Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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

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

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

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Razavi Khorasan

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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

Street address

Campus of Gonabad University of Medical Science , Asian Highway (SENTO Road), Gonabad, Razavi Khorasan, Iran

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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 general 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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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

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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

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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