

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of acupressure on sleep quality in menopausal women in Mashhad: A Randomized Clinical Trial

Protocol summary

Summary

This study was to evaluate the effectiveness of acupressure on sleep quality of postmenopausal women. This double blind randomized clinical trial was performed on 105 qualified menopausal women at the age of 41-65 years, spending at least 12 months after amenorrhea, getting a score higher than 5 from the Pittsburgh Sleep Quality Index (PSQI). The participant with emotional stress during the last 6 months, taking hormonal drugs during 3 last months, using herbal medicine to improve the menopausal symptoms excluded. Sleep quality was measured with PSQI. In the first stage, samples were selected by using a systematic method and in the second one, they were randomly assigned to three groups: acupressure (n=37), sham acupressure (n=36) and control groups (n=32). These interventions were carried out for 4 consecutive weeks each night (except Fridays). Participants in acupressure group and sham acupressure group learned to carry out acupressure technique as a self care at home with the simultaneous massage techniques that were to be performed 1- 2 hours before sleep. Circular massage was performed with a 1 Cm circle diameter on the points of Shenmen on the wrist crease, Sanyinjiao point (SP6) on both feet, Fengchi on the hairline of the back neck (occipital area) and Yintang, at the top of the nose on the center line between the ends of the eyebrows. Non-acupoints, which were 1 to 3 CUN (Chinese unit of length) away from true acupoints were used in sham acupressure group. Whereas only conversation was used in the control group. Improvement of sleep quality was assessed at the end of the follow up period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100614910N1**

Registration date: **2014-01-21, 1392/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-21, 1392/11/01

Registrant information

Name

Zahra Abedian

Name of organization / entity

Mashhad University of Medical Science, School of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor, Mashhad University of Medical Science.

Expected recruitment start date

2009-12-29, 1388/10/08

Expected recruitment end date

2010-05-10, 1389/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure on sleep quality in menopausal women in Mashhad: A Randomized Clinical Trial

Public title

The effect of acupressure on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :spending at least 12 months after amenorrhea or Follicle Stimulating Hormone (FSH) serum level ≥ 40 (1 year menopause); healthy of the pressure points, having a full conscious and also having an acceptable ability of listening and speaking to receive training and doing the self- care techniques at home; no having mental and physical disorders; getting a score higher than 5 from the Pittsburgh Sleep Quality Index (PSQI) ; able to sit for about 30 minutes. Exclusion criteria: having emotional stress during the last 6 months ; having specific eating diets; addicted to narcotic drugs; using the drugs causing sleep disorders; suffering from special disease; taking hormonal drugs during 3 last months; using herbal medicine to improve the menopausal symptoms; body mass index (BMI) higher than 30; having the moderate and severe depression based on Beck Depression Inventory; feeling of severe fatigue and anxiety; having circular job specially night job; lack of cooperation with researchers

Age

From **41 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT01904578

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Science

Street address

Daneshgah street, Mashhad,Iran

City

Mashhad

Postal code

Approval date

2010-01-13, 1388/10/23

Ethics committee reference number

88410

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 in menopausal women

Timepoint

before & after interveantion

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Acupressure group: They were asked to massage the effective pressure points as a self-care method at home. The points were Shenmen on the wrist crease, Sanyinjiao point (SP6) on both feet, Fengchi on the hairline of the back neck (occipital area) and Yintang, at the top of the nose on the center line between the ends of the eyebrows. Intervention was done 1 to 2 hours before sleeping, each night (except Fridays) by circular massage with a 1 Cm circle diameter for 4 weeks. Participants were trained for the force of finger pressure. They needed to feel the full pressure of approximately 3-4 kg on the points but no feeling of pain.

Category

Treatment - Other

2

Description

Sham acupuncture group: They were asked to massage the sham pressure points as a self-care method at home. Non-acupoints, which were 1 to 3 CUN (Chinese unit of length) away from true acupoints (Shenmen, Sanyinjiao, Fengchi, Yintang) were used in sham acupuncture group. These points were out of the route of energy. Intervention was done 1 to 2 hours before sleeping, each night (except Fridays) by circular massage with a 1 cm circle diameter for 4 weeks. Participants were trained for the force of finger pressure. They needed to feel the full pressure of approximately 3-4 kg on the points but no feeling of pain.

Category

Treatment - Other

3

Description

The control group: They received the weekly control of blood pressure and speech communication for 4 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Population Research Center of Mashhad

Full name of responsible person

Zahra Abedian

Street address

School Nursing & Midwifery of Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Dr Tefaghodi

Street address

Daneshgah street, Mashhad, Iran

City

Mashhad

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 Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad School of Nursing and Midwifery

Full name of responsible person

Zahra Abedian

Position

Instructor of Midwifery Administrator for Research Affairs

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty