The effect of ear acupressure on sexual functioning among lactating women: A randomized sham controlled trial

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Highlights

- Ear acupressure was used as an intervention to increase women's sexual functioning
- Ear acupoints were genitalia, pelvis, master shoulder, and posterior hypophysis
- Ear acupressure showed a large effect on improvement of female sexual functioning
- Weekly frequency of sexual intercourse improved in the intervention group
- All changes were both statistically and clinically significant

The effect of ear acupressure on sexual functioning among lactating women: A randomized sham controlled trial

Running Head: Ear acupressure and sexual functioning

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Abstract

Introduction: Women experience more problems in their sexual functioning after childbirth. Due to the high prevalence of sexual problems during the lactation period, the World Health Organization suggested measures were needed to improve women's sexual functioning during breastfeeding. The present study investigated the effect of auricular acupressure on sexual functioning among lactating women.

Methods: A randomized, sham-controlled trial was conducted between October 2019 to March 2020 in urban comprehensive health centers of Qazvin, Iran. Seventy-six women who had been lactating between six months and one year postpartum were randomly assigned to auricular acupressure group (n=38) or sham control group (n=38) using a balanced block randomization method. The intervention group received ear acupressure in 10 sessions (at four-day intervals) and control group also received the sham intervention at the same intervals. Sexual functioning was the primary outcome of the study (assessed using the Female Sexual Function Index) before and at three time points post-intervention (immediately after, one month after, and two months after). The secondary outcome was sexual quality of life assessed using Sexual Quality of Life-Female Version.

Results: Auricular acupressure had a large effect size on female sexual functioning at all three post-intervention time points: immediately after the intervention (adjusted mean difference [95% CI]: 8.37 [6.27; 10.46] with Cohen's *d* [95% CI]: 1.81[1.28; 2.34]), one month after the intervention (adjusted mean difference [95% CI]: 8.44 [6.41; 10.48] with Cohen's *d* [95% CI]: 2.01 [1.46; 2.56]), and two months after the intervention (adjusted mean difference [95% CI]: 7.43 [5.12; 9.71] with Cohen's *d* [95% CI]: 1.57 [1.06; 2.08]). The intervention significantly increased participants' sexual quality of life on the Sexual Quality of Life-Female scale by 13.73 points in the intervention group compared to the control group ($p<0.001$). The effect size of intervention for female sexual quality was large (adjusted Cohen's *d* [95% CI]: 1.09 [0.58; 1.59]). Weekly frequency of sexual intercourse in the intervention group significantly increased compared to sham control group ($p<0.001$). These changes were clinically significant for sexual functioning and sexual quality of life.

Conclusion: Auricular acupressure appears to be an effective intervention for improving sexual functioning and sexual quality life of lactating women.

Keywords: breastfeeding, sexual functioning, sexual quality of life, ear acupressure

Trial registration: Registered of in the Clinical Trial Registration Center of Iran under decree code of IRCT20190626044028N1.

Abbreviation List

ANOVA: Analysis of variance

ANOVA/ANCOVA: Analysis of variance/covariance

CONSORT: Consolidated Standards of Reporting Trials

EPDS: Edinburgh Postpartum Depression Scale

FSFI: Female Sexual Function Index

MANOVA: Multivariate analysis of variance

MCID: Minimal clinically important difference

MD: Mean difference

SMD: Standardized mean difference

SPSS: Statistical Package for the Social Sciences

SQOL-F: Sexual Quality of Life-Female

TCM: Traditional Chinese Medicine

WHO: World Health Organization

1 Introduction

Pregnancy and childbirth accompanied by major physical, psychological, social, and hormonal changes which may negatively impact the woman's sexuality and quality of the couple's sexual life [1]. Decreasing sex hormones (androgens and estrogens) during breastfeeding may lead to vaginal dryness, vaginal epithelial atrophy, dyspareunia, and reduced sexual functioning [2]. Also, taking care of the child(ren), fatigue, insomnia, as well as unwanted changes in body image can occur during breastfeeding which may lead to lack of sexual desire [3].

Many women experience at least one sexual problem during breastfeeding, such as decreased sexual desire, failure to reach the peak of sexual pleasure, pain during intercourse, and vaginal dryness, which usually resolve within the first year after childbirth [4]. Overall, women's sexual functioning tends to worsen after childbirth with a prevalence of 71.4% sexual dysfunction in the first months after childbirth [5]. The prevalence of sexual dysfunctions is reported to be 73.8% to 85.4% in different aspects of sexual functioning among lactating women [6].

This reason for a change in sexual functioning can also lead to a decrease in women's sexual quality of life after childbirth [7]. The sexual quality of life is an interactive and dynamic state, which can change over time and with changing circumstances [8]. Consequently, it is increasingly important to take action to improve the health of mothers and increase their quality of life in the postpartum period considering sexual issues [9].

Currently, worldwide there are few approved pharmacological treatments for some types of female sexual dysfunction [10]. Moreover, no treatments are approved for other female sexual dysfunctions (e.g., anorgasmia, dyspareunia, sexual arousal disorder, sexual distress, sexual dysfunctions after chronic disease or gynecological cancers) in other lifespan periods except menopause [10, 11]. Therefore, many types of female sexual dysfunction are treated by focusing on behavioral modifications (e.g., cognitive-behavioral and mindfulness-based therapies) [11] or off-label uses of medications [12]. Apart from phosphodiesterase type 5 inhibitors, which are the only drugs approved for female hypoactive sexual desire disorder, all other drugs used in the treatment of sexual disorders are used 'off-label' [12]. Consequently, the use of non-drug therapies and complementary medicine (including traditional Chinese medicine [TCM]) serve as potential alternatives to drug therapy [13].

The therapeutic effect of TCM methods (including acupuncture) for sexual dysfunction was reported in a recent systematic review [14]. Acupressure is a complementary TCM method which can be used in different acupoints [6]. A microsystem of acupoints are located in the ear, and used for ear acupressure (and also known as auricular acupressure) [15]. According to this theory, each part of the body is related to a specific part of the ear and is used as an indicator of the normal or pathological condition of the body, in which their stimulation can be used to alleviate pathological conditions in related parts of the body [16]. The promising effect of auricular acupressure has been observed in the treatment of sleep disorders like insomnia [17], menstrual pain and distress, dysmenorrhea [18], nausea and vomiting during chemotherapy [19], labor pain and duration [20], post-cesarean pain [21], and postpartum blues and depression [22].

Auricular acupressure is an non-invasive, easy and safe therapy that can easily be used by mothers who take care of their baby [16]. Based on selected acupoints and treatment protocol [16], it might improve both endocrine function (increased sex hormones including androgens and estrogens) and its physiological consequences (e.g., vaginal dryness, and vaginal epithelial atrophy) [2], as well as reducing fatigue and insomnia problems (which might increase sexual desire) [3]. The effect of auricular acupressure on sexual functioning has only been investigated in a few studies [23, 24] and further evidence is still needed concerning its efficacy. Due to high prevalence of sexual problems during the lactation period [5, 6], the WHO suggested assessing and improving sexual health and functioning of women during breastfeeding period [25]. Therefore, the present study investigated whether auricular acupressure can positively affect sexual functioning among lactating women.

2 Methods

2.1 Study design

A randomized, sham-controlled trial was conducted from October 2019 to March 2020. The study protocol has already been published [26].

2.2 Participants

Women who were lactating six months to one year after delivery were invited to participate in the study. They were included if they wanted to participate in the study, were literate, were primiparous, were breastfeeding, had full-term singleton delivery, had a healthy ear without lesions, had no ulcers or pain in the ear, and were able to attend all intervention sessions.

They were excluded if they were living away from their spouse, if their husband was polygamous, if they had postpartum depression (scoring 12 or more on the Edinburgh Postpartum Depression Scale), had a history of chronic mental and physical illness (based on their health records), had abused (and/or had a husband who abused) psychoactive substances, had used acupressure in the past three months, had any illnesses that affected their husband's sexual functioning (e.g., premature ejaculation, cardiovascular and thyroid disease, mental health disorders, cancer, or any active injuries in genital area), and used medicinal drugs that affected sexual functioning. The CONSORT flow diagram [27] is shown in Figure 1.

2.3 Sample size estimation

Total sample size was 76 individuals. The required sample size was calculated based on a study by Bokaie et al. [28] with the mean (standard deviation) of total sexual functioning score of 24.65 (3.47) and 22.27 (3.03) in the intervention and control groups, respectively. The samples for each group were estimated to 38 participants by considering type 1 error of 0.05 (95% confidence) and power of 80%, two-sided statistical tests, with the probability of 10% attrition rate.

2.4 Recruitment and randomization

Urban comprehensive health centers were selected as the study setting due to their high-coverage access to lactating women for providing care for themselves and their children (over 90% coverage of this population). Sampling was performed utilizing a two-stage sampling method. First, Qazvin city was considered as five geographical areas. Then, two health centers in each of these five areas were randomly selected (simple random selection). This first step was taken to ensure the maximum variation in socio-economic status of individuals. Second, women referred to selected health centers were evaluated for eligibility and willingness to participate in the study. After enrolling eligible individuals in the study, a balanced block randomization method with four blocks was used. After preparing the allocation order, the order was written on paper and placed in sealed envelopes that were numbered sequentially. The questionnaires were coded in the same way. The assignment order and concealment were performed by someone outside of the research team. Therefore, participants were randomly assigned to the auricular acupressure intervention group or the sham control group.

2.5 Blinding

Participants, outcome assessors, and data analysts were all blinded. Participants had no previous experience of auricular acupressure, so they were not aware that real adhesive tapes should have seeds. Outcomes were assessed by a trained interviewer outside of research team who was not aware of how real or sham auricular acupressure is practiced. Also, the analyst received a blind dataset with codes of 1 and 2 for grouping variables. After all analysis were conducted, the grouping codes were revealed.

2.6 Intervention

Auricular acupressure group: For performing the intervention, first, the ear was cleaned with 75% alcohol and then Vaccaria seeds with special non-latex-based adhesives were placed on five ear acupoints of genitalia points (two points), hip, master shoulder, and the posterior hypophysis (Figure 2). The intervention comprised 10 sessions with a time interval of four days between each session. Participants were instructed not to remove the seeds on their ears for three days, and during that time they should put pressure on each point at least three times a day for 30 seconds. They were told that the compression technique should be performed with moderate stimulation through steady, slightly tighter pressure until the individual felt slight tingling and discomfort. After three days, the individual could remove the seeds from her ear and rest for one day [29]. Text message reminders were sent to participants daily reminding them to press the acupoints and to visit the center on the fifth day to reattach the new seeds. It should also be noted that if the participants had problems for any reason such as displacement of seeds, seeds' removal, etc., she could remove the previous seeds and use new seeds.

Sham control group: For the sham control group, first, the ear was cleaned with 75% alcohol and then special non-latex-based adhesives without Vaccaria seeds were placed on five ear acupoints, the same as intervention group. They also had similar number of sessions. Using adhesive patches without the pellet or seed on the same ear acupoints as the experimental group is a common sham control for auricular acupressure interventions [30].

2.7 Ear acupoints selection

Ear acupoints were selected based on literature review [16, 31, 32] and an expert opinion who was one of the research team members (TO). Genitalia points (including external and internal genitalia points), hip, master shoulder, and the posterior hypophysis were selected acupoints

in the present study (Figure 2). The external genitalia acupoint is related to external genitalia including the clitoris in women, located in helix region that leaves the face (known as HX-4 in the ear chart). Stimulation of this point can relieve low back pain and facilitate sexual desire. The internal genitalia acupoint is related to function of the vagina in women, located on the underside of internal helix (known as IH 2). Stimulation of this point can improve vaginal function for lubrication during sexual functioning. Also, acupressure of this point can improve the healing process of the vagina after childbirth including tears and episiotomy. The hip acupoint is located on the lower aspect of the antihelix superior crus, peripheral to Shen Men (known as AH13). Acupressure on this point relieves hip pain, low back pain, and inflamed hip joints. Master shoulder is located in the inferior scaphoid fossa, inferior to the shoulder point, near the earlobe (known as SF 1). Stimulation of this point helps in relieving pain, tenderness, and strain. The posterior hypophysis, also known as neuro hypophysis is located on the inferior concha near the inferior side of the ear canal (known as IC 3). The posterior pituitary contains neurons from the hypothalamus which can release oxytocin (and which is also known as the love hormone) [16, 33].

2.8 Treatment fidelity

Auricular acupressure was conducted by the second author. She underwent an acupressure training course under the supervision of a traditional medicine specialist and acquired related certifications. After her performance to practicing auricular acupressure was confirmed, the intervention was performed on the participants. Also, the first 10 interventions were performed under the supervision of the traditional medicine specialist to ensure the correct implementation of the techniques.

2.9 Study outcome

The primary outcome of present study was female sexual functioning assessed using the Female Sexual Function Index at four measurement time points (i.e., before the intervention, immediately, one month, and two months after the intervention). The secondary outcomes were females' sexual quality of life and average frequency of weekly sexual intercourse. Sexual quality of life was assessed using the Sexual Quality of Life–Female version at two time points (i.e., before the intervention and two months after the intervention). The average frequency of weekly sexual intercourse was assessed using a one-item question at four

measurement time points (i.e., before intervention, immediately, one month, and two months after the intervention).

2.10 Measures

Demographic and obstetric questionnaire: A short demographic and obstetric questionnaire was used to collect information concerning age, education level, occupation, place of residence, economic status, age at marriage, and length of marriage. Also, obstetric questions were asked regarding the number of pregnancies, type of contraceptive method, delivery date of most recent child, desire of pregnancy, type of delivery, perineal injury, instrumental delivery, history of painful intercourse during pregnancy, infant gender, child birth weight, first lactation, and the first time of resumption of sexual intercourse after childbirth. Average frequency of sexual intercourse per week at different measurement time-points were also assessed.

Female Sexual Function Index (FSFI): The FSFI is 19-item scale that was used to evaluate sexual functioning among women over the past four weeks [34]. It comprises six subscales including sex desire, arousal, lubrication, orgasm, satisfaction, and pain. The items (e.g., *"Over the past 4 weeks, how often did you feel sexual desire or interest?"*) are rated from 1 (*Almost never or never*) to 5 (*Almost always or always*). Scores from each subscale are summed and than multiplied to their defined weights. Therefore, the scale scores range from 2 to 36 and higher scores indicate better sexual functioning. The Farsi version of the FSFI is valid and reliable [35].

Edinburgh Postpartum Depression Scale (EPDS): The EPDS is a 10-item scale that was used to assess postpartum depression from 6 weeks after delivery. The items (e.g., *"In the past 7 days, I have been able to laugh and see the funny side of things"*) are rated from 0 (*As much as I always could*) to 3 (*Not at all*). The scale scores range between 0 and 30, with a cutoff point 12. Scores above 12 indicate postpartum depression [36]. The Farsi version of the EPDS is valid and reliable [37].

Sexual Quality of Life-Female (SQOL-F): The SQOL-F is an 18-item scale that was used to assess the relationship between female sexual quality of life [38]. The items (e.g., *"When I think about my sex life, I see it as an enjoyable part of my whole life"*) are rated from 1 (*strongly disagree*) to 6 (*strongly agree*). The scale scores range from 18 to 108 and higher scores indicate better sexual quality life for women. The Farsi version of the SQOL-F is valid and reliable [39].

Adverse events: Participants were asked about experiencing any adverse events including local skin irritation and discomfort, infection of manipulated acupoints, mild tenderness or pain, and dizziness.

2.11 Statistical analysis

For data analysis, SPSS software version 24 was used. The normality of the variables (total score of the FSFI and SQoL) were examined and confirmed using the Shapiro-Wilks test for the indicators of central tendency, dispersion, and histogram diagram. Intergroup comparisons were performed to evaluate the distribution of variables based on the method proposed by Imbens and Rubin, taking into account the standardized mean difference criteria of <0.25 for continuous quantitative variables and <10% risk difference index for categorical variables [40].

To compare the mean score of FSFI and average frequency of weekly sexual intercourse between study groups in different measurement time points, repeated measures analysis of variance–covariance (RM ANOVA-ANCOVA) was used. Mean scores of sexual quality of life were analyzed using analysis of variance–covariance statistics (ANOVA-ANCOVA). All analysis was done with a crude model, an adjusted model (controlling the effect of potential covariates including depression mean score, spouse's sexual desire and educational status, the contraception method, and history of dyspareunia during pregnancy). Bonferroni corrections for multiple comparisons were also performed. The effect sizes of the mean difference (MD) and the standardized mean difference (SMD) were calculated based on Cohen's *d*. A Cohen *d* effect size of 0.2-0.5 was considered as small effect size; 0.8-0.5 was considered as medium effect size; and more than 0.8 was interpreted as large effect size [41]. 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 [42].

The mean difference was examined for minimal clinically important difference (MCID). It is recommended to calculate the MCID for patient-reported outcomes using the distribution-based method [43]. Based on Jacobson et al. [44], MCID is calculated by the following formula:

$$MCID = 1.96 * SD_{base} * \sqrt{2 * (1 - ICC)}$$

Considering SD_{base} of 9.39 for FSFI, and an ICC of 0.986 from four measurement time-points, the calculated MCID was 3.08. Considering SD_{base} of 22.74 for SQoL, and an ICC of 0.97 from two measurement time-points, the calculated MCID for SQoL was 10.92. Also, SD_{base} for the average frequency of weekly intercourse was 0.825 with an ICC of 0.896 from four measurement time-points, the calculated MCID became 0.74 for average frequency of weekly intercourse. The calculated MCID was used to assess clinical significance of intervention and placebo. If the mean difference was higher than the calculated MCID at any follow-up time point, it was deemed to be clinically significant. All analysis were adjusted for identified covariates as aforementioned. The significance level of all tests was considered to be $p<0.05$.

2.12 Missing data management

The primary approach for statistical analysis was partial ITT approach, in which participants who dropped out were excluded from analysis [45]. Considering 15.8% dropped out in the intervention group (6 out of 38 individuals), a conservative approach was taken and missing data were considered as not at random missing [46]. When not at random missing is probable, then sensitivity analysis using imputation methods are needed to explore the effect of missing values on estimated effect size of intervention on variables of interest [47]. For the imputation phase, missing values were estimated using a regression model. Then missing data were replaced and data were re-analyzed using an ITT model. Results before (adjusted model) and after imputation (adjusted model with missing values imputed) were compared to assess the effect of missing values on estimated effect size.

2.13 Ethical considerations and trial registration

The required permits were obtained from the officials of Qazvin University of Medical Sciences to access the health centers of Qazvin province. The research protocol was reviewed and approved by the Ethics and Human Research Committee of Qazvin University of Medical Sciences (Reference: IR.QUMS.REC.1398.056). The present study was registered with the code of IRCT20190626044028N1 in the Clinical Trial Registration Center of Iran. Obtaining informed written consent, voluntary participation in the research, cancellation of the study at any time, and observance of the principle of confidentiality of information even at the time of publication were considered during the study process.

3 Results

3.1 Distribution of baseline characteristics

In the present study, 76 lactating women participated. Table 1 shows the distribution of baseline characteristics. There were significant differences between the two groups regarding baseline score of FSFI and SQoL mean scores, depression mean score, spouse's sexual desire and educational status, contraception method used, and history of dyspareunia during pregnancy. These variables were controlled as covariance.

3.2 Attrition

The attrition rate in present study was 15.8%. Six individuals from the intervention group dropped out of the study. Two dropped out due to minor ear infection in the location of instilling adhesive tape with a seed and one dropped out due to feeling pain when pressing on the location of the adhesive tape with a seed. Three women dropped out before starting the intervention session because their spouse did not want them placing adhesive tapes on their ears. Missing values were managed using the multiple imputation method. Results of the sensitivity analysis are reported as Model 3 in assessing the effect of auricular acupressure on outcome variables.

3.3 Sexual functioning

The results of analysis of variance for repeated measures for crude, adjusted for baseline scores, and covariates with and without multiple imputation (to manage missing values) are shown in Table 2. Auricular acupressure had a significant effect on sexual functioning in the intervention group. In the adjusted model (Model 2, Table 2), the intervention with auricular acupressure significantly increased the mean scores of sexual functioning in the intervention group compared to the control group by 8.37, 8.44, and 7.43 points respectively in three follow-ups (p<0.001).

These changes were also clinically significant, considering mean scores changed after intervention in different follow-ups were much higher than the estimated minimum clinically significant change of 3.08 point for total score of sexual functioning. In addition, the magnitude of the intervention was significant immediately after the intervention (adjusted mean difference [95% CI]: 8.37 [6.27; 10.46] with Cohen's d [95% CI]: 1.81[1.28; 2.34]), one month after the intervention (adjusted mean difference [95% CI]: 8.44 [6.41; 10.48] with

Cohen's *d* [95% CI]: 2.01 [1.46; 2.56]), and two months after the intervention (adjusted mean difference [95% CI]: 7.43 [5.12; 9.71] with Cohen's *d* [95% CI]: 1.57 [1.06; 2.08]).

In order to manage missing values, multiple imputation based on regression method was used. Then all analysis were done by adjusting for baseline score and other potential covariates (Table 2, Model 3). This model confirmed that the estimated effect of intervention with auricular acupressure on sexual functioning among lactating women was not affected by missing values. The mean scores of sexual functioning in the intervention significantly increased compared to the control group by 7.80, 8.47 and 7.91 points respectively in three follow-ups (p<0.001). Also, the magnitude of effect after imputation was still considerable. Comparing the percentage of changes in the magnitude of effect of intervention in Model 2 compared to Model 1 showed 29%, 39% and 18% increase in adjusted Cohen's *d* values. Therefore, the effect of baseline FSFI score (as the only significant covariate in between-participant comparisons) was considerable. However, comparing the percentages of changes in the magnitude of effect of intervention in Model 3 compared to Model 2 showed 6%, 2.5% and 1.3% decrease in adjusted Cohen's *d* values. As these changes were less than 10%, it can be inferred that the missing values did not affect the results of the present study.

3.4 Sexual quality of life

The results of analysis of variance for crude, adjusted for baseline scores, and covariates with and without multiple imputation (to manage missing values) are shown in Table 3. The intervention with auricular acupressure was effective in increasing the mean sexual quality of life scores in the adjusted model for baseline SQoL scores (Table 3). The intervention significantly increased participants sexual quality of life scores on the SQOL-F by 13.73 points in the intervention group compared to the control group (p<0.001). Considering MCID of 10.92 for SQoL-F, this change was clinically significant. The effect size of intervention for female sexual quality was large (adjusted Cohen's *d* [95% CI]: 1.09 [0.58; 1.59]).

Model 3 was conducted to manage missing values based on multiple imputation (Table 3, Model 3). This model confirmed that the estimated effect of intervention with auricular acupressure on female sexual quality of life among lactating women was not affected by missing values. The mean scores of SQoL in the intervention significantly increased compared to the control group by 12.36 points (p<0.001). Also, the magnitude of effect after imputation was still considerable (adjusted Cohen's *d* [95% CI]: 0.99 [0.50; 1.45]). Comparing the percentages of changes in the magnitude of effect of the intervention in Model

2 compared to Model 1 showed 100% increase in adjusted Cohen's *d* values. Therefore, the effect of baseline SQoL score (as the only significant covariate in between-participant comparisons) was considerable. But comparing the percentages of changes in the magnitude of effect of intervention in Model 3 compared to Model 2 showed 9.9% decrease in adjusted Cohen's *d* values. Therefore, the missing values did not affect the results in the present study.

3.5 Frequency of weekly sexual intercourse

The results of analysis of variance for frequency of weekly sexual intercourse using crude, adjusted for baseline scores, and covariates with and without multiple imputation (to manage missing values) are shown in Table 4. The mean frequency of weekly sexual intercourse increased significantly in the intervention group compared to the control group ($p<0.001$) with magnitude of effect equal to 1.14 (0.65; 1.62) immediately after the intervention; 1.07 (0.59; 1.55) one month after the intervention, and 0.8 (0.33; 1.27) two months after the intervention based on Cohen's *d*. Considering the MCID of 0.74, these changes were not clinically significant.

Model 3 was conducted to manage missing values based on multiple imputation (Table 4, Model 3). This model confirmed that the estimated effect of the intervention with auricular acupressure on frequency of weekly intercourse among lactating women was not affected by missing values. The mean scores of weekly sexual intercourse frequency in the intervention significantly increased compared to the control group ($p<0.001$). Comparing the percentages of changes in the magnitude of effect of intervention in Model 2 compared to Model 1 showed 110%, 78%, and 78% increase in adjusted Cohen's *d* values respectively at measurement time points. Therefore, the effect of baseline frequency of weekly sexual intercourse (as only significant covariate in between-participant comparisons) was considerable. However, comparing the percentages of changes in the magnitude of effect of the intervention in Model 3 compared to Model 2 showed 7%, 27%, and 10% decrease in adjusted Cohen's *d* values. Therefore, missing values did not affect the results in the present study.

3.6 Adverse events

Two of the participants dropped out of the intervention due to a minor ear infection, which could have been due to high pressure being applied by the individual at this acupoint. In addition, appropriate treatment measures were performed by the researcher for these

participants (e.g., they were referred to an ear specialist for medical treatment if needed). Moreover, one participant dropped out due to pain in place of seed instillation after the first session.

4 Discussion

The present study investigated the effect of auricular acupressure on women's sexual functioning during their lactation period. The results showed that auricular acupressure had a positive significant effect on sexual functioning of the intervention group immediately, one month, and two months after the intervention compared to the control group. This improvement in sexual functioning was also clinically significant.

Promising effects of auricular acupressure have been reported on various outcomes during the postpartum period including reducing cortisol levels, heart rate, anxiety and fatigue during early postpartum period among women with cesarean section [48], post-cesarean pain [21], and postpartum blues and depression [22]. However, few studies have examined the effect of auricular acupressure on female sexual functioning. Consistent with the results of the present study, previous studies have reported the positive effect of auricular acupressure on sexual functioning among primiparous breastfeeding women [24] and postmenopausal women [23]. Based on selected acupoints and treatment protocol [16], auricular acupressure might improve individuals' sexual functioning by affecting their endocrine function and physiological mechanism related to sexual functioning [2].

While few studies have been conducted using auricular acupressure for improving sexual functioning, various studies have been conducted on the effect of acupuncture. Consistent with results of the present study, previous studies have reported the positive effect of acupuncture including (i) reducing sexual distress and increasing sexual functioning among postmenopausal women [49], (ii) reducing vulvar pain and dyspareunia among women with vulvodynia, (iii) improving sexual desire and lubrication [50], (iv) improvements in perceived sexual health, pain relief, and mental well-being among women with provoked vestibulodynia [51], and (v) effective management of sexual dysfunction secondary to antidepressants among both men and women [52]. Although these studies used acupuncture, acupressure and acupuncture follow the same principles in traditional Chinese medicine.

Auricular acupressure and acupuncture can direct health signal patterns produced from the brain as a result of ear stimulation to different parts of the body [53]. The earlobe is

innervated by various nerves (great auricular nerve, glossopharyngeal nerve, auriculotemporal nerve). Therefore, the earlobe is potentially the best place for direct stimulation of the central nervous system [54, 55]. Due to the rich and numerous connections of the ear with the central nervous system, ear acupuncture and acupressure can be effective in modulating endogenous systems, the sympathetic-parasympathetic nervous system, and the endocrine and neuroendocrine systems [54, 55].

According to the secondary objectives, the results of the present study showed that auricular acupressure increased sexual quality of life and the frequency of monthly sexual intercourse among those undergoing auricular acupressure compared to the control group. The relationship between sexual functioning and sexual quality of life has been documented [56], which confirms the results of the present study. Sexual functioning can significantly affect an individual's quality of life, and an integral part of quality of life is the sexual quality of life [57].

4.1 Limitations

To best of the present authors' knowledge, the present study is one of the first to investigate the effect of auricular acupressure on sexual functioning among lactating women. Moreover, the present study tried to provide a better understanding of changes in sexual functioning and sexual quality of life after auricular acupressure over time. However, the interpretation of the study results should consider the following limitations: (i) a self-report method (i.e., questionnaire) was used to evaluate women's sexual functioning. These measures are patient-reported and vulnerable to various types of bias including social desirability bias. The research team did not have financial support to assess objective biomarkers; (ii) failing to examine the husband's sexual functioning at baseline and follow-up, (iii) there were also problems regarding baseline imbalance distribution of some characteristics between groups and high dropout rate in the intervention group which might have affected the estimated effect size of the intervention. The authors tried to control this limitation while conducting statistical analysis by running adjusted analysis and controlling baseline scores of variables of interest as well as the imbalanced distributed baseline characteristics; (iv) there were also missing values in intervention group for follow-ups. While the missing values were near 16%, it was not expected that this would affect the study results [58]. However, to be more conservative, the authors used multiple imputation method based on regression method to account for missing values. All analyses were conducted with multiple imputed missing data.

Then, estimated effect sizes were compared with adjusted models. Because the percentage changes were less than 10% in almost all study variables through time points, it was concluded that the missing data did not affect the present results considerably; (v) the final limitation related to type of sham pressure used in the present study. Using adhesive tapes with no seed is a common sham manipulation used in literature [30], but finger pressure on acupoints without seeds might have had some therapeutic effect. However, the therapeutic effect of finger pressure on acupoints was not observed in present study because change in FSFI and SQoL mean scores in control group were not significant over study time points.

5 Conclusion

The results of present study showed that the intervention of auricular acupressure was effective in increasing quality of sexual life and sexual functioning among lactating women. Although further research is needed to confirm the efficacy of auricular acupressure, based on the present study's findings, the use of auricular acupressure by women's healthcare providers after childbirth is recommended.

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Data Availability: Data will be available by email to corresponding author.

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Table 1. Distribution of demographic and obstetrics characteristics based on study groups			
Variables		Group	
		Intervention (N=38)	Control (N=38)
		Mean (SD)	Mean (SD)
Age (year)		30.79 (5.87)	30.66 (5.22)
Spouse's age (year)		34.89 (5.99)	34.71 (6.75)
Marriage duration (year)		8.47 (5.38)	8.58 (4.91)
First intercourse after delivery (month)		2.11 (0.93)	2.04 (1.30)
Postpartum depression score		8.97 (2.37)	7.18 (2.89)
Spouse' sexual desire		3.45 (1.11)	3.11 (0.89)
		Frequency (%)	Frequency (%)
Educational status	Under Diploma	9 (23.7)	9 (23.7)
	Diploma	14 (36.8)	15 (39.5)
	Academic	15 (39.5)	14 (36.8)
Spouse' educational status	Under Diploma	18 (47.4)	10 (26.4)
	Diploma	11 (28.9)	16 (42.1)
	Academic	9 (23.7)	12 (31.6)
Spouse's job	Employed	38 (100)	38 (100)
Job	Housewife	37 (97.4)	37 (97.4)
	Employed	1 (2.6)	1 (2.6)
Economic status	Poor	2 (5.3)	1 (2.6)
	Moderate	27 (71.1)	32 (84.2)
	Good	9 (23.7)	5 (13.2)
Housing condition	Rental	19 (50.0)	20 (52.6)
	Landlord	19 (50.0)	18 (47.4)
Mode of Delivery	Normal vaginal delivery with episiotomy	11 (28.9)	11 (28.9)
	Normal vaginal delivery	7 (18.4)	9 (23.7)
	Cesarean section	20 (52.6)	18 (47.4)
Number of children	1	18 (47.4)	14 (36.8)
	2	18 (47.4)	19 (50.0)
	3	2 (5.2)	5 (13.2)
Dyspareunia experienced before pregnancy	No	30 (78.9)	32 (84.2)
	Yes	8 (21.1)	6 (15.8)
Dyspareunia experienced during pregnancy	No	29 (76.3)	35 (92.1)
	Yes	9 (23.7)	3 (7.9)
Neonatal gender	Girl	18 (47.4)	19 (50.0)
	Boy	20 (52.6)	19 (50.0)
Neonatal feeding	Breastfed	32 (84.2)	36 (94.7)
	Both formula and breastfed	6 (15.8)	2 (5.2)
Breastfeeding per day	Less than 8 times	5 (13.2)	2 (5.3)
	8 times or more	33 (86.8)	36 (94.7)
Contraception	Withdrawal	16 (42.1)	22 (57.8)
	Condom	16 (42.1)	8 (21.1)
	Other methods	6 (15.8)	8 (21.1)

Table 2. Results of repeated measure analysis of variance-covariance (RM ANOVA-ANCOVA) to investigate the effect of auricular acupressure on female sexual functioning

Model	Time	Intervention (N=38 at baseline / 32 in follow-ups)	Sham (N=38)	Intervention vs. Sham		Time points comparison		Statistical results for RM ANOVA-ANCOVA			
				MD [95% CI]	SMD [95% CI]	*t*	*p*	Effect	F	*p*	Partial η^2
	Baseline	20.44 (8.69)	23.52 (9.31)	-3.08 [-7.21; 1.04]	-0.40 [-0.86; - 0.05]	-1.49	0.14				
1	Follow-up 1	29.35 (4.72)	23.50 (9.32)	5.84 [2.21; 9.47]	0.79 [0.33; 1.26]	3.39	0.001	Time	44.50	<0.001	0.396
	Follow-up 2	29.59 (4.02)	23.59 (9.26)	6.00 [2.48; 9.52]	0.84 [0.37; 1.31]	3.61	0.001	Group	3.43	0.07	0.048
	Follow-up 3	28.94 (4.89)	23.78 (8.83)	5.16 [1.66; 8.66]	0.72 [0.26; 1.19]	3.09	0.003	Time & Group	42.82	<0.001	0.386
2	Follow-up 1	30.71 (4.33)	22.35 (4.33)	8.37 [6.27; 10.46]	1.81 [1.28; 2.34]	52.866	<0.001	Time	2.92	0.07	0.045
	Follow-up 2	30.92 (4.20)	22.47 (4.20)	8.44 [6.41; 10.48]	2.01 [1.46; 2.56]	61.669	<0.001	Group	56.54	<0.001	0.477
	Follow-up 3	30.17 (4.73)	22.74 (4.73)	7.43 [5.12; 9.71]	1.57 [1.06; 2.08]	41.31	<0.001	Time & Group	1.02	0.36	0.358
3	Follow-up 1	30.34 (4.39)	22.54 (4.39)	7.80 [5.70; 9.90]	1.78 [1.25; 2.31]	54.716	<0.001	Time	4.70	<0.001	0.065
	Follow-up 2	30.81 (4.33)	22.34 (4.33)	8.47 [6.40; 10.55]	1.96 [1.41; 2.50]	66.514	<0.001	Group	61.74	<0.001	0.476
	Follow-up 3	30.38 (4.97)	22.48 (4.97)	7.91 [5.52; 10.29]	1.59 [1.07; 2.11]	43.86	<0.001	Time & Group	0.570	0.55	0.008

MD: Mean difference; SMD: Standardized mean difference; Partial η^2: Partial eta square.
Follow-up 1was immediately after intervention; Follow-up 2 was one month after intervention; Follow-up 3 was two months after intervention.

Table 3. Results of analysis of variance-covariance (ANOVA-ANCOVA) to investigate the effect of auricular acupressure on sexual quality of life

Model	Time point	Intervention (N=38 at baseline / 32 in follow-ups)	Comparison (n=38)	MD (95% CI)	SMD (95% CI)	F	*p*-value	**Partial η^2**
	Baseline	73.39 (23.85)	88.37 (19.09)	-14.97 (-	-0.69 (-1.15; -	9.13	0.003	**0.110**

Model 1: Crude analyzed using RM ANOVA statistics

Model 2: Adjusted for baseline scores and other covariates using RM ANOVA-ANCOVA statistics. In adjusted model, the only significant covariate was FSFI baseline score ($p< 0.001$). Other covariates including postpartum depression score ($p=0.53$), spouse's sexual desire ($p=0.25$), spouse's education level (p=0.55), history of painful intercourse during pregnancy ($p=0.18$), and contraceptive method type (p=0.97).

Model 3: Multiple imputation for missing values with regression model and adjusted for baseline scores and other covariates using RM ANOVA-ANCOVA statistics. In adjusted model after multiple imputation, the only significant covariate was FSFI baseline score ($p<0.001$). Other covariates including postpartum depression score ($p=0.43$), spouse's sexual desire ($p=0.10$), spouse's education level ($p=0.77$), history of painful intercourse during pregnancy ($p=0.14$), and contraceptive method type ($p=0.90$).

				24.85; -5.10)	0.22)			
1	Post-intervention	87.63 (22.89)	87.45 (19.26)	0.17 (-9.87; 10.22)	0.01 (-0.44; 0.45)	0.001	0.97	**0.000**
2	Post-intervention	94.98 (12.74)	81.25 (12.61)	13.73 (7.33; 20.13)	1.09 (0.58; 1.59)	18.41	<0.001	**0.229**
3	Post-intervention	93.30 (12.63)	80.94 (12.63)	12.36 (6.25; 18.46)	0.98 (0.50; 1.45)	16.33	0.001	**0.194**

MD: Mean difference; SMD: Standardized mean difference; Partial η^2: Partial eta square.
Post-intervention assessment was two months after intervention
Model 1: Crude analyzed using RM ANOVA statistics
Model 2: Adjusted for baseline scores and other covariates using ANOVA-ANCOVA statistics. In adjusted model, the only significant covariate was SQoL baseline score (p<0.001). Other covariates including postpartum depression score (p=0.56), spouse's sexual desire (p=0.76), spouse's education level (p=0.14), history of painful intercourse during pregnancy (p=0.75), and contraceptive method type (p=0.75).
Model 3: Multiple imputation for missing values with regression model and adjusted for baseline scores and other covariates using ANOVA-ANCOVA statistics. In adjusted model after multiple imputation, the only significant covariate was SQoL baseline score (p<0.001). Other covariates including postpartum depression score (p=0.69), spouse's sexual desire (p=0.17), spouse's education level (p=0.45), history of painful intercourse during pregnancy (p=0.38), and contraceptive method type (p=0.63).

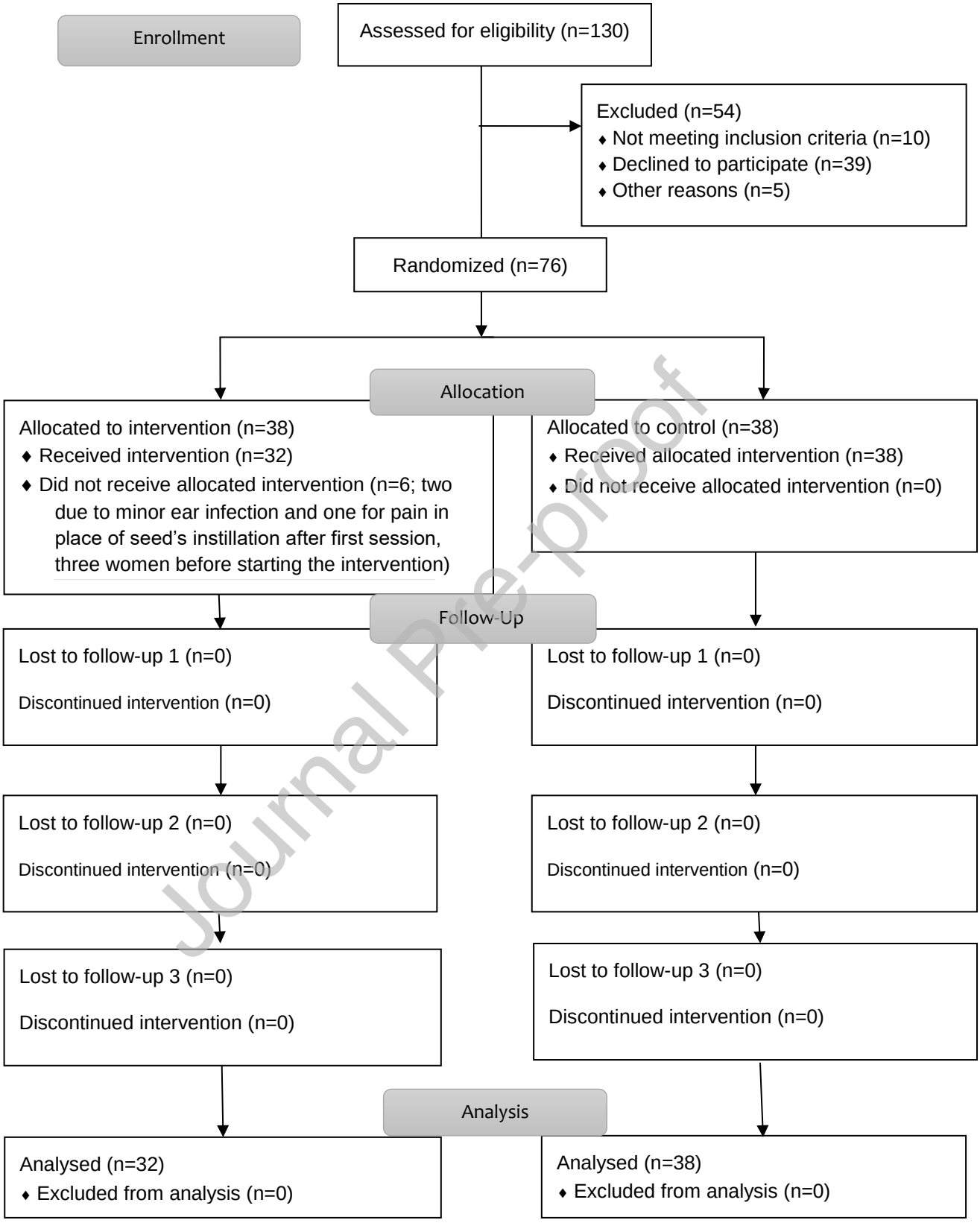
ANCOVA) to investigate the effect of ear acupressure on frequency of sexual intercourse per week

Model	Time point	Intervention (N=38 at baseline / 32 in follow-ups)	Comparison N=38	Intervention vs. Sham		Time points comparison		Statistical results for RM ANOVA-ANCOVA			
				MD (95% CI)	SMD (95% CI)	*t*	*p*-value	Effect	F	*p*-value	Partial η^2
	Baseline	2.16 (0.87)	2.53 (0.73)	-0.37 (-0.74; 0.002)	-0.46 (-0.92;-0.01)	-1.98	0.05				
1	Follow-up 1	2.91 (0.69)	2.53 (0.73)	0.38 (0.04; 0.72)	0.54 (0.08; 0.99)	2.23	0.03	Time	18.59	<0.001	0.217
	Follow-up 2	3.00 (0.84)	2.55 (0.69)	0.45 (0.08; 0.81)	0.60 (0.14; 1.06)	2.45	0.02	Group	1.52	0.22	0.022
	Follow-up 3	2.90 (0.79)	2.58 (0.64)	0.32 (-0.02; 0.67)	0.45 (-0.01 - 0.9)	1.88	0.06	Time & Group	16.37	<0.001	0.196
2	Follow-up 1	3.02 (0.52)	2.43 (0.52)	0.59 (0.33; 0.85)	1.14 (0.65; 1.62)	20.88	<0.001	Time	2.92	0.05	0.046
	Follow-up 2	3.11 (0.58)	2.46 (0.63)	0.65 (0.33; 0.97)	1.07 (0.59; 1.55)	16.86	<0.001	Group	18.67	<0.001	0.234
	Follow-up 3	3.01 (0.65)	2.49 (0.64)	0.52 (0.1	0.8 (0.33; 1.27)	9.97	0.002	Time & Gro	0.27	0.72	0.004

				9; 0.84)				up			
3	Follow-up 1	2.97 (0.52)	2.42 (0.52)	0.55 (0.30; 0.80)	1.06 (0.58; 1.54)	19.31	0.002	Time	2.43	0.09	0.035
	Follow-up 2	3.02 (0.71)	2.47 (0.71)	0.55 (0.21; 0.89)	0.78 (0.31; 1.21)	10.25	0.002	Group	17.81	<0.001	0.208
	Follow-up 3	3.04 (0.64)	2.48 (0.64)	0.56 (0.25; 0.87)	0.88 (0.40; 1.35)	12.99	0.001	Time & Group	0.086	0.917	0.001

MD: Mean difference; SMD: Standardized mean difference; Partial η^2: Partial eta square.
Follow-up 1 was immediately after intervention; Follow-up 2 was one month after intervention; Follow-up 3 was two months after intervention.
Model 1: Crude analyzed using RM ANOVA statistics
Model 2: Adjusted for baseline scores and other covariates using ANOVA-ANCOVA statistics. In adjusted model, the only significant covariate was frequency of weekly sexual intercourse at baseline (p< 0.001). Other covariates including postpartum depression score (p=0.56), spouse's sexual desire (p=0.67), spouse's education level (p=0.20), history of painful intercourse during pregnancy (p=0.51), and contraceptive method type (p=0.62).
Model 3: Multiple imputation for missing values with regression model and adjusted for baseline scores and other covariates using ANOVA-ANCOVA statistics. In adjusted model after multiple imputation, the only significant covariate was frequency of weekly sexual intercourse at baseline (p<0.001). Other covariates including postpartum depression score (p=0.94), spouse's sexual desire (p=0.35), spouse's education level (p=0.05), history of painful intercourse during pregnancy (p=0.49), and contraceptive method type (p=0.92).

Figure 1. CONSORT flow diagram



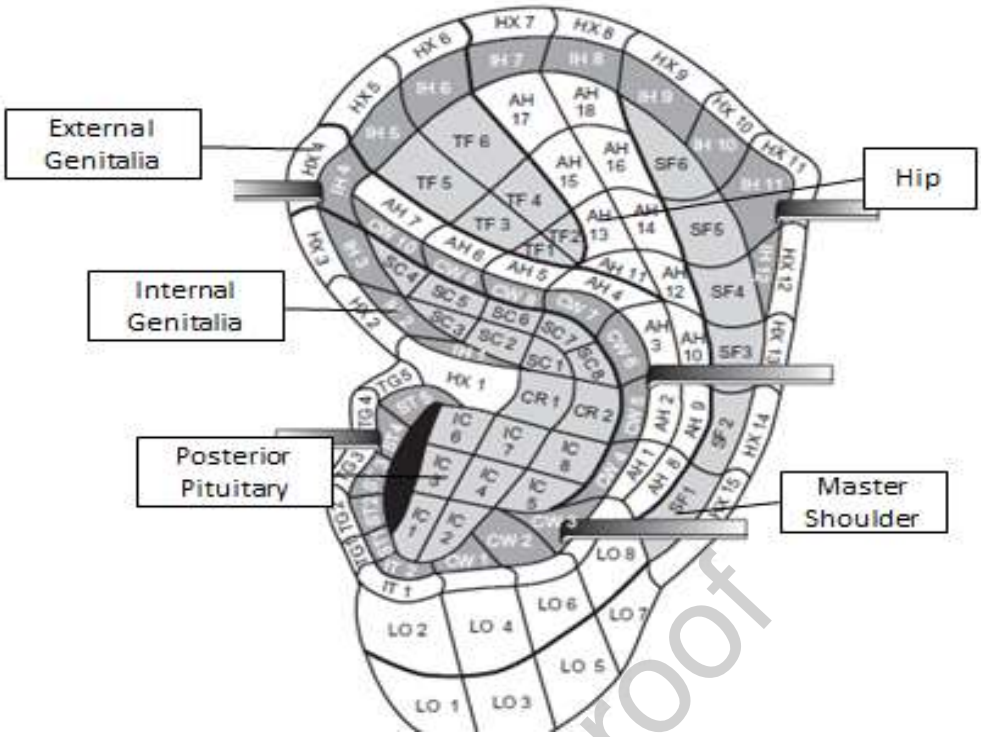


Figure 2. The selected ear acupoints

Authors' contributions

SB, ZA, NB, MHA & TO contribute to design of the study. SB, NB, MHA and ZA drafted the preliminary manuscript. TO and MG revised the manuscript and prepared the final version of manuscript. All authors revised the manuscript, agreed to be fully accountable for ensuring the integrity and accuracy of the study, and read and approved the final version of the manuscript to be published. All the authors met the criteria for authorship and listed as co-authors on the title page.

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.

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