Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of ear acupressure on Quality of Life among menopausal women : A randomized sham controlled trial

Protocol summary

Study aim
Investigate the effect of auricular acupressure on quality of life in postmenopausal women

Design
Clinical trial with sham control group with parallel groups, double-blind, randomized, phase 3 on 120 patients, randomization by quadruple blocking method using randomizer website

Settings and conduct
The present study will be conducted in urban comprehensive health centers of Qazvin University of Medical Sciences on 120 postmenopausal women randomly assigned into intervention or sham control group. For blinding, the placebo group will be used in such a way that none of the eligible people know which group they are in, and in the placebo group, special adhesives without Vacaria seeds will be pasted in the same ear acupoints. The outcome assessor and the person who will perform the analysis will also perform the analysis based on the codes and will not know about the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being married, being menopausal (absence of menstruation in the past year), having a normal earlobe without lesions, wounds and pain in the earlobe, being available during the study period.
Exclusion criteria: having a history of chronic mental and physical illness, substance abuse in the individual or his spouse, history of using acupressure in the last three months, history of stressful events in the last three months

Intervention groups
Ear acupressure group: special adhesives contain Vakaria seeds will be attached on designated points on the person's ear. A number of 10 sessions are held with four-day intervals for each person. During this time, she should press each point for twenty seconds three times a day. Placebo group (sham): They will be visited the same as the intervention group, and the same special adhesives without Vakaria seeds will be placed in the same ear acupoints.

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180218038789N7**
Registration date: **2023-07-28, 1402/05/06**
Registration timing: **prospective**

Last update: **2023-07-28, 1402/05/06**
Update count: **0**

Registration date
2023-07-28, 1402/05/06

Registrant information

Name
Zainab Alimoradi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2024-02-04, 1402/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of ear acupressure on Quality of Life among menopausal women : A randomized sham controlled trial

Public title
The effect of ear acupressure on Quality of Life among menopausal women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being married Being menopause Has a natural earlobe without lesions, sores and pain in the earlobe Having a literacy education Availability during the study period
Exclusion criteria:
History of chronic mental and physical illness (self-report and review of the individual's file) Substance abuse in the person or his spouse History of using acupressure in the last three months History of stressful events in the last three months (such as the loss of a loved one)
Age
From **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be done by balanced blocks randomization method with blocks size of 4. The randomization unit will be the participants. Each letter is assigned to each group to construct the allocation sequence (A: Ear Acupressure Intervention Group, B: Sham control Group). The allocation sequence will then be generated using online methods without individual intervention. Then, to conceal the allocation sequence, the sequence is written on the sheets and placed in sealed envelopes, respectively.
Blinding (investigator's opinion)
Triple blinded
Blinding description
For blinding, the placebo group will be used as a sham. The sham group is used in such a way that special labels for auriculotherapy, which contain SID to create pressure in the position, will be used in the auriculotherapy group. In the sham group, the same labels but without seeds will be used to remove the pressure effect at the same points. In this way, none of the eligible people know which group they are in. The outcome assessment will be done by a trained person outside the research team without knowing the assigned group of people and using a telephone interview. The person who will do the analysis will also do the analysis only based on the codes and will not know about the intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Qazvin, Bahonar blevard
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2023-07-12, 1402/04/21
Ethics committee reference number
IR.QUMS.REC.1402.096

Health conditions studied

1

Description of health condition studied
Quality of life
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life of postmenopausal women
Timepoint
Before the intervention, one and two months after the end of the intervention
Method of measurement
Quality of life questionnaire for postmenopausal women

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group with ear acupressure: acupressure intervention will be done by placing special adhesives containing Vacaria seeds on points of the ear including Chinese and European uterine points, ovary point, zero point, Shan Man point and brain point, gonadotrophin point and sympathetic point. A number of 10 sessions will be held at intervals of four days for each person, and during this period, each point should press selected ear acupoints three times a day for twenty seconds. The material used in this study is special auriculotherapy adhesives containing vacaria seeds, which is a product of China. This product will be available from medical equipment stores.

Category
Treatment - Other

2

Description
Control group (sham): will receive the same visits as the intervention group. In this group, special adhesives without Vacaria seeds will be placed on the same points of the ear as the intervention group. A number of 10 sessions will be held at four-day intervals for each person, and they are also asked to press the identified ear acupoints three times a day for twenty seconds.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Urban Health Centers of Qazvin University of Medical Sciences

Full name of responsible person
Zainab Alimoradi

Street address
Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Mahdi Mirhashemi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Zainab Alimoradi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data can be shared after de-identifying individuals in correspondence with the responsible researcher.

When the data will become available and for how long
As soon as the findings are published as articles in scientific journals

To whom data/document is available
For academic researchers and after submitting a formal request and explaining the reasons for needing access to the data

Under which criteria data/document could be used
For use in secondary analysis and meta-analysis

From where data/document is obtainable
Send the request to the responsible researcher's email (Zainab Alimoradi)

What processes are involved for a request to access data/document
The data will be sent to the requester within one month after sending the request with sufficient explanation

Comments