Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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 Flushes in Postmenopausal Women

Public title

Cognitive-Behavioral Therapy (CBT) on hot flushes 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

Khouzestan

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 flushes 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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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