

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Investigating the effect of implementing a training package based on cognitive behavioral therapy on sleep quality and mental health of elderly men living in nursing homes

#### Protocol summary

##### Study aim

Investigating the effect of implementing an educational package based on cognitive behavioral therapy on sleep quality and mental health of elderly men living in nursing homes

##### Design

This is a double-blind clinical trial with the available sampling method, among 68 elderly men living in nursing homes, will be randomly divided into an intervention group (34 people) and a control group (34 people) with 4 permutation blocks.

##### Settings and conduct

Before the start of the intervention, both groups will be pre-tested using the PSQ and GHQ. The intervention group has 8 sessions of 45 minutes in 8 weeks, as a group in the form of questions and answers, lectures, pamphlets and educational animations in the form of a storyline and presentation of homework based on the treatment plan of Colin Espy, and the control group will not receive special treatment. The completion of the questionnaires (before the intervention, at the end of the intervention and one month after the end of the study) will be done by the secretary, who after completing the questionnaires, the secretary will enter the data into SPSS 26 software, and the statistical analysis will be done by the statistical consultant who won't know allocation and intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 65 years and older, having minimum reading and writing literacy, not participating in a similar training course, obtaining a score of 24 or higher in MMSE, willingness to participate in research  
Exclusion criteria: use of sleeping pills, smoking, absence of more than two sessions

##### Intervention groups

Intervention group: 8 sessions of 45 minutes in 8 weeks, in group discussion, lectures, pamphlets and animations

in the form of a storyline with assignments based on Colin Espy's plan. Control group: they will receive usual daily care and verbal communication.

##### Main outcome variables

Sleep quality, mental health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230808059089N1**

Registration date: **2024-02-15, 1402/11/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-02-15, 1402/11/26**

Update count: **0**

##### Registration date

2024-02-15, 1402/11/26

##### Registrant information

##### Name

MohammadHossein Sahami Gilan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 4523 9603

##### Email address

sahami.mh@medilam.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-08, 1402/10/18

##### Expected recruitment end date

2024-03-08, 1402/12/18

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of implementing a training package based on cognitive behavioral therapy on sleep quality and mental health of elderly men living in nursing homes

**Public title**

The effect of cognitive behavioral therapy on sleep quality and mental health

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 65 years Having at least reading and writing literacy Willingness to participate in research Sign the written consent

**Exclusion criteria:**

Participating in a similar training course Taking sleeping pills Drug abuse and Smoking Suffering from cognitive diseases such as Alzheimer's based on obtaining a score of less than 24 on the brief examination of mental status

**Age**From **65 years** old**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**Target sample size: **68****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The present study is a double-blind clinical trial with a pre-test, post-test and follow-up with a control group, which is available as a sampling from among the elderly men aged 65 and older living in Kermanshah nursing home who consent to participate in the study and are eligible. The conditions and criteria for entering the study are, in the form of a permutation block of 4 people, 68 of these people were randomly assigned to 2 intervention groups receiving an educational package based on cognitive behavioral therapy (34 people) and control (34 people), with the aim of investigating the effect of the package Training based on cognitive behavioral therapy on sleep quality and mental health of elderly men living in Kermanshah nursing home will be conducted in 1403. After receiving the code of ethics and registration in the clinical trial center of Iran and a written permission from the research vice-chancellor of Ilam University of Medical Sciences, first go to the general welfare department of Kermanshah city and after going through the legal

procedures, considering the ethical principles of the research and introducing them to the relevant nursing home. A written informed consent will be obtained from the elderly referring to the nursing home who are willing to participate in the study and who meet the criteria for entering the study, and after being divided into intervention and control groups, a pre-test will be conducted using a quality questionnaire. Pittsburgh Sleep and Goldberg Public Health will be completed by the secretary. The method of assigning people to the intervention and control groups will be as follows: 1) PPCC 2) PCPC 3) PCCP 4) CAPP 5) CPCP and 6) CPPC will be written on 6 separate sheets, where the letter P means Practice (educational package based on cognitive behavioral therapy) and the letter C means Control (without intervention). We will put 6 sheets in 6 separate envelopes. In the target nursing home, there are 4 buildings, buildings number 1 and 2 will be considered as one block and buildings number 3 and 4 will be considered as one block, and by throwing a coin, it will be determined whether they are intervention or control, then by referring to each The elderly person will be given an envelope to the nursing home center if they meet the entry criteria and personal satisfaction, based on the 4 permutation block randomization method, which contains the desired sequences, and after the sequence appears, if the letter P is displayed (educational package based on cognitive behavioral therapy) he is given a container containing two balls with the numbers of the intervention building (after determining the intervention building) to randomly choose one and enter one of the intervention buildings, and if the letter C (control) is displayed He is given a container containing two balls with the numbers of the control building, so that he randomly chooses one and enters one of the control buildings, which will determine the status of the next 3 people besides himself, and the next 3 people will be given only the container containing the balls. will be given and the next envelope will be opened by the fifth person. The above process will continue until the desired sample volume is reached. To hide the created sequence, envelopes will be embedded that will be completely similar to each other. This method will continue until the end of allocating samples.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Blinding in this study is a double-blind type that is implemented at several levels. Those responsible for data collection and data analysis in this study are not aware of the nature of the groups; In this way, a secretary will be hired to collect data through questionnaires, and this secretary will not know the type of intervention or its duration, nor will he know about the nature of the groups and how the participants will be assigned to the groups. The same secretary responsible for data collection also enters the collected data into SPSS software. The statistical consultant analyzing the data will be blinded to the nature of the allocation of participants to groups and the type of intervention.

**Placebo**

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

##### Street address

Ilam University of Medical Sciences, Ilam University of Medical Sciences, Banganjab, Ilam City, 3rd Floor, Secretariat Unit

##### City

Ilam

##### Province

Ilam

##### Postal code

6939177143

#### Approval date

2024-01-08, 1402/10/18

#### Ethics committee reference number

IR.MEDILAM.REC.1402.213

## Health conditions studied

### 1

#### Description of health condition studied

sleep quality

#### ICD-10 code

G47.9

#### ICD-10 code description

Sleep disorder, unspecified

### 2

#### Description of health condition studied

mental health

#### ICD-10 code

Z04.6

#### ICD-10 code description

Encounter for general psychiatric examination, requested by authority

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

before the start of the intervention, 8 weeks after the start of the intervention and 4 weeks after the end of the intervention

## Method of measurement

Pittsburgh Sleep Quality Questionnaire

### 2

#### Description

mental health

#### Timepoint

before the start of the intervention, 8 weeks after the start of the intervention and 4 weeks after the end of the intervention

#### Method of measurement

Goldberg General Health Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: In this study, for the group receiving a training package based on cognitive behavioral therapy, 8 sessions of 45 minutes in 8 weeks (each week includes one session) as a group in the conference hall of the nursing home or a room with a suitable capacity and Computer system and video projector in the form of questions and answers, lectures, presenting examples, audio-visual aids such as video pamphlets, animations and educational motion graphics in the form of storylines and presenting assignments for the training of intervention groups based on Colin Spee's treatment plan. The content of the meetings is given in Table 1. The information and method of implementing cognitive behavioral intervention for sleep has been confirmed by one of the experienced professors in the field of clinical psychology who also has a doctorate in this field, and the researcher also has a degree in cognitive behavioral therapy. The structure of the meetings is such that in the first meeting, while welcoming and getting to know the participants, the rules of the group and the purpose of the study will be stated. In the second session, participants are given information and training about sleep and its stages. The third session, while reviewing the previous session, includes training and information about stimulus control and how to do it. In the fourth session, while reviewing the third session, the participants are taught about sleep hygiene. In the fifth session, while reviewing the fourth session, participants are given training about sleep-related thoughts and how to control them. In the sixth session, while reviewing the fifth session, people are taught about relaxation methods. In the seventh session, in addition to reviewing the sixth session, information and training about sleep restriction and how to apply it will be given to the participants. In the eighth session, while reviewing the previous sessions, the end of the course will be reviewed and the related problems of the participants will be fixed. At the end of all sessions, in order not to forget the information, the summary of the session in the form of a visual pamphlet along with a

brief written explanation below the images will be provided to the samples, and the content of each session will be provided to the nurses in the nursing home as a software that can be installed on the mobile phone. will take After the end of the interventions, the post-test will be taken again by the statistical secretary of the participants and a follow-up will be done one month later to determine whether the effectiveness of the educational package based on cognitive behavioral therapy will continue or not. Pre-test, post-test and follow-up will be taken from the intervention group before the start of the intervention, 8 weeks after the start of the intervention and 4 weeks after the end of the intervention. A checklist will be used to follow up the members of the intervention group, which will be completed with the cooperation of the nurse based in the nursing home, and the elderly who will be absent for more than 2 sessions and do not complete the homework will be removed according to the table.

### Category

Lifestyle

## 2

### Description

Control group: During the research period, the control group, which, like the intervention group, consists of 34 people, will not receive any special treatment, except for routine daily care and verbal communication. Before the start of the intervention, 8 weeks after the start of the intervention and 4 weeks after the end of the intervention, pre-test, post-test and follow-up will be taken respectively.

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Welfare Department

##### Full name of responsible person

Shahpur Hosseini

##### Street address

Education Street, Jalilian Blvd, Mosli neighborhood

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

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##### Phone

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##### Email

Sahami3621@gmail.com

##### Web page address

<https://www.behzisti.ir/service/province/kermanshah>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ilam University of Medical Sciences

##### Full name of responsible person

Dr. Abbas Maleki

##### Street address

Secretariat, 3rd Floor, Vice-Chancellor Building, Ilam University of Medical Sciences, Banganjab, Research Blvd

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##### Province

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##### Postal code

6931851147

##### Phone

+98 918 741 9401

##### Email

abbasmaleki\_ilam@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

The study is only a thesis and the costs are borne by the student.

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ilam University of Medical Sciences

##### Full name of responsible person

MohammadHosseini Sahami Gilan

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

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##### Province

Kermanshah

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### 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