Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Group Cognitive-Behavioral Therapy(CBT) on Sleep disorders in Postmenopausal Women

Protocol summary

Study aim
Determining the Effect of Group Cognitive-Behavioral Therapy(CBT) on Sleep disorders in Postmenopausal Women

Design
This study is a randomized controlled trial in which randomization will be done using block randomization method

Settings and conduct
The study will be done on postmenopausal women with sleep disorders, who will be referred to the Menopausal Clinic at Ahvaz Imam Khomeini Hospital. The study will be a randomized controlled trial with two intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Postmenopausal women that at least one year and up to five years passed from their menopause, with age of 40 to 60 years, and those who will be eligible to participate in the study according to the questionnaire of identifying sleep problems. No-inclusion criteria: Severe anxiety and depression; taking antipsychotics drugs.

Intervention groups
At first, participants will be evaluated for sleep disorders using the related questionnaires Then women with sleep disorders will randomly be assigned into two groups of intervention and control. Then 6 counseling sessions according to the cognitive-behavior treatment for insomnia will be held for postmenopausal women in intervention group. For the control group, participants will complete the sleep disorder questionnaires and they will receive the routine care from postmenopausal clinic at the Imam Khomeini Hospital in Ahvaz.

Main outcome variables
Sleep disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180313039082N1**
Registration date: **2018-06-26, 1397/04/05**
Registration timing: **retrospective**

Last update: **2018-06-26, 1397/04/05**
Update count: **0**

Registration date
2018-06-26, 1397/04/05

Registrant information

Name
Hadis Moradifarsani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-05-22, 1397/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Group Cognitive-Behavioral Therapy(CBT) on Sleep disorders in Postmenopausal Women

Public title
The Effect of Group Cognitive-Behavioral Therapy(CBT) on Sleep disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 40- 60 years Passing for at least one year and up to 5 years from menopause Being married Literacy at least at a high school education Having sleep disorder, according to the Insomnia Severity Index and Pitsburg Sleep Quality questionnaire Willingness to participate in this study and providing written consent
Exclusion criteria:
Presence of medical problems Interfering with sleep disorders Work at night shift recent participation in psychotherapy or cognitive-behavioral therapy for other problems. Recent severe trauma during the last three months Taking sleeping and antipsychotics medications Having mental illnesses such as severe depression and severe anxiety, that may leading to sleep problems Smoking (more than 10 cigarettes a day), drug and alcohol use
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: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to do the intervention, the women will be divided into two groups of 23 participant as control and intervention groups using block randomization with a block size of four and allocation ratio of one. For allocation concealment of women in the intervention and control groups, 23 4-digit even numbers will be chosen from random numbers as codes for participants of control group and 23 4-digit odd numbers for participants of intervention group will be chosen from random numbers table and they will be written according to the order of blocks. Then, the number of intervention and control groups will put in the opac envelops and then the envelops will be closed and they will be given randomly to the eligible women in the study by the secretary of menopause clinic (the researcher and the participant will not informed about allocation until the last moment
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
A randomized controlled trial with a control group, randomized, with a block allocation to the groups

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University Medical Science, Golestan Ave. Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2018-04-21, 1397/02/01
Ethics committee reference number
IR.AJUMS.REC.1397.014

Health conditions studied

1

Description of health condition studied
sleep disorders in menopausal women
ICD-10 code
G47
ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Sleep disorders
Timepoint
Sleep disorders (at the beginning of the intervention), before the intervention, 3, 6, and 10 weeks after the intervention.
Method of measurement
Insomnia Severity Index, Pitsburg Sleep Quality Index, Sleep Log

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:for this group 6 sessions of 90 minutes counseling of cognitive behavior therapy will be

held weekly.The content of sessions will be as follow: First session: introduction and orientation with group members, concept of menopause and changes during menopause, concept of insomnia models, sleep restriction and controlling the stimulants.Second and third sessions: management of sleep health and therapeutic cognitive with the aim of modifying the dysfunctional beliefs about sleep and effects of insomnia on daily performance will be tought. Fourth and fifth sessions: cognitive-behavioral treatment principles will be reinforced, and the sleep program will be adjusted according to the information of daily sleep log report. Sixth session: it will be focused on prevention from relapse and skills to deal with failures.

Category

Treatment - Other

2

Description

Control group: For this group, participants will complete the sleep disorder questionnaires and they will receive the routine care at postmenopausal clinic of the Imam Khomeini Hospital in Ahvaz.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Menopause Clinic at Ahvaz Imam Khomeini Hospital

Full name of responsible person

Parvin Abedi

Street address

Menopausal Clinic, Imam Khomeini Hospital, Azadegan Ave, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Poorandokht Afshari

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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

Poorandokht Afshari

Position

assistant professor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
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Position
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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
All data will be shareable after making the patients unidentifiable.

When the data will become available and for how long
Start the access period one year after the publication

To whom data/document is available
Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data are accessible by mentioning the name of the investigator and for clinical and research actions.

From where data/document is obtainable
Ms. Poorandokht Afshari. Faculty Member of Ahvaz Jundishapur University. Email address: p_afshary@yahoo.com

What processes are involved for a request to access data/document
Send the request by email and respond as soon as possible

Comments