Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of acupuncture points stimulation with transcutaneous electrical acupoint stimulation device on sleep quality and menopausal symptoms in postmenopausal women

Protocol summary

Study aim

Study the effect of acupuncture points stimulation with transcutaneous electrical acupoint stimulation device on sleep quality and menopausal symptoms in postmenopausal women

Design

This study is a non-blind clinical trial with a parallel design and a control group. The study population will include all postmenopausal women referring to Sanandaj health center. 39 eligible people will be selected conveniently. Random blocks are used for randomization and participants are assigned to three groups (one intervention group and two controls).

Settings and conduct

This study is a non-blinded clinical trial. In this study, acupuncture will be performed with electrical impulses with a voltage of 3.5 volts, a frequency of 2.5 Hz, and a current of 500 microamperes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of acupuncture; A minimum of one year and a maximum of 4 years have elapsed since the last menstrual period; No use of hormone therapy for the past 6 months; A normal menopause Exclusion criteria: Very severe menopausal symptoms that affect sleep quality; Severe depressive disorder and anxiety; Drug addiction

Intervention groups

In the intervention group, six bilateral HT7, P6, and LI4 acupuncture points will be performed for four weeks twice a week (eight sessions) for five minutes each time for fifty seconds for each point. In the first control group, six bilateral HT7, P6, and LI4 acupuncture points will be performed for four weeks twice a week (eight sessions) for five minutes each time for fifty seconds for each point, but the device is off. In the second control group, no intervention will be performed

Main outcome variables

Sleep quality, Flushing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N167**
Registration date: **2021-04-18, 1400/01/29**
Registration timing: **prospective**

Last update: **2021-04-18, 1400/01/29**
Update count: **0**

Registration date

2021-04-18, 1400/01/29

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupuncture points stimulation with transcutaneous electrical acupoint stimulation device on sleep quality and menopausal symptoms in postmenopausal women

Public title

The effect of acupuncture points stimulation on sleep quality and menopausal symptoms in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of acupuncture; A minimum of one year and a maximum of 4 years have elapsed since the last menstrual period No use of hormone therapy for the past 6 months A normal menopause

Exclusion criteria:

Very severe menopausal symptoms that affect sleep quality Severe depressive disorder and anxiety Drug addiction

Age

From **47 years** old to **57 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

The permutation random block is used for randomization. In this way, first, the total sample size and the ratio of sample size in groups are determined. Then, the number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block is 0.5. Block 4-0 for the first group and block 5-9 for the second treatment can be used. Based on the selected numbers from the table of random numbers and the determination of blocks, it is clear in which group each person who enters the study will be placed.

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 Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

ir.kums.rec.1400.001

Health conditions studied

1

Description of health condition studied

Quality of Sleep

ICD-10 code

G47.9

ICD-10 code description

Sleep Disorder, Unspecified

2

Description of health condition studied

Menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Sleep quality

Timepoint

End of the intervention and one month after the end of the intervention

Method of measurement

Based on the Pittsburgh Sleep Quality Questionnaire

2

Description

Flushing

Timepoint

Before and after the intervention (one month later)

Method of measurement

Using the Visual Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, six bilateral HT7, P6 and LI4 acupuncture points will be performed for four weeks twice a week (eight sessions) for five minutes each time for fifty seconds for each point.

Category

Treatment - Other

2

Description

In the first control group, six bilateral HT7, P6 and LI4 acupuncture points will be performed for four weeks twice a week (eight sessions) for five minutes each time for fifty seconds for each point, but the device is off.

Category

Other

3

Description

In the second control group, no intervention will be performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sanandaj Health Center

Full name of responsible person

Somayeh Parvandi

Street address

Salahuddin Ayoubi Street, Taleghani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Somayeh Parvandi

Position

Master student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available