Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of auricular acupressure on the quality of life of postmenopausal women

Protocol summary

Study aim
The aim of this study is to determine the effect of auricular acupressure on the quality of life of postmenopausal women.

Design
Three arm parallel group, randomised trial, with single-blind outcome assessment

Settings and conduct
This three arm clinical trials will be conducted on postmenopausal women who have inclusion criteria. After confirming the inclusion criteria demographic and specific quality of life questionnaire for menopause will be completed. Then, the patients were randomly allocated to interventional and control groups.The sample size, including the attrition will be 45 for each group. The midwife who help to complete the questionnaires is unaware of the type of group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patient's willingness to participate in this study Residence in Mashhad Having an age between 45-60 Non-use of tobacco Non-menstruation at least 12 months ago natural Menopause Women who have any of the physical and psychological symptoms such as flushing, sweating, sleeplessness, anxiety, depression, etc. Menopause is less than 10 years No history of surgery on the ovary No current use of any herbal medicine Not receiving hormonal and non-hormonal drugs in the last 6 months to reduce menopausal complications No history of cardiovascular disease in the past 6 months Not having thyroid disease Not having a history of abnormal vaginal bleeding Not using other complementary therapies Exclusion criteria: Unwillingness to continue cooperation Doing Acupressure less than twice a week

Intervention groups
Three groups of intervention (1-auricular acupressure with seed) and 2- control group (auricular acupressure without seed) and (routine care)

Main outcome variables
The quality of life for menopause, which in fact measures the annoying symptoms of this period

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160731029134N2**
Registration date: **2019-01-11, 1397/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-11, 1397/10/21**
Update count: **0**

Registration date
2019-01-11, 1397/10/21

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3845 1795

Email address
hadizadehz941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2019-03-03, 1397/12/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of auricular acupressure on the quality of life of postmenopausal women

Public title
The effect of auricular acupressure on the quality of life of postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's willingness to participate in this study Residence in Mashhad Having an age between 45-60 Non-use of tobacco Non-menstruation at least 12 months ago natural Menopause Women who have any of the physical and psychological symptoms such as flushing, sweating, sleeplessness, anxiety, depression, etc Menopause is less than 10 years No history of surgery on the ovary No current use of any herbal medicine Not receiving hormonal and non-hormonal drugs in the last 6 months to reduce menopausal complications No history of cardiovascular disease in the past 6 months Not having thyroid disease Not having a history of abnormal vaginal bleeding Not using other complementary therapies

Exclusion criteria:
Unwillingness to continue cooperation Doing Acupressure less than twice a week

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
The eligible patients are selected using convenience sampling method and then, using random numbers table, samples will be divided into three groups A, B and C.

Blinding (investigator's opinion)
Single blinded

Blinding description
Variables are measured by the assessor (a trained midwife) who is blind to blind intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Avenue next to the cinema Hoveizeh- Mashhad Medical Sciences, Ghoreishi building

City
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Razavi Khorasan

Postal code
345 - 91375

Approval date
2017-05-06, 1396/02/16

Ethics committee reference number
IR.MUMS.REC.1396.23

Health conditions studied

1

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
The quality of life for menopause, which in fact measures the annoying symptoms of this period.Determining the Four Dimensions of Quality of Life in Postmenopausal Women (Vasomotor, Psychosocial, Physical and Sexual)

Timepoint
At the beginning of the study and after four weeks

Method of measurement
Menopause-Specific Quality of Life Questionnaire

Secondary outcomes

1

Description
Signs and common complications of menopause including duration and severity of daily hot flashes

Timepoint
Daily

Method of measurement
Daily hot flash recording form

2

Description
Sleep status
Timepoint
At the beginning of the study and after four weeks
Method of measurement
Pittsburgh Sleep Quality Questionnaire

3

Description
Anxiety
Timepoint
At the beginning of the study and after four weeks
Method of measurement
Hamilton Anxiety Rating Scale

Intervention groups

1

Description
Intervention group: in the auricular acupressure group (AG), participants received ear adhesive tape with seed, on the ear sympathetic (AH6a), shenmen (TF4), adrenal gland (TG2p), subcortex (AT4), endocrine (CO18), kidney (CO10), heart (CO15) and liver (CO12) points for both ears.The patients were asked to press the acupoints by themselves four times a day for a 20 second duration each time for four week.It was explainedthat the strength of the pressing should make the local auriclecongestive, flushed, hot and achy.
Category
Treatment - Other

2

Description
Control group: In one control group , participants received ear adhesive tape without seed, on the ear sympathetic (AH6a), shenmen (TF4), adrenal gland (TG2p), subcortex (AT4), endocrine (CO18), kidney (CO10), heart (CO15) and liver (CO12) points for both ears.We note control group not to touch the adhesive.To use the potential psychological effects of adhesive, people are said these adhesives can improve symptoms.
Category
Placebo

3

Description
Control group: routine care includes self-care, including doing exercise and walking, diet (such as dairy consumption, a diet containing soy, no spices) and calcium supplementation and vitamin D, exposure to sunlight wearing appropriate cotton clothing, deep breathing during flushing, avoid being near-smoker, do not smoke, recommendations to lie down, or sit on a chair and tilted her head back in the time of flushing, activities to improve sleep, such as shower before bed, eat 1 cup of warm milk, no tea and coffee at the end of the night, ointment lubricant to reduce vaginal dryness during intercourse, it is recommended to maintain sexual relations regularly, activities to reduce anxiety such as doing yoga, and socially active.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Acupuncture Centers & Health Centers
Full name of responsible person
Zahra Hadizadeh-talasaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Ghoreishi building, Mashhad University of Medical Science،behind of Hoveyzeh cinema،Danesgah street، Mashhad
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+98 51 3841 3007
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presidentoffice@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Hadizadeh-talasaz

Position

Ph.D. student of reproductive health

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Latest degree

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Midwifery

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Person responsible for updating data

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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