Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of auricular acupressure compared to sham control on sexual function in postmenopausal women

Protocol summary

Study aim
The effect of auricular acupressure on sexual function in postmenopausal women

Design
Clinical trial with sham control group with parallel groups, double-blind, randomized, phase 3 on 90 patients, randomization by quadruple blocking method using randomizer website

Settings and conduct
The present study will be performed in Kowsar Hospital and the Comprehensive Urban Health Centers of Qazvin University of Medical Sciences. This study will be performed on 90 postmenopausal women who will be randomly divided into intervention and control groups. Questionnaires will be completed by the participants before and after the intervention. Placebo group will be used for blinding. In this way, none of the eligible people know in which group they are and the person who will perform the analysis will also perform the analysis based only on the codes and will not have information about the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion: Being menopause (lack of menstruation in the past year) Having a natural earlobe without lesions, sores and pain in the earlobe Having a literacy education Having a spouse Availability during the study period Exclusion: History of chronic mental and physical illness 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

Intervention groups
Ear Acupressure: Vaccaria seeds are attached with special adhesives to the parts of the ear that affect a person's sexual function. There are 10 sessions with four-day intervals for each person. During this time he should press each point three times a day for twenty seconds. Placebo (Sham) control: Similar to the intervention group, they will be visited and special adhesives without Vaccaria seeds will be installed in the same acupoints.

Main outcome variables
sexual function

General information

Reason for update
Enter the actual date of start and end of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20180218038789N6**
Registration date: **2022-04-13, 1401/01/24**
Registration timing: **prospective**

Last update: **2023-06-02, 1402/03/12**
Update count: **1**

Registration date
2022-04-13, 1401/01/24

Registrant information

Name
Zainab Alimoradi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
2022-06-20, 1401/03/30

Actual recruitment end date
2022-09-24, 1401/07/02
Trial completion date
2023-01-30, 1401/11/10

Scientific title
The effect of auricular acupressure compared to sham control on sexual function in postmenopausal women

Public title
The effect of auricular acupressure on sexual function in postmenopausal women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Married women 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
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**
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: Comparison 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)
Double blinded
Blinding description
For blinding, placebo group will be used as sham. The sham group is used in such a way that special auricular therapy labels that contain a sieve to put pressure on the position will be used in the auriculotherapy group. In the sham group, the same labels but without the seed will be used to remove the pressure effect in the same places. In this way, none of the eligible people know in which group they are and the person who will perform the analysis will also perform the analysis based only on the codes and will not have information 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
Shahid Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
59811-34197
Approval date
2022-02-14, 1400/11/25
Ethics committee reference number
IR.QUMS.REC.1400.450

Health conditions studied

1

Description of health condition studied
The effect of auricular acupressure on sexual function in postmenopausal women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Evaluation of sexual function of postmenopausal women
Timepoint
Evaluation of sexual function in both intervention and control groups before intervention and immediately, one and two months after the intervention
Method of measurement
Use of questionnaires: sexual dysfunction, female sexual function index

Secondary outcomes

1

Description
Sexual distress
Timepoint
Assessment of sexual distress in both the intervention and control groups before intervention and immediately, one and two months after the end of the intervention
Method of measurement
Female sexual distress scale

Intervention groups

1

Description
Acupressure group: Vaccaria seeds with special adhesives on parts of the ear (Chinese and European genital points, libido point, ovarian point, zero point, Shenmen point and brain point) which affects a person's sexual function , Is pasted. There are 10 sessions with four-day intervals for each person and during this period, each point should be pressed three times a day for twenty seconds. The material used in this study is special adhesives for uriculotherapy containing Vakaria seed, which is a product of China. This product will be available from medical equipment stores.
Category
Treatment - Other

2

Description
Control group: Sham group, which will receive similar visits to the auricular therapy group. In this group, special adhesives but without Vacaria seeds are applied to areas of the ear that are similar to the intervention group. 10 sessions are held at intervals of four days for each person and they are also asked to press the place of non-sided adhesives three times a day at each point for twenty seconds.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital, Qazvin University of Medical Sciences
Full name of responsible person
Zainab Alimoradi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyed Mehdi Mirhashemi
Street address
Qazvin, Shahid Bahonar Boulevard, School of Nursing and Midwifery
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researchdpt@qums.ac.ir
Web page address
https://vcr.qums.ac.ir/fa-IR/vcr.qums.ac/
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available