

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effectiveness of Cognitive-Behavioral Therapy for Insomnia on Severity and Quality of Sleep and Quality of Life in Elderly women

Protocol summary

2017-05-04, 1396/02/14

Summary

(1) Objectives: This study aimed to assess the efficacy of cognitive-behavioral therapy for insomnia on different aspects of sleep and quality of life in elderly women . (2) Design: This study is a Quasi-Experimental Research Method, containing pretest and post test design and a control group. The statistical population was all elderly women in Mashhad city that 20 people of them were selected voluntarily by Insomnia Severity Index and randomly divided into two 10 control and experimental groups .(3) Setting and conduct: at the baseline Both groups completed Insomnia Severity Index, Pittsburgh sleep quality and lei pad quality of life questionnaires and then The experimental group received treatment for 4 weeks with 2 sessions per week in 60 minutes but control group did not receive any treatment. After intervention, both groups completed the questionnaires again. (4) Participants including major eligibility criteria: The sample of this study includes and elderly women with primary insomnia disorder older than 60 years old, having the entry and exit conditions. (5) Intervention: Experimental group went under cognitive behavioral therapy for insomnia based on the Morin instruction including sleep hygiene, sleep restriction, modifying beliefs and cognitive errors.(6)Main outcome measures: Quality of life, Quality of sleep and Insomnia severity.

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

By researcher

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Cognitive-Behavioral Therapy for Insomnia on Severity and Quality of Sleep and Quality of Life in Elderly women

Public title

Effectiveness of Cognitive-Behavioral Therapy for Insomnia on Severity and Quality of Sleep and Quality of Life in Elderly women

Purpose

Health service research

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091223955N2**

Registration date: **2017-05-04, 1396/02/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Inclusion criteria: The score higher than 7 in Insomnia Severity: The age over than 60 years old: Ability to write: Absence of Dementia and other Cognitive and major psychiatric deficits: Ability to understand and analyze: Desire to participate in the intervention. Exclusion criteria: Secondary insomnia disorder: Medical problems and general medicine that leads to insomnia: Senior's disinterest about the program: The participant's death.

Age

From **60 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ferdowsi University of Mashhad

Street address

Faculty of psychology, Ferdowsi University of Mashhad, Azadi Sq, Mashhad

City

Mashhad

Postal code

Approval date

2014-06-11, 1393/03/21

Ethics committee reference number

567

Health conditions studied

1

Description of health condition studied

Nonorganic Insomnia

ICD-10 code

F51.0

ICD-10 code description

A condition of unsatisfactory quantity and/or quality of sleep

Primary outcomes

1

Description

Quality of Life

Timepoint

Before intervention - After intervention

Method of measurement

LEIPAD elderly quality of life questionnaire

2

Description

Quality of sleep

Timepoint

Before intervention - After intervention

Method of measurement

The Pittsburgh Sleep Quality Index

3

Description

Insomna severity

Timepoint

Pre test - Post test

Method of measurement

Insomna Severity Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive behavior intervention comes in group sessions based on Morin instruction twice a week 60 minutes per sessions for 4 weeks. This approach comes with instruction for sleep restriction, sleep hygiene, muscle relaxation, problem solving methods, training obstruction thought, mental imagery, opposite planning, clearing thoughts and skills to summarize distressing thoughts in a particular hours of a day.

Category

Behavior

2

Description

Control group: Control group had received no intervention at all they were analyzed for the sleep quality and quality of life before the intervention and after that using Insomnia severity index, Pittsburgh Sleep Quality and Leipad Quality of Life questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Education and Psychologys Clinic

Full name of responsible person

Dr.Seeyed Mohsen Asgari Nekah

Street address

Faculty of Education and Psychologys clinic, Ferdowsi University of Mashhad, Mashhad

City

Mashhhd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ferdowsi University of Mashhad

Full name of responsible person

Bahrami Ahmad

Street address

Vice president for research, Ferdowsi University of Mashhad , Azadi, Sq, Mashhad, Iran, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Ferdowsi University of Mashhad

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Malihe Hajary

Position

Master in Clinical Psychology

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty