Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the effectiveness of psychological education of the patient and spouse in people with obstructive sleep apnea following the CPAP device, improving sleep quality and reducing daily sleepiness

Protocol summary

Study aim
Investigating the effectiveness of psychological education of the patient and spouse in people with obstructive sleep apnea following the CPAP device, improving sleep quality and reducing daily sleepiness.

Design
A clinical trial with a control and intervention group, a blinded strain, Randomized

Settings and conduct
The place of the study is in the sleep clinic of Ibn Sina Hospital, and the patients are not aware of the research process

Participants/Inclusion and exclusion criteria
A patient with obstructive sleep apnea Patients who want to use a CPAP machine Completing questionnaires related to sleep quality and daily sleepiness Marital status

Intervention groups
the control group will have self-monitoring for 5 weeks. Intervention group meetings will be in person or online. Psychological training sessions using cognitive behavioral approach (CBT).1.Diagnostic interview based on DSM-5 for each participating member with an approximate time of 45 minutes in one session (diagnosis of severe mental illnesses)2. Psychoeducation about the nature of the disease in one session to the patient and spouse and motivational interview.At first, clients are taught a complete explanation about the content of obstructive sleep apnea, the CPAP machine, and the consequences and complications of not using the machine.This training can be in the form of slides and different types of educational videos. Such information about daily sleep quality and daily sleepiness will also be provided to patients.

Main outcome variables
Adherence to the CPAP device

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240203060885N1**
Registration date: **2024-02-20, 1402/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-20, 1402/12/01**
Update count: **0**

Registration date
2024-02-20, 1402/12/01

Registrant information

Name
Mahdiye Faramarzi Moghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 991 073 6552

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faramarzimahdiye01@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-13, 1402/11/24

Expected recruitment end date
2024-04-12, 1403/01/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of psychological education of the patient and spouse in people with obstructive sleep apnea following the CPAP device, improving sleep quality and reducing daily sleepiness

Public title
Investigating the effectiveness of psychological education of the patient and spouse in people with obstructive sleep apnea following the CPAP device, improving sleep quality and reducing daily sleepiness

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with obstructive sleep apnea patients who want to use CPAP device completing questionnaires related to sleep quality and daily sleepiness marriage

Exclusion criteria:
suffering from severe mental illnesses (psychotic, bipolar)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, permutation blocks method was used to generate the sequence of random assignment of people to the studied groups. Random allocation sequence of people was done using Random Allocation Software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of studied groups. In this study, there are six blocks AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5) and BAAB (6). One of the blocks is randomly selected. If the first block, AABB, is selected, the first and second people are assigned to group A, and the third and fourth people are assigned to group B, and this process continues until all the samples are assigned. The characteristic of this method is that the two study groups will have equal numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants in this research do not know about the sampling method and the members of the control group and only receive the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
East Hedayat St., Hedayat 2.1, plauqe. 83, second floor

City
Mashhad

Province
Razavi Khorasan

Postal code
9194873999

Approval date
2024-02-04, 1402/11/15

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.477

Health conditions studied

1

Description of health condition studied
Patients with obstructive sleep apnea

ICD-10 code
G47.3

ICD-10 code description
Sleep apnea

Primary outcomes

1

Description
Patients with obstructive sleep apnea who use a CPAP machine

Timepoint
The measurement is done before the start of the intervention, immediately after the end of the intervention and eight weeks after the intervention

Method of measurement
Using the Petersburg Sleep Quality Questionnaire and Epworth Daily Sleepiness Questionnaire

Secondary outcomes

1

Description
improving sleep quality

Timepoint
The measurement is done before the start of the intervention, immediately after the end of the intervention and eight weeks after the intervention

Method of measurement
Using the Petersburg Sleep Quality Questionnaire and the Epworth Daily Sleepiness Questionnaire

2

Description
reducing daily sleepiness
Timepoint
The measurement is done before the start of the intervention, immediately after the end of the intervention and eight weeks after the intervention
Method of measurement
Using the Petersburg Sleep Quality Questionnaire and the Epworth Daily Sleepiness Questionnaire

Intervention groups

1

Description
Intervention group: This group includes 17 patients with their partner, the affected patient has used the CPAP machine for one month, and after one month, intervention sessions (5 sessions) will be held for each person in person or online.The content of the sessions will be based on the cognitive-behavioral approach. In this way, one session of psychoeducation, two sessions of working on false beliefs of the patient and partner about apnea and the use of (cognitive) device, and two sessions will be behavioral.After finishing the sessions, the patient will use the device again for one month to determine the effectiveness of the intervention sessions.
Category
N/A

2

Description
Intervention group: This group includes 17 patients without a partner, the affected patient has used the CPAP machine for one month, and after one month, intervention sessions (5 sessions) will be held for the patient in person or online. The content of the sessions will be based on the cognitive-behavioral approach.In this way, one session of psychoeducation, two sessions of working on the patient's false beliefs about apnea and the use of the (cognitive) device, and two sessions will be behavioral. After finishing the sessions, the patient will use the device again for one month to determine the effectiveness of the intervention sessions.
Category
N/A

3

Description
Control group: The control group includes 17 patients along with their partner, the affected patient used the CPAP machine for one month, and after one month, all the content related to the intervention sessions was given to the patient and partner in the form of brochures without conducting the sessions. to be read weekly. After five weeks, the patient will use the device again for one month to determine the effectiveness of the intervention sessions.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina Hospital, Mashhad
Full name of responsible person
Dr. Seyed Kaveh Hojjat
Street address
Second floor, No. 83, Hedayat 2/1, East Hedayat St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Mouhebati
Street address
University Street, next to Hoizeh Cinema, University of Medical Sciences, 3rd floor, University Research and Technology Vice-Chancellor
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Province
Razavi Khorasan
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9138813944
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+98 51 3841 1538
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahdiye Faramarzi Moghaddam
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available