

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparing efficacy of cognitive behavioral therapy & cognitive behavioral therapy with metacognitive techniques on biological & psychological hyper-arousal in people with chronic insomnia disorder.

Protocol summary

Study aim

Evaluation efficacy of cognitive behavioral therapy and cognitive behavioral therapy with metacognitive techniques on hyper-arousal

Design

Randomized clinical trial without control group, parallel group, single blind. Randomization will carry out by someone who will be blinded about study goals.

Settings and conduct

After ending of recruitment of patients from two health centers and taking initial evaluation and checking out inclusive and exclusive criteria, patients will be allocated randomly to two intervention groups. During receiving and after end of treatments, all patients will be assessed six times by evaluator. Randomizer will be unaware of the study goal. Researchers and therapists will have no role in evaluation of study outcomes. Also, evaluator will be unaware of who belongs to which group and the study goal.

Participants/Inclusion and exclusion criteria

Inclusive criteria: Duration of insomnia disorder should be 3 months or more; Informed consent should be completed. Exclusive criteria: An untreated or undiagnosed psychiatric disorder and a condition or disorder; Comorbidity with schizophrenia, trauma brain injury, seizure and bipolar disorder, other sleep disorders; Using medications for treating of insomnia; Cognitive impairment that makes it impossible to follow treatment instructions; Use of substances and alcohol at least six months before the study; Having variable shift work.

Intervention groups

Intervention group 1: Cognitive behavioral therapy include stimulus control therapy, sleep restriction therapy, sleep hygiene education, and cognitive therapy; Intervention group 2: Cognitive behavioral therapy with meta-cognitive techniques include stimulus control

therapy, sleep restriction therapy, sleep hygiene education, detached mindfulness, and worry & rumination postponement.

Main outcome variables

Biological & psychological hyper-arousal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043300N1**

Registration date: **2019-06-04, 1398/03/14**

Registration timing: **retrospective**

Last update: **2019-06-04, 1398/03/14**

Update count: **0**

Registration date

2019-06-04, 1398/03/14

Registrant information

Name

Behzad Salmani

Name of organization / entity

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 31 5568 3234

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-10-12, 1397/07/20
Actual recruitment start date
 2018-08-12, 1397/05/21
Actual recruitment end date
 2018-10-12, 1397/07/20
Trial completion date
 2019-01-15, 1397/10/25

Scientific title
 Comparing efficacy of cognitive behavioral therapy & cognitive behavioral therapy with metacognitive techniques on biological & psychological hyper-arousal in people with chronic insomnia disorder.

Public title
 Effect of cognitive behavioral therapy in insomnia disorder.

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 suffered from insomnia for 3 or more months Older than 18 years Education equal to or higher than 12 grade Informed consent
Exclusion criteria:
 Suffering from undiagnosed or untreated illnesses or psychiatric disorders that have variable nature. Older than 55 years old Co-morbidity with schizophrenia, traumatic brain injury, epilepsy, bipolar disorder & other sleep disorders Consuming medications for treating insomnia disorder Cognitive impairment that make hard to understand treatment instructions. Abusing of drugs & alcohol until six months before study begins. Variable shift work

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

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider

Sample size
 Target sample size: **6**
 Actual sample size reached: **6**

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)
 Single blinded

Blinding description
 After randomization, someone who was in charge of randomization, call to all participants and asked they to refer to clinic in determined days. Participants does not received any information about who was belong to which

group. In fact, all participants were unaware from who belong to which group till session five of treatment. In the session, patients received cognitive or metacognitive techniques. Therefore, nature of received therapy was specified. Researchers and therapists was aware from who does belong to which group but have not any role in evaluating of study outcomes. Evaluation of outcomes is done in center near the clinic. Evaluator was unaware from goal of the study and who belong to which group.

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
 G47.00
ICD-10 code description
 Insomnia, unspecified

Primary outcomes

1

Description
 Biological hyper-arousal
Timepoint
 Pretreatment, session 3, session 5, post-treatment, 1-month follow-up, 3-month follow-up
Method of measurement
 Indirect calorimetry

2

Description

Psychological Hyper-arousal

Timepoint

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

Method of measurement

Pre-sleep arousal scale

Secondary outcomes

1

Description

Sleep Efficiency Index

Timepoint

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

Method of measurement

Formula

Intervention groups

1

Description

Intervention group 1: 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 2: Cognitive behavioral therapy with metacognitive techniques: Eight weekly sessions; include stimulus control therapy, sleep restriction therapy, sleep hygiene education, and metacognitive techniques include detached mindfulness and worry and rumination postponement. Duration of each session: 30 to 90 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Health Center

Full name of responsible person

Mehdi Khoobi

Street address

Standard st, Danesh boulevard

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Kashan

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Isfahan

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Email

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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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Postal code

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Phone

+98 21 8884 8944

Email

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

Behzad Salmani

Position

Ph.D. in Health Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

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

Not applicable

Data Dictionary

Not applicable