# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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)

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+98 21 3032 1111

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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
**Street address**
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
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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
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Psychology
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## Person responsible for updating data

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mehdi.bazi@yahoo.com

## 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