Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Cognitive – Behavior Therapy – Recovery Oriented in Patients with Insomnia Comorbid with Anxiety and (or) Depressive Disorder

Protocol summary

Study aim
Main Objective: To determine the effectiveness of cognitive-behavioral therapy with a recovery-oriented approach in patients with insomnia co-morbid with anxiety disorders or depression.

Design
This research is a single-case experimental design consisting of a multiple baseline design among several subjects. Due to the single-subject design, the number of samples will be 8 people.

Settings and conduct
The statistical population of this study is patients with chronic insomnia comorbid with anxiety or depression disorders. After referral from the centers, the patients are screened based on the entry and exit criteria by interviewing the principal investigator. Then, a structured clinical interview is conducted and they are examined for the presence of sleep disorders. Patients who meet the criteria are entered into the study and answer the questionnaires. Then, the participants receive cognitive therapy with a recovery-oriented approach in 10 sessions according to the designed protocol and for 50 to 60 minutes. All subjects answer the questionnaires again during the treatment process, before the start of treatment, at the 5th and 10th sessions, and 2 months after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - At least 18 years of age, - Fluency in Persian, - Minimum education of a high school diploma, - Chronic insomnia with anxiety or depression disorders or both - Drug dose should be stable for six months before starting treatment and no increase in drug dose or start of new drug during treatment Exclusion criteria: - Psychosis, bipolar disorder, substance dependence or substance abuse, - Having obvious suicidal thoughts,

Intervention groups
Cognitive-behavioral therapy with a recovery-oriented approach

Main outcome variables
Cognitive therapy with a recovery-oriented approach; Insomnia symptoms; Anxiety severity; Depression severity; Quality of life;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250531066001N1**
Registration date: **2026-01-02, 1404/10/12**
Registration timing: **retrospective**

Last update: **2026-01-02, 1404/10/12**
Update count: **0**

Registration date
2026-01-02, 1404/10/12

Registrant information

Name
Abbas DanandehpourKhameneh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2285 4159

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-05, 1404/02/15

Expected recruitment end date
2025-10-07, 1404/07/15

Actual recruitment start date
2025-05-05, 1404/02/15
Actual recruitment end date
2025-10-07, 1404/07/15
Trial completion date
2025-10-07, 1404/07/15

Scientific title
Effectiveness of Cognitive – Behavior Therapy – Recovery Oriented in Patients with Insomnia Comorbid with Anxiety and (or) Depressive Disorder

Public title
Effectiveness of Cognitive – Behavior Therapy – Recovery Oriented in Patients with Insomnia Comorbid with Anxiety and (or) Depressive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
- Must be at least 18 years of age, - Fluent in Persian, - Minimum education: Diploma, - Having chronic insomnia disorder according to DSM5 diagnostic criteria, - Having anxiety or depression disorders or both according to SCID-I, - Having a stable drug dose for six months before starting treatment and not increasing the drug dose or starting a new drug during treatment
Exclusion criteria:
- Having psychosis, bipolar disorder, substance dependence or abuse, - Being involved in other concurrent psychological treatments, ,- Having overt suicidal thoughts, - Having a debilitating physical illness or serious medical condition
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **8**
Actual sample size reached: **8**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences
Street address
No. 15, Zomorodkar Alley, Shavari Alley, Shariati Street, Qolhak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1948743161
Approval date
2025-04-30, 1404/02/10
Ethics committee reference number
IR.USWR.REC.1404.022

Health conditions studied

1

Description of health condition studied
Insomnia
ICD-10 code
G47.0
ICD-10 code description
Insomnia

Primary outcomes

1

Description
Insomnia
Timepoint
Before starting cognitive therapy with a recovery-oriented approach, during sessions 5 and 10 of treatment, and then 2 months after treatment
Method of measurement
Response to the Insomnia Severity Index (ISI) questionnaire

2

Description
Anxiety
Timepoint
Before starting cognitive therapy with a recovery-oriented approach, during sessions 5 and 10 of treatment, and then 2 months after treatment
Method of measurement
Answers to the Beck Anxiety Inventory BAI Anxiety Severity Index

3

Description

Depression

Timepoint

Before starting cognitive therapy with a recovery-oriented approach, during sessions 5 and 10 of treatment, and then 2 months after treatment

Method of measurement

Response to the Beck Depression Inventory - Second Edition (BDI-II) Depression Severity Index

4

Description

Quality of life

Timepoint

Before starting cognitive therapy with a recovery-oriented approach, during sessions 5 and 10 of treatment, and then 2 months after treatment

Method of measurement

Response to the World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) Quality of Life Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After referral from the centers, the patients are screened based on the entry and exit criteria by interviewing the principal investigator. Then, a structured clinical interview is conducted by the researcher, who is a fourth-year resident assistant, and they are examined for the presence of sleep disorders. Patients who meet the criteria are included in the study and answer the questionnaires. Then, the participants receive cognitive therapy with a recovery-oriented approach in 10 sessions according to the designed protocol and for 50 to 60 minutes. All subjects answer the questionnaires again during the treatment process, before the start of treatment, at sessions 5 and 10, and 2 months after treatment.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Educational and Treatment Center (Aminabad)

Full name of responsible person

Abbas Danandehpour Khameneh

Street address

Tehran, Shahr-e Ray - Taghi Abad intersection - Shahid Rastegar Boulevard - Razi Psychiatric Educational and Treatment Center

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Saeed Khanjani

Street address

Tehran, Velenjak, Daneshjoo Blvd., Kadayar Dead End, University of Rehabilitation and Social Health Sciences

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Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Abbas DanandehPour khameneh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
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