

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison of the effect of acupuncture and drug therapy on controlling hot flash and sleep disorders in menopause women

#### Protocol summary

##### Study aim

The comparison of the effect of acupuncture and drug therapy on hot flash and sleep disorders in menopausal women

##### Design

After obtaining written consent from eligible clients, individuals were randomly assigned based on randomly numbers table to two groups.

##### Settings and conduct

Acupuncture performed by a physician with acupuncture specialty. In the case group (acupuncture), acupuncture performed three times a week, each session took last for 20 minutes. Intervention duration were 4 weeks.

Acupuncture points determined based on traditional Korean medicine, including ST36, SP6, L14, PC6, HT7, HT8, and a point at the bottom of the CV4 abdomen. A total of 7 points selected to reduce hot flashes. Subjects followed for 12 weeks after acupuncture. In the control group (routine care), fluoxetine administered for 4 weeks and subjects then followed for 12 weeks.

##### Participants/Inclusion and exclusion criteria

1 - Lack of menstruation at least in the past 12 months 2- Natural menopause 3. No history of ovarian surgery or hysterectomy 4- Lack of diabetes, migraine or receiving medication for any internal disorder

##### Intervention groups

Menopausal women with hot flash and sleep disorders

##### Main outcome variables

Evaluation of the frequency of hot flashes during day and night Evaluation of the severity of hot flashes during day and night

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171104037220N2**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **retrospective**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

##### Registration date

2020-06-28, 1399/04/08

##### Registrant information

###### Name

Tahereh Fathi Najafi

###### Name of organization / entity

Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3225 0044

###### Email address

fathi\_midwife@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-01-29, 1392/11/09

##### Expected recruitment end date

2017-12-31, 1396/10/10

##### Actual recruitment start date

2014-05-01, 1393/02/11

##### Actual recruitment end date

2019-12-31, 1398/10/10

##### Trial completion date

2020-01-21, 1398/11/01

##### Scientific title

The comparison of the effect of acupuncture and drug therapy on controlling hot flash and sleep disorders in menopause women

##### Public title

Acupuncture and menopausal disorders control

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having adequate literacy to fill out the forms  
Lack of menstruation at least in the past 12 months  
Natural menopause  
Experiencing at least 4 hot flashes during the day  
No history of ovarian surgery  
Confirmation of menopause with the help of hormonal testing and confirmation of  $E2 < 18$  pg/ml,  $FSH = 30-110$  IU/L  
Lack of thyroid disorders and  $TSH = 0.4-4$  IU/mL  
Not using any over-the-counter herbal medicine based on doctor prescription to reduce hot flashes  
Lack of diabetes, migraine or receiving medication for any internal disorder  
Lack of chronic infections

### Exclusion criteria:

## Age

From **45 years** old to **65 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **82**

Actual sample size reached: **89**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Menopausal women who referred to the Gynecology Clinic of Imam Reza Hospital due to hot flashes and were eligible to participate in the study based on inclusion and exclusion criteria randomly assigned to intervention and control groups based on random block allocation with a block size of 2. Each block stratified based on the frequency of hot flushed per day (less than 7 times and more than 7 times) and age at menopause (younger than 45 years old and older than 45 years old). Random allocation performed by assigning the first subject based on the frequency of hot flush per day to intervention or control group and assigning its pair based on frequency of hot flush to the other group. This method ensured the similar allocation number in the study groups. To protect patients' rights, if the subjects did not like to continue acupuncture, they referred to the normal care.

## 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

Ethical Committee of the Mashhad University of Medical Sciences

#### Street address

Daneshgah Avenue, Mashhad, Razavi Khorasan Province, Iran

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91375345

### Approval date

2014-01-29, 1392/11/09

### Ethics committee reference number

IR.MUMS.REC.1393.44

## Health conditions studied

## 1

### Description of health condition studied

Hot flash and sleep disorders

### ICD-10 code

N95.1

### ICD-10 code description

Menopausal and female climacteric states

## Primary outcomes

## 1

### Description

Evaluation of the frequency and severity of hot flashes

### Timepoint

Before acupuncture, at the end of acupuncture period (4th week) and 12 weeks after acupuncture in the acupuncture group, before fluoxetine treatment, 4 weeks after treatment initiation and 12 weeks after treatment

### Method of measurement

Severity of hot flash and Pittsburgh sleep disorder questionnaire

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Acupuncture performed three times a week, each session took last for 20 minutes. Intervention duration was 4 weeks. Acupuncture points determined based on traditional Korean medicine, including ST36, SP6, L14, PC6, HT7, HT8, and a point at the bottom of the CV4 abdomen. A total of 7 points selected to reduce hot flashes. Metal disposable needles

used for the acupuncture in the mentioned points for 20 minutes. The length of the needles were 40 mm. The needles inserted 3-15 mm deep in the mentioned points.

**Category**

Treatment - Other

**2****Description**

Control group: Were received fluoxetine for 4 weeks and subjects were then be followed for 12 weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam reza hospital

**Full name of responsible person**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Leyla Porali

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**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**

Islamic Azad University

**Full name of responsible person**

Tahereh Fathi Najafi

**Position**

Assisstant Professore

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associated Professor

**Latest degree**

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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**

No - There is not 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

**Title and more details about the data/document**

The comparison of the effects of acupuncture and drug therapy on controlling the frequency and severity of hot flashes among menopausal women

**When the data will become available and for how long**

From now to 6 months later

**To whom data/document is available**

Midwives, Obstetricians and gynecologist and acupuncturists

**Under which criteria data/document could be used**

Protocol and its results

**From where data/document is obtainable**

Tahereh fathi Najafi

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

The request will be sent by email

**Comments**