

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 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)

Phone

+98 918 432 5825

Email address

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

City

Ahvaz

Province

Khouzestan

Postal code

6164644461

Phone

+98 61 3222 2114

Email

parvinabedi@gmail.com

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

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8383

Fax

+98 61 3373 8294

Email

itc@ajums.ac.ir

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

Midwifery

Street address

Golestan Street , Ahvaz University of Medical Sciences, Faculty of Midwifery Nursing

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8619

Email

p_afshary@yahoo.com

Person responsible for scientific 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

Midwifery

Street address

Golestan Street, Ahvaz University of Medical Sciences, Faculty of Midwifery Nursing

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8619

Email

p_afshary@yahoo.com

Email

Maedeh.Ajloo1378@gmail.com

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Ajloo

Position

Master's student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shahrsanati, Atlasieh Bala, Azarab Residential Houses

City

Arak

Province

Markazi

Postal code

3819863837

Phone

+98 918 432 5825