

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing Face-to-Face and Telephone-Based Cognitive Behavioral Therapy on Hot Flushes in Postmenopausal Women

#### Protocol summary

##### Study aim

Comparing Face-to-Face and Telephone-Based CBT on Postmenopausal Hot Flushes

##### Design

This is a randomized clinical trial with two intervention groups of 20 people, community based and pragmatic, with parallel groups and there is no blindness

##### Settings and conduct

This research will be conducted in the menopausal clinic of Imam Hospital. Our subjects will be selected among eligible registered documents and then women will be invited to participate in this study via phone call .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: normal menopause; passing at least one year and maximum five years from the cessation of menstruation; being able to read and write; having at least 10 hot flashes per week in a duration of one month; having a score of more than 1 in response to the kupperman index; having a cell phone. Non-entry criteria: known mental and physical illnesses; history of CBT; drug and other psychotropic substances abuse; under medication for hot flashes

##### Intervention groups

There will be held six sessions of 30 minutes cognitive-behavioral counseling on a weekly basis for each group. These sessions composed of: providing information about physiology of menopause; introducing cognitive behavioral model (including physiological, cognitive, behavioral and emotional components for hot flashes), teaching breath and relaxation techniques, emphasize the role of stress in boosting hot flashes and cognitive behavioral strategies for reducing it, focus on cognitive responses (Tragedy thoughts and extreme negative beliefs about hot flushes) and behavioral reactions (avoidance and activity) on hot flushes, providing weekly assignments, implementing cognitive behavioral strategies for hot flushes management and breathing techniques and finally, preparing the main list of beliefs, their variability and methods for changing

negative beliefs.

##### Main outcome variables

Hot flushes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180918041065N1**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **retrospective**

Last update: **2018-11-20, 1397/08/29**

Update count: **0**

##### Registration date

2018-11-20, 1397/08/29

##### Registrant information

##### Name

Nasim Sadeghijoola

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3552 2957

##### Email address

nasim.sadeghijoola@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-06, 1397/04/15

##### Expected recruitment end date

2018-09-06, 1397/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparing Face-to-Face and Telephone-Based Cognitive Behavioral Therapy on Hot Flashes in Postmenopausal Women

**Public title**  
Cognitive-Behavioral Therapy (CBT) on hot flashes in postmenopausal women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Normal Menopause Passing at least one year and maximum five years from the cessation of menstruation  
Being able to read and write  
Having at least 10 hot flashes per week in a duration of one month  
Having a score of more than 1 in response to the kupperman index  
Having a cell phone

**Exclusion criteria:**

Known Mental and Physical illnesses  
History of Cognitive Behavioral Therapy(CBT)  
Drug and other psychotropic substances abuse  
Under medication for hot flashes

**Age**  
From **40 years** old to **60 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, eligible individuals will be randomly assigned to two groups of telephone counseling (N=20) and face-to-face counseling (N=20) using block randomization (block size: 4 and allocation ratio: 1). For allocation concealment, 20 four digit numbers will be selected for each participant in the telephone group and face-to face group respectively and will be arranged according to the block size. Then in order to hide the allocation, the numbers will be arranged in blocks of opaque envelop, respectively and will be given randomly to eligible individuals by the secretary.

**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 Ahvaz Jundishapur University of Medical Sciences

**Street address**

Iran, Ahvaz, Golestan Blv, Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15794

**Approval date**

2018-06-30, 1397/04/09

**Ethics committee reference number**

IR.AJUMS.REC.1397.289

## Health conditions studied

### 1

**Description of health condition studied**

Hot flashes in Postmenopausal women

**ICD-10 code**

N95.1

**ICD-10 code description**

Menopausal and female climacteric states

## Primary outcomes

### 1

**Description**

Hot flush score in the Kupperman index

**Timepoint**

Hot flush at baseline, at the end of intervention, six weeks after intervention, and two months after intervention

**Method of measurement**

Kupperman Index

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

For the face-to face group, six sessions of 30 minutes each of cognitive-behavioral counseling will be held on a weekly basis for one intervention groups. These sessions composed of the following issues: expression of the rules and objectives of the study, providing information about physiology of menopause as well its complications and treatment, introducing cognitive behavioral model

including physiological, cognitive, behavioral and emotional components for hot flashes and night sweats, teaching breath and relaxation techniques, emphasizing the role of stress in boosting hot flashes, night sweats and cognitive behavioral strategies for reducing it, focusing on cognitive responses (tragedy thoughts and extreme negative beliefs about hot flushes) and behavioral reactions (avoidance and activity) on hot flushes, providing weekly assignments, implementing cognitive behavioral strategies for hot flushes management, breathing techniques and relaxation for home work and finally preparing the main list of beliefs and cognition as well as their variability and methods to change negative beliefs.

#### Category

Treatment - Other

## 2

#### Description

For the telephone based counseling, there will be six sessions of 20-30 minutes telephone cognitive-behavioral counseling on a weekly basis. The content of these sessions are as follows: expression of the rules and objectives of the study, providing information on physiology of menopause as well as its complications and treatment, introducing cognitive behavioral model including physiological, cognitive, behavioral and emotional components for hot flashes and night sweats, teaching breath and relaxation techniques, emphasizing the role of stress in boosting hot flashes, night sweats and cognitive behavioral strategies for reducing it, focusing on cognitive responses (tragedy thoughts and extreme negative beliefs about hot flushes) and behavioral reactions (avoidance and activity) on hot flushes, providing weekly assignments, implementing cognitive behavioral strategies for hot flushes management, breathing techniques and relaxation for home work and finally preparing the main list of beliefs and cognition as well as their variability and methods to change negative beliefs.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Menopause Clinic of Ahvaz Imam Khomeini Hospital

##### Full name of responsible person

Porandokht Afshary

##### Street address

Iran, Ahvaz, Azadegan Ave, Imam Khomeini Hospital, Menopause clinic

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673111

##### Phone

+98 61 3373 8619

##### Email

P\_afshary@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

mohammad badvi

##### Street address

Ahvaz, Golestan Ave, Ahvaz Jundishapur University of Medical Sciences, Vice-Chancellor for Research of Jundishapur University of Medical Sciences

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##### Province

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##### Fax

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##### Email

itc@ajums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Porandokht Afshary

##### Position

Assistant Professor

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

**Street address**

Ahvaz, Golestan Ave, Ahvaz Jundishapur University of Medical Sciences, Nursing & Midwifery School, Menopause Research Center

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P\_afshary@yahoo.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Porandokht Afshary

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nasim Sadeghijoola

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

No.41, West khajenejad Ave., Zibashahr Blvd., Ahvaz Town

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**Province**

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**Postal code**

6184734444

**Phone**

+98 61 3552 2957

**Fax****Email**

sadeghijoola.n@ajums.ac.ir

**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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The entire data can be shared after anonymize participants

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

Data can be accessed after publication for a period of one year.

**To whom data/document is available**

Only for scholars working in the scientific institution

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

The data are available upon referencing name of investigators, clinical trials and research

**From where data/document is obtainable**

Pourandokht Afshary, Faculty Member of Ahvaz Jundishapur University of Medical Sciences Email: P\_afshary@yahoo.com

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

Send the request via email, will be answered as soon as possible

**Comments**