

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of foot massage on the sleep quality of postmenopausal women.

Protocol summary

Study aim

Main purpose: To evaluate the effect of foot massage on sleep quality in postmenopausal women
Specific Objectives: 1- Determining the effect of foot massage on the duration of sleep in postmenopausal women 2- Determining the effect of foot massage on the sleep adequacy of postmenopausal women 3- Determining the effect of foot massage on the mental quality of sleep in postmenopausal women 4- Determining the effect of foot massage on the duration of sleep period of postmenopausal women

Design

Clinical trial with control group, randomized with permutation blocks, on 74 participants

Settings and conduct

Location: Selseh County Health Network
To perform the massage, the participant is asked to lie down in a dark and quiet room in a comfortable position, then place his legs above the body surface by placing a pillow under them so that the participant's legs are in front of the massager, then the person doing the massage, after washing his hands and drying them to reduce friction, dip his hands in the lubricant (olive oil) and perform the massage.

Participants/Inclusion and exclusion criteria

Admission requirements: Age 60-45 years - At least one year has passed since the last menstrual period.
Withdrawal conditions: Any physical and mental illness that causes sleep disorders - taking medication and hormone therapy

Intervention groups

The intervention is performed by a family member of a postmenopausal woman. The foot massage is performed in a simple way the night before bed for 30 minutes (15 minutes per foot) every night for 8 weeks. There is no intervention in the control group.

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210824052276N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **prospective**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Fatemeh Valipouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3252 3400

Email address

valipouri.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-28, 1400/07/06

Expected recruitment end date

2022-03-26, 1401/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage on the sleep quality of postmenopausal women.

Public title

The effect of foot massage on sleep quality of postmenopausal women.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least one year has passed since the last menstrual period. Age 45 to 60 years Having a companion (someone who lives with a participant who can do massage). Women with a Pizza Leaf Sleep Quality Questionnaire score of 5 or higher (a score of 5 or higher indicates significant sleep disturbance). Giving informed consent

Exclusion criteria:

Any physical or mental illness that interferes with sleep. Taking medication and hormone therapy Fractures, infections, wounds and skin diseases of the lower extremities. Employment in jobs with night shifts.

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: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The assignment of the intervention to individuals is random and by the method of random permutation blocks with random block sizes of 4, 6 and 8 (using the table related to random permutations) with an allocation ratio of 1: 1. The tool for generating random block sequences is blockrand software package in R software environment. Coding is done by a biostatistics expert to set up a random list. Concealment: The intervention used in this study, according to a randomized list, is assigned by an out-of-study person who is unaware of the research objectives and according to the corresponding codes in the sealed envelopes.

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 Ahwaz Jundishapur University of Medical Sciences

Street address

Ahvaz - Golestn - Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.AJUMS.REC.1400.312

Health conditions studied**1****Description of health condition studied**

sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes**1****Description**

Sleep quality score on the Pittsburgh Questionnaire

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes**1****Description**

Mental quality of sleep

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Intervention groups

1

Description

Intervention group: Foot massage increases blood circulation, releases endorphins and, as a result, relieves insomnia. The sole of the foot is done in a simple way at night before going to bed for 30 minutes (15 minutes each foot with olive oil) every night for 8 weeks.

Category

Lifestyle

2

Description

Control group: No intervention is performed in the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Selseleh city health network.

Full name of responsible person

Dr. Karam Hossein Hassanvand

Street address

Alshtar, Ayatollah Boroujerdi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi Moghadam

Street address

Ahvaz University City - Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences and Health Services - Ground Floor

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Grant name

Grant code / Reference number

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

No

Title of funding source

Ahvaz Jundishapur 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

Khadijeh Hekmat

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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

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

Yes - There is 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

Title and more details about the data/document

Part of the data related to the main outcome is shared.

When the data will become available and for how long

Access period starts 4 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in research work

From where data/document is obtainable

Khadijeh Hekmat Contact number: 09161117300 Email: Hekmat1346@Gmail.com Address: Ahvaz - Golestan - Jundishapur University of Medical Sciences - School of Nursing and Midwifery

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

Request from the responsible executor via email and provide the purpose of data access.

Comments