

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of Cognitive rehabilitation therapy (CRT) and Relaxation therapy (RT) on patients with insomnia

Protocol summary

Study aim

Comparing the effectiveness of cognitive rehabilitation therapy and Progressive Muscle Relaxation on insomnia symptoms, cognitive symptoms and emotional symptoms in patients with insomnia disorder.

Design

This clinical trial study has two experimental groups and is randomized on 34 people. G POWER program is used to estimate the sample size and Random Generator software is used for randomization.

Settings and conduct

The sample will be selected from individuals who refer to psychiatric clinics of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-age older than 18 2-Meeting DSM-5 criteria for insomnia disorder 3-No presence of suicidal ideation or plans 4-No presence of organic diseases or degenerative and unstable medical condition • Exclusion criteria: 1-Not attending more than one session of rehabilitation or relaxation treatment 2-Presence of another untreated concurrent sleep disorder 3-Presence of severe psychiatric disorders (e.g; psychotic disorders, severe depression, bipolar disorder, substance dependence, or substance abuse) 4-Initiation of any psychological or medical treatment 5-taking drugs that activate the central nervous system

Intervention groups

The research sample includes 34 people who were randomly divided into two groups of 17 people. The first experimental group received cognitive rehabilitation therapy according to a protocol in the form of 12 sessions (3 days a week), each session lasting 60 minutes. The second experimental group received progressive muscle relaxation treatment according to a protocol in the form of 12 sessions (3 days a week) for 45 minutes each session.

Main outcome variables

Insomnia symptoms, cognitive symptoms and emotional

symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220817055739N1**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-31, 1401/10/10**

Update count: **0**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Mehdi Bazi Alahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3032 1111

Email address

mehdi.bazi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of Cognitive rehabilitation therapy (CRT) and Relaxation therapy (RT) on patients with insomnia

Public title
Comparison of the effectiveness of Cognitive rehabilitation therapy (CRT) and Relaxation therapy (RT) on patients with Insomnia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age older than 18 Meeting DSM-5 criteria for insomnia disorder No presence of suicidal ideation or plans No presence of organic diseases or degenerative and unstable medical condition
Exclusion criteria:
Not attending more than one session of rehabilitation or relaxation treatment Presence of another untreated concurrent sleep disorder Presence of severe psychiatric disorders (e.g; psychotic disorders, severe depression, bipolar disorder, substance dependence, or substance abuse) Initiation of any psychological or medical treatment taking drugs that activate the central nervous system

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
N/A

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 Shahid Beheshti University of Medical Sciences

Street address

Iran - Tehran - Shahid Chamran Highway Yemen Street - Shahid Arabi Street - next to Ayatollah Taleghani Hospital - Shahid Beheshti School of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-09-06, 1401/06/15

Ethics committee reference number

IR.SBMU.MSP.REC.1401.249

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

Symptoms of insomnia

Timepoint

Before the start of the interventions, during interventions, two months after the intervention

Method of measurement

1-Insomnia Severity Index (ISI), 2-Consensus Sleep Diary (CSD)

2

Description

Cognitive symptoms

Timepoint

Before the start of the interventions, during interventions, two months after the intervention

Method of measurement

1-Stroop Color and Word Test (SCWT), 2-Tower of London Test (TOL)

3

Description

Emotional symptoms

Timepoint

Before the start of the interventions, during interventions, two months after the intervention

Method of measurement

1- Beck Depression Inventory-II (BDI-II), 2- Beck Anxiety Inventory(BAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group receives cognitive rehabilitation therapy according to a protocol in the form of 12 sessions (3 days a week), each session lasting 60 minutes.

Category

Rehabilitation

2

Description

Intervention group: The experimental group received Progressive Muscle Relaxation according to a protocol in the form of 12 sessions (3 days a week), each session lasting 45 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Mehdi Bazi Alahri

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Psychology Group, Floor4, Taleghani hospital, Erabi Ave., Yaman Ave., Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afsin Zarghi

Street address

Vice-Chancellor of Research Affairs, Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Erabi Ave., Chamran highway

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Intl-office@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hoda Doos Ali Vand

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehdi Bazi Alahri

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology