

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of education-based cognitive-behavioral approach on beliefs, behaviors, and symptoms of hot flashes and insomnia among menopausal transition women: A randomized controlled trial

#### Protocol summary

Severity and frequency of hot flashes, hot flash beliefs, hot flash behaviors, the severity of insomnia.

#### Study aim

The effect of education-based cognitive-behavioral approach on beliefs, behaviors, and symptoms of hot flashes and insomnia among menopausal transition women

#### Design

A randomized controlled clinical trial with parallel groups, involving 64 patients in each group. Participants will be allocated to the intervention and control groups using random block assignments of 2 and 4.

#### Settings and conduct

Eligible women are randomly assigned to intervention or control groups. Before the intervention, all complete symptom and characteristic questionnaires. Intervention group: Attends six 2-hour sessions over 6 weeks at Shahid Fayazbakhsh Gonabad Health Center, covering psychoeducation, stress management, breathing techniques, and cognitive distortions. Control group: Receives only an educational booklet on menopause. After the intervention, both groups retake the questionnaires to assess changes.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 45-55, Natural menopause, Hot flashes/night sweats (score more than 2) for 1 month, Insomnia for 1 month. Exclusion criteria: Medications affecting hot flashes, Medical/psychological conditions preventing participation, Special diet/supplements affecting menopause, Breast cancer (less than 6 months post-treatment).

#### Intervention groups

In the intervention group, participants will attend 2-hour weekly sessions for 6 weeks (total 12 hours). Sessions will focus on cognitive-behavioral techniques, stress management, and recognizing cognitive distortions. The control group will receive an educational booklet on menopause and symptom management.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250120064452N1**

Registration date: **2025-04-10, 1404/01/21**

Registration timing: **prospective**

Last update: **2025-04-10, 1404/01/21**

Update count: **0**

##### Registration date

2025-04-10, 1404/01/21

##### Registrant information

##### Name

Elahe AkramiNejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3605 2551

##### Email address

eliakraminezhad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-05-10, 1404/02/20

##### Expected recruitment end date

2025-09-11, 1404/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of education-based cognitive-behavioral approach on beliefs, behaviors, and symptoms of hot flashes and insomnia among menopausal transition women: A randomized controlled trial

**Public title**  
The effect of education-based cognitive-behavioral approach on beliefs, behaviors, and symptoms of hot flashes and insomnia among women

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Completion of the Informed Consent Form Iranian and a resident of Gonabad city Ability to read and write Menopause transition years (45 to 55 years) In the event of menopause, the menopause must have occurred naturally (not due to surgery) Having hot flashes/night sweats (a score above 2 on the hot flash rating scale) for at least 1 month Having insomnia for at least 1 month  
**Exclusion criteria:**  
Use of effective medications for hot flashes (Estrogen and Progesterone, SSRIs, and SNRIs, Antihypertensive and Anticonvulsant drugs) Presence of medical or psychological conditions that prevent participation in the study Occurrence of a stressful event in the past six months (as reported by the participant) Specific diet and soy supplements consumption or other plant-based compounds affecting menopausal symptoms, including isoflavone consumption (as reported by the participant) Breast cancer (provided that less than six months have passed since the end of treatment) Presence of medical conditions that may affect hot flashes (as reported by the participant) Use of prescription or over-the-counter treatments for hot flashes in the past 30 days (as reported by the participant) Use of sex steroid hormones or hormonal contraceptives drugs (within the past 2 months) (as reported by the participant) History of treatment or training based on cognitive behavioral therapy

**Age**  
From **45 years** old to **55 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **128**

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

**Randomization description**  
Convenience sampling, randomized allocation method, using permuted blocks of size 2 and 4 into two groups: experimental and control

**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 Gonabad Medical University  
**Street address**  
Campus of Gonabad University of Medical Sciences, Asian Highway Margin, Gonabad, Khorasan Razavi  
**City**  
Gonabad  
**Province**  
Razavi Khorasan  
**Postal code**  
9691793718  
**Approval date**  
2025-03-10, 1403/12/20  
**Ethics committee reference number**  
IR.GMU.REC.1403.188

**Health conditions studied**

**1**

**Description of health condition studied**  
Menopause, Hot Flash, Insomnia  
**ICD-10 code**  
N95.1  
**ICD-10 code description**  
Menopausal and female climacteric states

**Primary outcomes**

**1**

**Description**  
Hot flash severity on the Hot Flash Frequency And Problem Rating Scale  
**Timepoint**  
Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention  
**Method of measurement**  
Hot Flash Frequency And Problem Rating Scale

**2**

**Description**

Hot flash frequency on the Hot Flash Frequency And Problem Rating Scale

**Timepoint**

Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention

**Method of measurement**

Hot Flash Frequency And Problem Rating Scale

**3**

**Description**

insomnia severity on the Insomnia Severity Index

**Timepoint**

Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention

**Method of measurement**

Insomnia Severity Index

**4**

**Description**

Night sweats score on Hot Flash Frequency And Problem Rating Scale

**Timepoint**

Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention

**Method of measurement**

Hot Flash Frequency And Problem Rating Scale

**5**

**Description**

Hot Flash Behavior score on the Hot Flush Behavior Scale

**Timepoint**

Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention

**Method of measurement**

Hot Flush Behavior Scale

**6**

**Description**

Hot Flash Beliefs Score on the Hot Flash Beliefs Scale

**Timepoint**

Measuring the severity of hot flashes at the beginning of the intervention (before the start of the intervention), immediately after completion of the intervention, and one month after completion of the intervention

**Method of measurement**

Hot Flash Beliefs Scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Two-hour training sessions, once a week, for six weeks. A cognitive-behavioral approach will be used to structure the content of the sessions, focusing on psychoeducation, stress management, proper breathing, training and identification of cognitive errors, and other items related to the cognitive-behavioral approach, including setting individual goals and assigning homework. The training sessions will use lectures with slides and clips on the topic of relaxed/rapid breathing, and educational pamphlets.

**Category**

Behavior

**2**

**Description**

Control group: Participants will receive an educational booklet about menopause, its symptoms, and strategies for reducing vasomotor symptoms.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Fayyazbakhsh Comprehensive Health Center, Gonabad

**Full name of responsible person**

Narjes Bahri

**Street address**

Shahid Fayyaz Bakhsh Comprehensive Health Center No. 1, Next to the Blood Transfusion Organization, Ghadir Square

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691977469

**Phone**

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**Email**

info@gmu.ac.ir

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Vice-Chancellor for Research and Technology of

Gonabad University of Medical Sciences

nargesbahri@yahoo.com

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Campus of Gonabad University of Medical Science ,  
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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**

Gonabad 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 scientific inquiries**

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Narjes Bahri Binabaj

**Position**

Associate Professor of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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Campus of Gonabad University of Medical Sciences,  
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**Person responsible for general inquiries**

**Contact**

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**Full name of responsible person**

Narjes Bahri Binabaj

**Position**

Associate Professor of Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Elahe AkramiNejad

**Position**

Master student of midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

2nd Floor, No. 38, Emamat 60, Emamat street,  
Mashhad

**City**

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eliakraminezhad@gmail.com

## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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