

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating the comparative effectiveness of biofeedback and auriculotherapy on menopoused women's hot flashes referred to private clinics of gynecologists in Kerman city, 2019

#### Protocol summary

##### Study aim

Investigating the comparative effectiveness of biofeedback and auriculotherapy on menopoused women's hot flashes referred to private clinics of gynecologists

##### Design

**Biofeedback Group:** This group uses a Canadian biofeedback device by a researcher to run the biofeedback. The biofeedbacks of each subject were recorded in the office and under controlled conditions and recorded as baseline (respiratory biofeedback, skin electrical response, skin temperature). **Auriculotherapy Group:** The researcher, after disinfecting the ear with 70% alcohol in endocrine, ovarian, Shen-man, Long-ears in the left ear, and Mr. Schuller in the right ear, stimulated anxiety, thalamic in the right ear by an Excel 2 device, and then labeled the Vakaria plant ( Sides) that can remain in the ear for three days in the ear at the specified point.r.

##### Settings and conduct

The present study is a quasi-experimental clinical trial study with control and intervention groups and pre- and post-test design. The sample of the study is women from the same community who meet the inclusion criteria.

##### Participants/Inclusion and exclusion criteria

1- At least one year after menstruation 2 - Hot flashes at least twice a day 3 - age 60-45 years 4. Willingness to participate in the research project and to complete the written consent form 5- Being Iranian

##### Intervention groups

The control, biofeedback and uriculotherapy groups were randomly divided. Before intervention, demographic questionnaires and hot flash questionnaires were completed by all three groups. The intervention will receive two sessions per week and each session runs 30 minutes individually for 5 weeks.

##### Main outcome variables

Hot flashes

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20190728044351N1**

Registration date: **2019-08-27, 1398/06/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-27, 1398/06/05**

Update count: **0**

##### Registration date

2019-08-27, 1398/06/05

##### Registrant information

##### Name

somayeh eslami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3372 9130

##### Email address

sos.eslami@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2019-11-22, 1398/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the comparative effectiveness of biofeedback and auriculotherapy on menopausal women's hot flashes referred to private clinics of gynecologists in Kerman city, 2019

**Public title**  
Investigating the comparative effectiveness of biofeedback and auriculotherapy on menopausal women's hot flashes referred to private clinics of gynecologists

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
At least one year after menstruation Hot flashes at least twice a day Age 60-45 years old Willingness to participate in the research project and to complete the written consent form Being Iranian

**Exclusion criteria:**  
History of hysterectomy and oophorectomy Hypertension and Cardiovascular Diseases, Thromboembolic, Thyroid Endocrine Use of tobacco or alcohol Malignancy Abnormal vaginal bleeding taking hormones and taking drugs that affect vasomotor symptoms

**Age**  
From **45 years** old to **60 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **39**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple random and accessible All postmenopausal women referred to the gynecologist's office within the first 4 days of the week Which are divided into throwing coins into specified groups.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**

Not used  
**Assignment**

Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

#### Street address

Seven Garden Alavi Highway

#### City

Kerman

#### Province

Kerman

#### Postal code

7616913555

#### Approval date

2019-07-24, 1398/05/02

#### Ethics committee reference number

IR.KMU.REC.1398.202

## Health conditions studied

1

### Description of health condition studied

Hot flashes

#### ICD-10 code

Z76.89

#### ICD-10 code description

Chapter XXIFactors influencing health status and contact with health services(Z00-Z99)

## Primary outcomes

1

### Description

Hot flashes

#### Timepoint

Before intervention, demographic questionnaire and hot flash questionnaire were completed by all three groups and completed 4 weeks and 8 weeks after the intervention.

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Biofeedback Group:In this group of Canadian biofeedback device BioGraph Infiniti V4 Plus (Infiniti SN: CB1726 \ Enc Key Cod:(848981408 \ App Key Code: 1589114055 is used by the researcher to perform biofeedback. Each subject in the office and under controlled conditions, the relevant biofeedback is recorded and recorded as a baseline.Respiratory Biofeedback: In a respiratory biofeedback, the relevant

sensors are installed around the person's chest and the person is instructed to look at the training monitor to change their breathing pattern. Biofeedback for heart rate: This type of biofeedback is known as a method for heart rate variability. As the name implies, it helps the person control their heart rate. Skin response: In skin response method, the sweat of the skin surface is measured. The level of sweating on the skin, called the skin's electrical response, is a good criterion for examining emotions in a person. That is, the emotional state of the skin's electrical response changes. Skin temperature: People experience a decrease in skin temperature during stress. By monitoring skin temperature, people learn when to enter the stress and anxiety phase and how they can control it.

**Category**

Behavior

**2****Description**

Intervention group: Biofeedback Group: Uriculotherapy Group: Researcher after disinfecting the ear with 70% alcohol in endocrine, ovarian, Shen Man, Long I in the left ear and Master Scholler points in anxiety, thalamic in the right ear by Excel 2 device, stimulated each point for 5 seconds and then Put labels containing the plant Vakaria (Say) that can remain in spots for three days at the specified points in the ears and teach the study subjects to sit on the spot every two hours for one minute with Press the finger (emphasis added to the extent that it causes pain and burning in the outer ear).

**Category**

Treatment - Devices

**3****Description**

Control group: Control group receiving routine care

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Gynecologist's office

**Full name of responsible person**

Somayeh Sadat Eslami

**Street address**

Seven Garden Alavi Highway

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3340 1256

**Email**

sos.eslami@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr.Pardakhti

**Street address**

Jahad Street

**City**

Kerman

**Province**

Kerman

**Postal code**

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+98 34 3340 1256

**Email**

sos.eslami@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Neuroscience Research Center

**Proportion provided by this source**

60

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Somayeh Sadat Eslami

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Seven Garden Alavi Highway

**City**

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**Province**

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**Postal code**

7616913555

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**Email**

sos.eslami@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Somayeh Sadat Eslami

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Somayeh Sadat Eslami

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Phone**

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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**

All individual data of study participants are shared after unidentifiable individuals

**When the data will become available and for how long**

The access period begins 6 months after the results are published

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Applicable to complementary medicine groups

**From where data/document is obtainable**

Email address, or website, and phone and fax numbers, along with the names and addresses of the respondent

**What processes are involved for a request to access data/document**

Minimum time needed to get one week of documentation

**Comments**