Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Comparing the effectiveness of virtual cognitive behavioral counseling with face-to-face cognitive behavioral counseling on sleep disorders of menopausal women

Protocol summary

Study aim
Comparing the effectiveness of virtual cognitive behavioral counseling with face-to-face cognitive behavioral counseling on sleep disorders of menopausal women

Design
Clinical trial with control group, with randomized parallel groups without blinding on 63 postmenopausal women. Blocks of four and two-by-two allocation are used for randomization using computer software.

Settings and conduct
The people who are eligible to participate in the study based on the relevant questionnaires will be randomly divided into three groups of 21 people: face-to-face counseling, virtual counseling and a control group in Ahvaz city . The intervention includes face-to-face and virtual cognitive-behavioral counseling for two intervention groups, and the control group will receive an educational pamphlet.

Participants/Inclusion and exclusion criteria
Menopausal women who are at least one year and at most five years past their menopause and are 45-60 years old and have the characteristics of the research samples based on the questionnaires intended to diagnose sleep problems. Suffering from severe anxiety and depression and taking antipsychotic drugs are the main conditions of non-entry.

Intervention groups
For the people of the virtual cognitive behavioral counseling group and the people of the face-to-face cognitive-behavioral counseling group, 8 sessions of cognitive-behavioral therapy will be held in virtual and face-to-face respectively. For the control group, routine care of Ahvaz health centers will be provided along with educational pamphlets.

Main outcome variables
Improvement of Pittsburgh Sleep Disorder and Sleep Quality Index score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240930063215N1**
Registration date: **2024-10-02, 1403/07/11**
Registration timing: **prospective**

Last update: **2024-10-02, 1403/07/11**
Update count: **0**

Registration date
2024-10-02, 1403/07/11

Registrant information

Name
Fatemeh Ajloo

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 918 432 5825

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maedeh.ajloo1378@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-21, 1403/07/30

Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of virtual cognitive behavioral counseling with face-to-face cognitive behavioral counseling on sleep disorders of menopausal women

Public title
The effect of face-to-face and virtual cognitive-behavioral counseling on sleep disorders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 45 and 60 years Passing at least one year and at most 5 years from menopause Being married Reading and writing literacy at the minimum level Diagnosis of sleep disorder based on insomnia severity index questionnaires and Pittsburgh sleep quality questionnaire Willingness to participate in the project Having written consent

Exclusion criteria:
Having a medical illness that interferes with sleep problems working in a night shift job recent participation in psychotherapy programs or cognitive behavioral therapy for other problems recent severe trauma during the past three months taking an unstable amount of sleeping pills and taking antipsychotic drugs getting sick mental disorders including severe depression and severe anxiety, which lead to sleep problems use of tobacco (more than 10 cigarettes per day) and drugs and alcohol

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: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples were first through clustering and referring to the existing files and through phone calls or after visiting the clinics in person, using computer software into three groups of 21 people, face-to-face cognitive behavioral counseling, virtual cognitive behavioral counseling And the control group will be divided. The codes assigned to each participant are written on a piece of paper and kept by the secretary of the center. Therefore, before the start of the intervention, the researchers and the participants do not know about the grouping of the participants.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
A clinical trial with a control group, randomized, with allocation to groups in blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address
Golestan area

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2024-09-29, 1403/07/08

Ethics committee reference number
IR.AJUMS.REC.1403.326

Health conditions studied

1

Description of health condition studied
Sleep disorder

ICD-10 code
G47

ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Improving indicators of sleep disorders

Timepoint
Before the start of the intervention , 4 weeks after the start of the intervention, one week and one month after the end of the intervention

Method of measurement
Insomnia Severity Index Questionnaire, Pittsburgh Sleep Quality Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the face-to-face counseling group, 8 cognitive-behavioral counseling sessions will be held in person and for the virtual counseling group, 8 cognitive-behavioral counseling sessions will be held virtually. The control group will receive the usual care along with the educational booklet. In order to evaluate the results of the treatment, relevant questionnaires will be completed by the participants before the intervention, four weeks after the intervention, one week and one month after the end of the intervention and will be used for statistical analysis.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Ahvaz
Full name of responsible person
Fatemeh Ajloo
Street address
Ahvaz, Azadegan Street, Imam Khomeini Hospital, Menopause Clinic
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Ahvaz , Golestan Street, Ahvaz University of Medical Sciences, School of Midwifery Nursing, Menopause and Andropause Research Center, Ahvaz
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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 Afshari
Position
assistant professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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 data of the study are classified and coded so that the names of the people cannot be identified .
When the data will become available and for how long
Access to the study data is possible after the results are published in the journal.
To whom data/document is available
All people who want to use the data in this field can access the study data.
Under which criteria data/document could be used
Study data can be used for comparison with other results.
From where data/document is obtainable
Mrs. Purandakht Afshari. Member of the academic staff of Jundishapur University, Ahvaz. Email address: p_afshary@yahoo.com
What processes are involved for a request to access data/document
The request is sent by e-mail to the person in charge of the scientific or general responsibility of the study. p_afshary@yahoo.com
Comments