Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Comparison of the effectiveness of cognitive-behavioral approach with two methods of guided self-help and group counseling on problematic hot flashes in menopause

Protocol summary

Summary

Aims: To determine the amount of hot flash in postmenopausal women in experimental and control groups before intervention, immediately after intervention, 8 weeks after intervention and 5 months after intervention. Design: parallel. How to do: In the call from health volunteers, the installation of a notice in health centers and midwifery offices will be invited from postmenopausal women. Individuals with entry criteria are randomly divided into three groups of self-help (CBT), group counseling (CBT) and control group. inclusive criteria: Postmenopausal women aged 45-60; Problem flushing; End of hormone therapy at least 2 months before randomization; Women who continue to treat HF / NS but still sign; Farsi language. exclusive criteria: Non-hormone therapies such as clonidine; megestrol acetate; selective serotonin reuptake inhibitors; physical or mental disabilities that affect the ability of individual involvement; women under hormone therapy; those with symptoms similar to hot flashes. Main effect: Problem hot flashes. Group counseling: 4 weekly cognitive-behavioral counseling sessions for 90 minutes at Shahrood Health Centers. Self-help group: A preparatory session, a follow-up phone call 2 weeks after the start of the study. Participants in this group receive educational content, will spend an unlimited period of four weeks. The control group does not receive cognitive-behavioral counseling, but will receive 4 weekly training sessions on bleeding and menopausal symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101135980N2**
Registration date: **2017-10-24, 1396/08/02**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-10-24, 1396/08/02

Registrant information

Name
Zohreh Asghari
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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2017-12-06, 1396/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of cognitive-behavioral approach with two methods of guided self-help and group counseling on problematic hot flashes in menopause

Public title

Effectiveness of cognitive-behavioral Intervention on

menopausal hot flashes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: postmenopausal women aged 45-60; problem flushing (score higher than 2 in HFRS and at least 10 hot flashes per week for at least one month before intervention); end of hormone therapy at least 2 months before randomization; women To treat HF / NS, they still mark and seek further treatment; persian language. Exclusion criteria: non-hormone therapies such as clonidine, Megace (megestrol acetate); selective serotonin reuptake inhibitors (SSRIs); physical or mental disabilities that affect the ability of one's participation; women under hormone therapy; Symptoms of hot flush such as hyperthyroidism, pheochromocytoma and carcinoid syndrome.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences

City

Shahroud

Postal code

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.SHMU.REC.1396.94

Health conditions studied

1

Description of health condition studied

Menopausal Hot flushes

ICD-10 code

N95

ICD-10 code description

N95.1

Primary outcomes

1

Description

Amount problematic hot flashes in menopause

Timepoint

Before the intervention, immediately after the intervention, 8 weeks after the intervention, 5 months after the intervention

Method of measurement

Hot Flush Problem-Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Individuals with inclusion criteria are randomly divided into three groups: Guided Self-Help, group counseling, control group. Counseling sessions for the CBT group: 4 weekly counseling sessions for 90 minutes at Shahrood Municipal Health Services Center focusing on psychosocial education, stress management, effective respiration, cognitive-behavioral intervention, as well as the determination of individual goals and home-homes. The materials used include PowerPoint, Buccettle, Calcium Tetanol, and Respiratory Techniques.

Category

Behavior

2

Description

Counseling for guide self-help CBT group:Includes an educational session and a telephone counseling, 2 weeks after the start of the study. The participants in this group, Buccett and CD will receive educational content, the duration of the 4-week course was absent.

Category

Behavior

3

Description

The control group does not receive cognitive-behavioral counseling, but in order to reduce the error in the

research, the control group will receive 4 weekly training sessions on menstrual bleeding and risk symptoms.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sharif Health Center

Full name of responsible person
Asghari Zohreh

Street address
Shahid Sharif health Center, Meysam Tamar street, Shahid Mostafa Khomeini Boulevard, Imam town.

City
Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Hasan-Emamian

Street address
Central building of Shahroud University of Medical Sciences, 7th Tir square

City
Shahroud

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Shahroud University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Soltani Fatemeh

Position
Research Officer

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD in Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty