

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparing social response to cognitive behavioral therapy with cognitive behavioral therapy with metacognitive techniques in people with chronic insomnia disorder

Protocol summary

Study aim

Comparing efficacy of therapies on perceived social support

Design

Randomized clinical trial with parallel group (cognitive behavioral therapy with metacognitive techniques). Both intervention group and parallel groups include 2 participant. Randomization will carry out by someone who will blinded about study goals.

Settings and conduct

All patients will allocated randomly to two intervention groups. During receiving and after end of treatments, all patients will assess five times by evaluator. Randomizer will unaware of the study goal. Researchers and therapists will have no role in evaluation of study outcomes. Also, evaluator will unaware of who belong to which group and the study goal.

Participants/Inclusion and exclusion criteria

Inclusive criteria: Age between 18 to 55 years old; Suffering from insomnia for three months or more; Education equal to or more than 12 grade; Completing informed consent form. Exclusive criteria: Suffering from an unstable or undiagnosed disorder or disease; Comorbidity with schizophrenia, epilepsy, traumatic brain injury (TBI), bipolar disorder, and other sleep disorders; Taking a medication for treating insomnia disorder; Suffering from a cognitive impairment that makes it impossible to follow treatment instructions; Consuming drugs and alcohol until equal to or less than six months before the study begins; Having night or unstable work shift.

Intervention groups

Intervention group 1: Cognitive behavioral therapy includes stimulus control therapy, sleep restriction therapy, sleep hygiene education, and cognitive therapy
Intervention group 2: Cognitive behavioral therapy with metacognitive techniques includes detached

mindfulness, and worry/rumination postponement techniques

Main outcome variables

Perceived social support; Sleep efficiency index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043300N3**

Registration date: **2019-08-21, 1398/05/30**

Registration timing: **retrospective**

Last update: **2019-08-21, 1398/05/30**

Update count: **0**

Registration date

2019-08-21, 1398/05/30

Registrant information

Name

Behzad Salmani

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 31 5568 3234

Email address

std_b.salmani@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

2018-11-06, 1397/08/15

Actual recruitment end date

2019-02-09, 1397/11/20

Trial completion date

2019-03-01, 1397/12/10

Scientific title

Comparing social response to cognitive behavioral therapy with cognitive behavioral therapy with metacognitive techniques in people with chronic insomnia disorder

Public title

Comparing social response to cognitive behavioral therapy with or without metacognitive techniques

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 55 years old Suffering from insomnia for three months or more Education equal to or more than 12 grade in Iran Completing informed consent form

Exclusion criteria:

Suffering from an unstable or undiagnosed disorder or disease Comorbidity with schizophrenia, epilepsy, traumatic brain injury (TBI), bipolar disorder, and other sleep disorders Taking a medication for treating insomnia disorder Suffering from a cognitive impairment that makes it impossible to follow treatment instructions Consuming drugs and alcohol until equal to or less than six months before the study begins Having night or unstable work shift

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **4**

Actual sample size reached: **4**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is used. In order to randomization, researchers were used sealed pocket. Someone who was not in charge of applying interventions and evaluating of outcomes and was unaware of the study goals, run randomization.

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**

Ethical committee of Kharazmi University

Street address

Somayyeh building, Kharazmi University, South Moffateh st, Tehran

City

Tehran

Province

Tehran

Postal code

15719-14911

Approval date

2019-05-02, 1398/02/12

Ethics committee reference number

IR.KHU.REC.1398.008

Health conditions studied**1****Description of health condition studied**

Chronic insomnia disorder

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes**1****Description**

Perceived social support

Timepoint

Pretreatment, session 3, session 5, post-treatment, 1-month follow-up, 3-month follow-up

Method of measurement

Social support scale

2**Description**

Sleep efficiency index

Timepoint

Pretreatment, session 3, session 5, post-treatment, 1-month follow-up, 3-month follow-up

Method of measurement

By formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive behavioral therapy: Eight weekly sessions; include stimulus control therapy, sleep restriction therapy, sleep hygiene education, and cognitive therapy. Duration of each session: 30 to 90 minutes.

Category

Behavior

2

Description

Intervention group: Cognitive behavioral therapy with metacognitive techniques: Eight weekly sessions; include stimulus control therapy, sleep restriction therapy, sleep hygiene education, and cognitive therapy. Duration of each session: 30 to 90 minutes with detached mindfulness and worry and rumination postponement from session 5 to 8.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Health Center

Full name of responsible person

Dr. Mehdi Khoobi

Street address

Standard st, Danesh boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research & technology assistance of Kharazmi University

Full name of responsible person

Dr. Jaafar Jahan Panah

Street address

Research & technology assistance, Somayyeh building, Kharazmi University, South mofatteh st.

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jahanpanah@khu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research & technology assistance of Kharazmi University

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

Kharazmi University

Full name of responsible person

Dr. Behzad Salmani

Position

Ph.D. in Health Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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

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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

Privacy in personal information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable