# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 performed1- 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. Imrovement 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 acupressure 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 acupressure 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 Tfaghodi

**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*