

# 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

##### Email address

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

#### City

Mashhad

#### Province

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#### Postal code

9194873999

#### Phone

+98 991 073 6552

#### Email

Faramarzimahdiye01@gmail.com

## 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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

#### Email

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

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**Email**

faramarzimahdiye01@gmail.com

**Person responsible for updating data****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

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**City**

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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