Effectiveness of Auricular Acupressure for Chronic Low Back Pain and Related Symptoms in Postmenopausal Women

Protocol version	Version 3
Protocol date	November 28, 2025
Study design	Randomized, parallel-group, sham-controlled interventional study
Planned sample size	70 participants (35 per group)
Study duration	From IRB approval through December 31, 2026
Funding source	Taiwan Nurses Association

1. Study Overview

This study evaluates the effectiveness of a four-week auricular acupressure intervention for chronic low back pain and related symptoms in women aged 50–65 years who are in the late menopausal/postmenopausal stage. Participants with nonspecific chronic low back pain lasting more than 12 weeks will be randomly assigned in a 1:1 ratio to an auricular point acupressure (APA) group or a sham auricular point (SAP) control group.

The study uses repeated outcome assessments at baseline, immediately after the four-week intervention, two weeks after completion of the intervention, and four weeks after completion of the intervention.

2. Background and Rationale

As women age, ovarian function gradually declines and female hormone secretion decreases, which may contribute to a range of physical and psychological symptoms. Chronic low back pain is a common symptom burden among women during and after the menopausal transition. Evidence specifically addressing auricular acupressure for chronic low back pain in postmenopausal women remains limited.

This study integrates concepts from traditional Chinese medicine and auricular acupressure to examine whether stimulation of selected auricular points can reduce chronic low back pain and improve menopause-related physical and psychological symptoms.

3. Study Objectives

3.1 Primary Objective

To evaluate the effectiveness of a four-week auricular acupressure intervention in reducing chronic low back pain–related outcomes in postmenopausal women.

3.2 Additional Objective

To evaluate changes in menopause-related symptoms following auricular acupressure and to determine whether changes differ between the intervention and sham-control groups over time.

4. Study Design

This is a prospective, randomized, parallel-group, sham-controlled interventional study with repeated measurements. Participants will be allocated in a 1:1 ratio to the APA group or SAP control group using a computer-generated randomization table created with Research Randomizer.

Randomization assignments will be placed in opaque envelopes. After completion of informed consent and baseline assessments, each participant will draw an envelope. The envelope will be provided to the nurse interventionist trained in traditional Chinese medicine nursing, who will implement the assigned auricular acupressure procedure. The protocol describes blinding of participants and the interventionist.

The planned enrollment is 70 participants, with 35 participants in each group.

5. Study Setting and Recruitment

Participants will be recruited from traditional Chinese medicine outpatient clinics at Kaohsiung Medical University Chung-Ho Memorial Hospital, Kaohsiung Medical University Gangshan Hospital, and community traditional Chinese medicine clinics in southern Taiwan.

Potential participants will be identified and assessed by physicians in the outpatient setting. Women who meet the eligibility criteria and express interest will meet with the principal investigator in a clinic consultation room or research room. The investigator will explain the study purpose, procedures, potential risks, participant rights, and follow-up requirements before written informed consent is obtained.

6. Study Population

6.1 Inclusion Criteria

- Women aged 50–65 years.
- Nonspecific low back pain lasting more than 12 weeks.

6.2 Exclusion Criteria

- Unable to read.
- Cardiovascular disease, including arrhythmia, heart failure, or coronary artery disease.
- Malignant tumor.
- Infection, skin breakdown, or other compromised skin around the ear.
- History of lumbar spine surgery.

7. Sample Size

Sample size estimation was performed using G*Power 3.1.9.4 for Windows. The calculation was based on an ANCOVA F test (fixed effects, main effects and interactions), with statistical power of 0.80, a two-sided alpha level of 0.05, and an effect size of 0.50. The estimated required sample size was 53 participants. After allowing for an anticipated 20% attrition rate, the target enrollment was increased to at least 70 participants, with 35 participants per group.

8. Interventions

8.1 Auricular Point Acupressure Group

Participants assigned to the APA group will receive bilateral auricular acupressure at four auricular points: Shenmen, Sympathetic, Subcortex, and Lower Back.

8.2 Sham Auricular Point Control Group

Participants assigned to the SAP control group will receive bilateral auricular acupressure at four auricular points selected as non-target points for chronic low back pain: Stomach, Mouth, Duodenum, and Tonsil.

8.3 Intervention Materials and Procedure

Both groups will receive magnetic beads manufactured by Sakamura Laboratory, Japan. Auricular acupressure will be administered by a nurse who has completed training in traditional Chinese medicine nursing.

Before application, the auricular skin will be disinfected with a 75% alcohol pad and allowed to dry. Using forceps, the interventionist will place adhesive tape containing a magnetic bead on each selected auricular point while stabilizing the auricle. Bilateral auricular acupressure will be applied.

Each weekly treatment cycle consists of five days with the magnetic beads in place followed by two days without the beads. Participants will return weekly to the hospital research room or outpatient clinic for replacement of the magnetic beads. Treatment will continue for four weeks.

Participants will be instructed to press the taped auricular points three times daily—morning, noon, and evening—for three minutes each time. Auricular acupressure materials will be removed at the end of Week 4.

9. Study Procedures and Assessment Schedule

Assessment	Baseline (T0)	Week 4 (T1)	2-week follow-up (T2)	4-week follow-up (T3)
Informed consent	X			
Demographic data	X			
Greene Climacteric Scale	X	X	X	X
Brief Pain Inventory–Taiwan Form	X	X	X	X
Roland–Morris Disability Questionnaire	X	X	X	X
Auricular acupressure		Weeks 1–4		

Baseline questionnaires will be completed before randomization. At Week 4, the auricular acupressure materials will be removed and post-intervention questionnaires will be completed. Follow-up questionnaires will be mailed to participants two and four weeks after completion of the intervention.

10. Outcome Measures

10.1 Greene Climacteric Scale (GCS)

The Greene Climacteric Scale will be used to assess menopause-related symptoms, including physical and psychological symptom responses.

10.2 Brief Pain Inventory–Taiwan Form (BPI-T)

The Chinese/Taiwan version of the Brief Pain Inventory will be used to assess pain-related outcomes, including pain severity and the interference of pain with daily functioning.

10.3 Roland–Morris Disability Questionnaire (RMDQ)

The Chinese version of the Roland–Morris Disability Questionnaire will be used to assess low back pain–related functional disability.

10.4 Demographic and Clinical Characteristics

Baseline demographic and clinical information will include variables such as age, body mass index, menarche age, reproductive history, menopausal status, marital status, education, work characteristics, smoking, chronic disease, hormone therapy, analgesic use, sedative use, chronic medication use, and exercise habits.

11. Statistical Analysis

Statistical analyses will be conducted using IBM SPSS Statistics Version 22.0. Descriptive statistics will be used to summarize participant characteristics and study outcomes. Categorical variables will be summarized using frequencies and percentages, and continuous variables will be summarized using means and standard deviations.

Chi-square tests will be used to compare categorical baseline characteristics between groups. Independent-samples t tests will be used to compare continuous baseline characteristics and selected between-group outcome differences. Paired-samples t tests will be used to examine within-group changes across study assessments.

Generalized estimating equations (GEE) will be used for repeated-measures analyses. The models will include group, time, and the group-by-time interaction as independent factors. Continuous outcome variables will include menopause-related symptoms and low back pain–related outcomes. The GEE analyses will evaluate whether the magnitude of change differs significantly between the APA and SAP groups across baseline, post-intervention, two-week follow-up, and four-week follow-up assessments.

12. Data Collection, Confidentiality, and Retention

Study questionnaires will be completed using coded study identifiers to protect participant privacy. Study data will be de-linked from direct personal identifiers. Only research personnel directly involved in the study will have access to the data.

Electronic study data will be stored in encrypted files on the principal investigator's computer. The data management location is the principal investigator's office at Kaohsiung Medical University Chung-Ho Memorial Hospital. Study data will be retained for three years after study completion and then securely destroyed. Electronic storage media will be reformatted as part of the final data destruction process.

13. Participant Compensation

Participants will receive NTD 200 after each auricular acupressure visit, for up to four intervention visits (maximum NTD 800). Participants will also receive NTD 200 after completion of each mailed follow-up questionnaire at two and four weeks after the intervention (maximum additional NTD 400).

14. Safety and Risk Management

This study does not involve blood collection, biological specimen collection, or invasive examinations. If a magnetic bead becomes detached or if a participant has questions or concerns related to auricular acupressure, the participant may contact the research team.

If a participant experiences fatigue, discomfort, or wishes to discontinue participation for any reason, the research team will assess the situation. Participation is voluntary, and a participant may discontinue study participation without affecting medical care or legal rights.

According to the source protocol, if pain is not relieved during the auricular acupressure intervention, a co-investigator may evaluate the participant and provide an appropriate analgesic regimen as clinically indicated. Questionnaire data will remain confidential.

15. Ethical Considerations and Informed Consent

The study will be conducted in accordance with the requirements of the institutional review board and applicable ethical principles for human-subject research. Potential participants will receive sufficient information about the study and will be given the opportunity to make a voluntary decision without coercion or undue influence.

Written informed consent will be obtained before any study-specific procedures are performed. Participation or refusal to participate will not affect a participant's medical care. Participants will not waive any legal rights by signing the informed consent form.

16. Withdrawal and Discontinuation

Participants may withdraw from the study at any time. If a participant experiences discomfort, fatigue, or another reason for discontinuation, the investigator will discuss the reason with the participant and determine whether study participation can safely continue. The participant's decision to withdraw will be respected.

17. Expected Benefits

Auricular acupressure may reduce chronic low back pain–related discomfort and may improve physical and psychological symptoms associated with menopause. The study is expected to provide evidence regarding the use of auricular acupressure as a noninvasive supportive intervention for postmenopausal women with chronic low back pain.

18. Study Sites

- Kaohsiung Medical University Chung-Ho Memorial Hospital, Department of Chinese Medicine.
- Kaohsiung Medical University Gangshan Hospital, Department of Chinese Medicine.
- Community traditional Chinese medicine clinics in southern Taiwan.

19. Funding

The study is funded by the Taiwan Nurses Association. The planned research budget reported in the source protocol is NTD 286,770.

20. Dissemination

Study findings are intended for publication in academic journals.

21. Protocol Source Note

This English protocol was rewritten from the Chinese IRB protocol (Version 3, dated November 28, 2025) for English-language clinical trial submission. It preserves the study design, eligibility criteria, intervention procedures, outcome assessments, planned sample size, statistical methods, safety procedures, and data-management provisions stated in the source protocol.