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. Schulder 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 menopoused 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 menopoused 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 ophorectomy 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

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Kerman

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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

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Province

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Postal code

7616913555

Phone

+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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Somayeh Sadat Eslami

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Kerman University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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