

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6003

##### Email address

z.alimoradi@qums.ac.ir

##### 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 auriculotherapy containing Vaccaria 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 Vaccaria 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

#### Street address

Qazvin, Taleghani Street

#### City

Qazvin

#### Province

Qazvin

#### Postal code

13176- 34156

### Phone

+98 28 3323 6378

### Email

itkosar@qums.ac.ir

## 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

#### City

Qazvin

#### Province

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59811-34197

#### Phone

+98 28 3334 4854

#### Email

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

Ph.D.

#### Other areas of specialty/work

Midwifery

#### Street address

Bahonar blevard, Qazvin university of Medical Science, School of Nursing & Midwifery

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**Email**

zainabalimoradi@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Zainab Alimoradi

**Position**

Associate Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

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**Name of organization / entity**

Qazvin University of Medical Sciences

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Zainab Alimoradi

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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