Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The effect of auriculotherapy on sleep quality in postmenopausal women

Protocol summary

Study aim
Determining the effect of Auriculotherapy on the quality of postmenopausal women

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 41 patients.

Settings and conduct
Clinical trial on the quality of sleep of postmenopausal women referring to health centers using Auricholotherapy device. After selecting the research units, the individuals will be randomly assigned a 1: 1 allocation ratio in 4 blocks, which will be used to hide the allocation of envelopes in the matte package, which will be numbered sequentially.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Amenorrhea for at least 12 months - Age 60-45 - Get a score of more than 5 from the Pittsburgh questionnaire Output Criteria: - Having a known underlying disease - The emergence of any physical and mental illness during the research - Use of hormone therapy The use of sleeping pills during the last three months and during the study - Alcohol and drug use - Severe uterine bleeding - Loss of a relative during the last 6 months and during the study - Using other traditional treatments and complementary medicine - The emergence of significant changes in sleep conditions unpredictably - Take any herbal or chemical sleeping pills - Having edema and inflammation in both ears

Intervention groups
Intervention group: Auricholotherapy by stimulating the main points Witness group: Auricholotherapy by stimulating false spots

Main outcome variables
sleep quality; Mental quality of sleep; Sleep duration; Delay in falling asleep; The number of times you wake up at night; Sleep efficiency; Daily dysfunction

General information

Reason for update
Change the time and place of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20200613047756N1**
Registration date: **2020-07-19, 1399/04/29**
Registration timing: **prospective**

Last update: **2021-01-11, 1399/10/22**
Update count: **1**

Registration date
2020-07-19, 1399/04/29

Registrant information

Name
mona eidani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5224 0028

Email address
eidani.m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of auriculotherapy on sleep quality in postmenopausal women

Public title

The effect of auriculotherapy on sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Amenorrhea for at least 12 months Ages 60-45 Get a score of more than 5 from the Pittsburgh Questionnaire

Exclusion criteria:

Having a known underlying disease (heart, kidney, thyroid, hypertension, diabetes, etc.) The emergence of any physical or mental illness during research that causes sleep disorders Use of hormone therapy, Armatase inhibitors, clonidine and antidepressants, sleeping pills during the last three months and during the study Consumption of alcohol and addictive substances and tobacco Severe uterine bleeding Loss of a relative during the last 6 months and during the study Use of other traditional therapies and complementary medicine in the last 4 weeks during the study Emergence of significant change in unpredictable sleep conditions, including travel, relocation Take any herbal or chemical sleeping pills Having edema and inflammation in both ears

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the research units, the individuals will be randomly assigned 1: 1 in blocks of 4. In order to hide the allocation, envelopes will be used in the matte package, which are numbered in order and the type of intervention is written inside them.These envelopes will be prepared by the researcher involved in collecting data that is not known from the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to hide the allocation, envelopes will be used in matte packages, which are numbered in order and the type of intervention is written inside them. These envelopes will be prepared by a non-involved researcher in data collection.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

North Abuzar Ally 10, Sadat St, Taleghani Town

City

Mahshahr

Province

Khouzestan

Postal code

63531-96474

Approval date

2020-06-10, 1399/03/21

Ethics committee reference number

IR.AJUMS.REC.1399.230

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

G47 G47.0

ICD-10 code description

VI Diseases of the nervous system , Sleep disorders , Disorders of initiating and maintaining sleep [insomnias], Disorders of excessive somnolence [hypersomnias] Disorders of the sleep-wake schedule. Sleep apnoea ,Narcolepsy and cataplexy , Other sleep

Primary outcomes

1

Description

Sleep quality score in the Pittsburgh questionnaire

Timepoint

Completion of the questionnaire then 4 weeks of intervention with the Auriculotherapy device and re-completion of the questionnaire

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

1

Description

Sleep Mental Quality Score in the Pittsburgh Questionnaire

Timepoint

Completion of the questionnaire, then 4 weeks of

intervention with the Auricotherapy device, then re-completion of the questionnaire

Method of measurement

Pittsburgh Questionnaire

2

Description

Sleep efficiency score on the Pittsburgh questionnaire

Timepoint

Completion of the questionnaire, then 4 weeks of intervention with the Auricotherapy device, then re-completion of the questionnaire

Method of measurement

Pittsburgh Questionnaire

3

Description

Daily Performance Disorder Score in the Pittsburgh Questionnaire

Timepoint

Completion of the questionnaire, then 4 weeks of intervention with the Auricotherapy device, then re-completion of the questionnaire

Method of measurement

Pittsburgh Questionnaire

Intervention groups

1

Description

Intervention group: In this experiment, using an Excel 2 AUrycolotherapy device made in China, the main points related to sleep in the right ear are stimulated for 15 seconds, The plantar warts are then attached to the irritated spots of Vakaria, and it is recommended that the person be pressured for one minute every hour except for bedtime and return after 6 days. The duration of the intervention was 4 weeks.

Category

Treatment - Devices

2

Description

Control group: n this experiment, using an Excel 2 Aurycolotherapy device made in China, the false spots on the back of the right ear are stimulated for 15 seconds.Then, on the irritated areas, the plantar fissures of Vakaria are glued without a nut, and it is recommended that the person press the seedlings for one minute every hour, except for bedtime, and return after 6 days. The intervention period was 4 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahshahr Health Centers

Full name of responsible person

Mona Eidani

Street address

North Abuzar Alley 10, Sadat St, Taleghani Town

City

Mahshahr

Province

Khouzestan

Postal code

63531-96474

Phone

+98 61 5244 0028

Email

m.eidany1363@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ground Floor, Ahwaz Jundishapur University of Medical Sciences and Health Services Vice Chancellor for Research and Technology,Academic City

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3336 2414

Email

iitc@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mona Eidani
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
North Abuzar Alley 10, Sadat St, Taleghani Town
City
Mahshahr
Province
Khouzestan
Postal code
63531-96474
Phone
+98 61 5244 0028
Email
m.eidany1363@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mona Eidani
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
North Abuzar Alley 10, Sadat St, Taleghani Town
City
Mahshar
Province
Khouzestan
Postal code
63531-96474
Phone
+98 61 5244 0028
Email
m.eidany1363@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mona Eidani
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
North Abuzar Alley 10, Sadat St, Taleghani Town
City
Mahshahr
Province
Khouzestan
Postal code
63531-96474
Phone
+98 61 5244 0028
Email
m.eidany1363@gmail.com

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
No - There is not 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 Study data includes primary and secondary outcomes and other study data after non-identifiable shareable individuals.
When the data will become available and for how long
Study data will be available 6 months after the results are published.
To whom data/document is available
Other study documents should be made available to the public.
Under which criteria data/document could be used
Individuals with the name of the study researcher are allowed to use the study documents, individuals are not allowed to analyze any of the submitted data.
From where data/document is obtainable
To receive the documents, people can contact the following mailing address: m.eidany1363@gmail.com
What processes are involved for a request to access data/document
The applicant of these documents will respond to the request within 24 hours after the request is sent via e-mail, and the relevant files will be provided to the applicant.
Comments