# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 it's 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 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**

Tahereh Fathi Najafi

**Street address**

Unit 9, No 55, 17 th Honarestan st

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9178755114

**Phone**

+98 51 3868 7122

**Email**

fathi_midwife@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Leyla Porali

**Street address**

Goreshi biulding, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179734688

**Phone**

+98 51 3841 2081

**Email**

pouralil@mums.ac.ir

**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

**Street address**

Dr Mohamad Shahinfar University, Sarab Bazarche, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179734688

**Phone**

+98 51 3225 0044

**Email**

fathi_midwife@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Leyla Porali

**Position**

Associated Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Gham Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179734688

**Phone**

+98 51 3859 1511

**Email**

pouralil@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Tahereh Fathi Najafi

**Position**

Assisstant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Sarab Bazarcheh

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9179734688

**Phone**

+98 51 3225 0044

**Email**

fathi_midwife@yahoo.com

## 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**