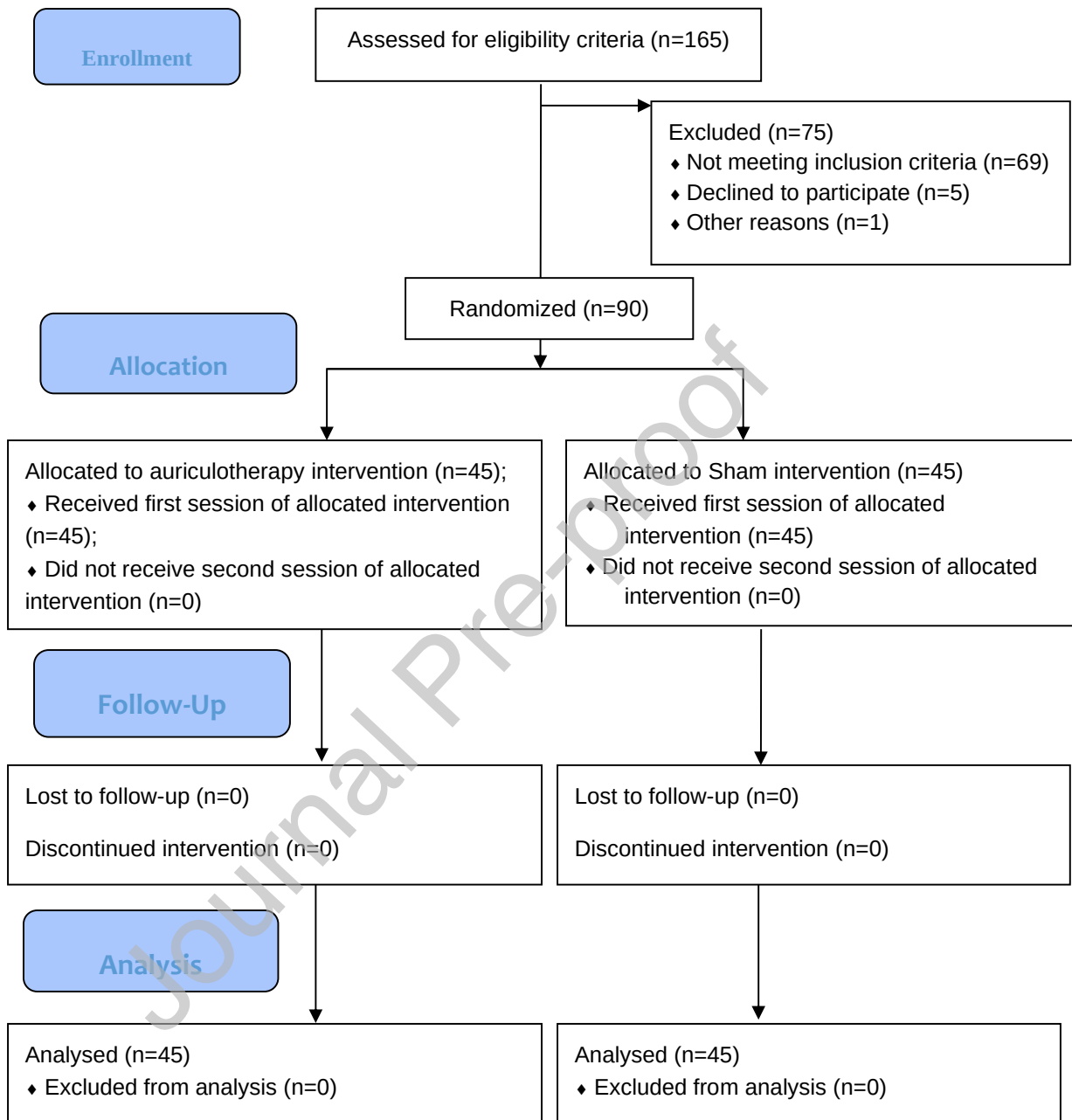


Figure 2. Recruitment and study procedures based on CONSORT flow diagram

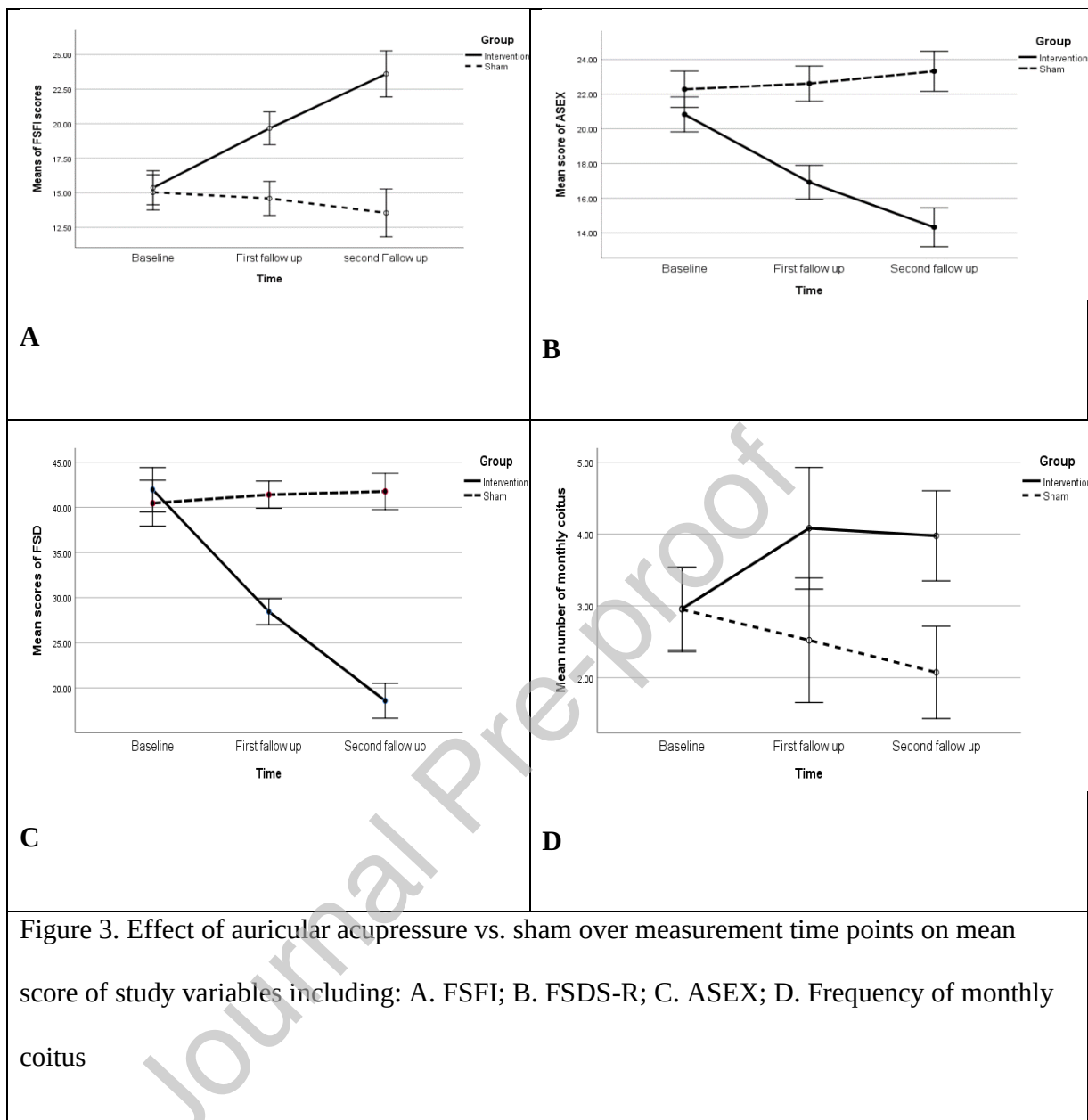


Table 1. Distribution of demographic and reproductive characteristics of participants based on study groups

Variables		Mean (SD) or No (%)	
		Intervention (n=45)	Sham (n=45)
Age (years)		65.02(6.09)	65.76 (5.10)
Menopause age (years)		52.67 (7.55)	54.36 (4.49)
Spouse age (years)		67.93 (6.17)	69.44 (4.03)
Marriage duration (years)		46.27 (7.80)	46.80 (6.24)
Number of childbirths		2.51 (1.18)	3.00 (1.58)
BMI (kg/m ²)		17.27 (7.18)	16.29 (4.66)
Education	Up to diploma	30 (66.7)	25 (56.5)
	Academic	15 (33.3)	20 (44.4)
Spouse education	Illiterate	5 (11.1)	8 (17.8)
	Up to diploma	9 (20.0)	9 (20.0)
	Academic	31 (68.9)	28 (62.2)
Regular health visit	No	23 (51.1)	27 (60.0)
	Yes	22 (48.9)	18 (40.0)
Family economic status	Weak	7 (15.6)	10 (22.2)
	Fair	28 (62.2)	30 (66.7)
	Good	10 (22.2)	5 (11.1)
Job	Housewife	36 (80.0)	35 (77.8)
	Employed	9 (20.0)	10 (22.2)
Addiction history	No	45 (100)	45 (100)
Surgery history	No	29 (64.4)	24 (53.3)
	Yes	16 (35.6)	21 (46.7)
Chronic disease history	No	18 (40.0)	16 (35.6)
	Yes	27 (60.0)	29 (64.4)
Spouse chronic disease history	No	33 (73.3)	27 (60.0)
	Yes	12 (26.7)	18 (40.0)
N.B. Based on Imbens and Rubin's ^[50] criteria of balanced distribution in trials, menopause age (year), spouse age (year), number of childbirths, and spouse chronic disease history appeared to have imbalanced distribution between study groups.			

Table 2. Mean (standard deviation) of FSFI as primary outcome at measurement times based on study groups

Model	Time	Intervention (N=45)	Sham (N=45)	Intervention vs. Sham		Statistical results for RM ANOVA-ANCOVA			
				MD [95% CI]	SMD [95% CI]	Effect	F	p	Partial η^2
Crude*	Baseline	15.53 (4.36)	14.86 (4.05)	0.82 [-0.95; 2.59]	0.16 [-0.26; 0.57]	Time	11.81	<0.001	0.122
	Follow-up 1	19.80 (2.87)	14.45 (4.94)	5.35 [3.60; 7.09]	1.32 [0.87; 1.78]	Group	68.59	<0.001	0.447
	Follow-up 2	23.58 (5.94)	13.57 (6.00)	10.14 [7.61; 12.67]	1.68 [1.20; 2.16]	Time*Group	22.36	<0.001	0.208
Adjusted**						Time	9.51	0.003	0.106
	Follow-up 1	19.67 (3.98)	14.57 (4.13)	5.12 [3.39; 6.85]	1.26 [0.81; 1.71]	Group	71.99	<0.001	0.474
	Follow-up 2	23.59 (5.69)	13.43 (5.82)	10.17 [7.71; 12.63]	1.77 [1.28; 2.25]	Time*Group	17.62	<0.001	0.180

* Analyzed using RM ANOVA

** Analyzed using RM ANOVA-ANCOVA considering covariates including baseline FSFI score (F=2.04, p=0.16), menopause age (F=1.86, p=0.18), spouse age (F=8.45, p=0.005), number of childbirths (F=0.37, p=0.54) and spouse chronic disease history (F=0.30, p=0.59).

Table 3. Mean (standard deviation) of ASEX, FSDS-R and frequency of monthly coitus as secondary outcome at measurement times based on study groups

outcomes	Time	Intervention (N=45)	Sham (N=45)	Intervention vs. Sham		Statistical results for RM ANOVA-ANCOVA			
				MD [95% CI]	SMD [95% CI]	Effect	F	p	Partial η^2
ASEX	Baseline	20.64 (3.53)	22.48 (3.60)	-2 [-3.50; -0.50]	-0.52 [-0.94; -0.07]	Time	1.14	0.29	0.014
	Follow-up 1	16.83 (3.33)	22.71 (3.46)	-5.89 [-7.34; -4.42]	-1.73 [-2.22; -1.25]	Group	120.83	<0.001	0.602
	Follow-up 2	14.33 (3.84)	23.40 (3.93)	-9.07 [-10.75; -7.39]	-2.33 [-2.87; -1.80]	Time*Group	14.69	<0.001	0.155
FSDS-R	Baseline	41.67 (8.92)	40.76 (8.06)	0.78 [-2.74; 4.29]	0.09 [0.32; 0.51]	Time	4.25	0.03	0.050
	Follow-up 1	28.13 (4.26)	41.74 (5.57)	-13.60 [-15.71; -11.50]	-2.75 [3.32; -2.17]	Group	205.83	<0.001	0.718
	Follow-up 2	18.38 (6.53)	41.98 (6.78)	-23.53 [-26.34; -20.72]	-3.55 [4.21; -2.88]	Time*Group	68.68	<0.001	0.459
Frequency of monthly coitus	Baseline	3.11 (2.40)	2.79 (1.86)	0.44 [-0.46; 1.35]	0.20 [-0.21; 0.62]	Time	5.46	0.005	0.062
	Follow-up 1	4.09 (2.00)	2.51 (3.38)	1.58 [0.41; 2.75]	0.57 [0.15; 0.99]	Group	14.63	<0.001	0.151
	Follow-up 2	4.00 (2.09)	2.05 (2.02)	1.96 [1.09; 2.82]	0.95 [0.51; 1.39]	Time*Group	4.09	0.02	0.048

** Analyzed using RM ANOVA-ANCOVA considering covariates including baseline score, menopause age, spouse age, number of childbirths and spouse chronic disease history

CRedit author statement

Zainab Alimoradi: Conceptualization, Methodology, Formal analysis, Supervision, Software, Validation, Data curation, Writing- Original draft,

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Mark D. Griffiths: Writing- Reviewing and Editing

Financial support:

No funding was received

Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: