

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The efficacy of Transdiagnostic Cognitive Behavior Therapy on emotional, cognitive and behavioral constructs sleep-related in people with emotional disorders comorbid with insomnia disorder

Protocol summary

Study aim

Determination of the efficacy of Transdiagnostic Cognitive Behavior Therapy on emotional, behavioral and cognitive constructs sleep-related in people with emotional disorders comorbid with insomnia disorder

Design

First, a sample of 300 people is selected from the population and after the initial screening of students, they are selected based on the cut line of Beck Depression Anxiety and Anxiety Tests and then Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version (ADIS-IV-L) and diagnostic interview is performed. A sample of 32 eligible students will be selected and will be randomly divided into two groups of 16 intervention and control based on their homogenization.

Settings and conduct

Study at Shahid Dr. Beheshti Educational and Medical Center in Zanjan on students of Zanjan University of Medical Sciences, without a placebo. Researchers and participants will be unaware of how randomization occurs.

Participants/Inclusion and exclusion criteria

Entry conditions: having a cut-off on Beck Depression and Anxiety Tests, Diagnosis of one of the emotional disorders based on the Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version (ADIS-IV-L), Morin's sleep scale cut-off. No entry conditions: ,Dont participate in one of the three evaluation stages, History of psychological interventions, especially cognitive-behavioral therapy, in more than five psychotherapy sessions

Intervention groups

In this study, Barlow unified protocol will be used to perform the intervention. - It will take 6 months. 18 sessions of approximately one hour. The control group will not receive any treatment.

Main outcome variables

the efficacy of Transdiagnostic Cognitive Behavior Therapy on insomnia severity, beliefs about sleep, emotion regulation, sleep quality and bedtime procrastination in people with emotional disorders comorbid with insomnia disorder

General information

Reason for update

Some variables are not registered in the previous edition designs

Acronym

IRCT registration information

IRCT registration number: **IRCT20200112046097N1**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-28, 1400/06/06**

Update count: **1**

Registration date

2020-07-26, 1399/05/05

Registrant information

Name

Mahdiyeh Mohammadi jam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5537 6333

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-10, 1399/04/20

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Transdiagnostic Cognitive Behavior Therapy on emotional, cognitive and behavioral constructs sleep-related in people with emotional disorders comorbid with insomnia disorder

Public title

The efficacy of Transdiagnostic Cognitive Behavior Therapy on insomnia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Living in the city of Zanjan while doing research
The desire to participate in research
Having a cut-off line score on Beck Depression and Anxiety Inventory
Diagnosis of one of the emotional disorders based on the Anxiety Disorders Interview Schedule for DSM-IV-Lifetime Version (ADIS-IV-L)
Morin's sleep scale cut-off line score
Full consent of the candidate to participate in the project

Exclusion criteria:

Absence of more than two consecutive sessions in the integrated protocol
Dont participate in one of the three evaluation stages
History of psychological interventions, especially cognitive-behavioral therapy, in more than five psychotherapy sessions

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, participants will be asked about Beck Depression and Anxiety Inventory and the Maureen Insomnia Scale. . In the next step, with random number generator software in Excel, we assign qualified people to two intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers were unaware of assignment to intervention and control groups, data evaluators were unaware of the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Boulevard, Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

45136-15788

Approval date

2020-06-24, 1399/04/04

Ethics committee reference number

IR.ZUMS.REC.1399.110

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

insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

2**Description of health condition studied**

Depressive episode

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

3**Description of health condition studied**

Social phobias

ICD-10 code

F40.1

ICD-10 code description

Social phobias

4

Description of health condition studied

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

5

Description of health condition studied

Phobic anxiety disorder

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

6

Description of health condition studied

Agoraphobia

ICD-10 code

F40.0

ICD-10 code description

Agoraphobia

7

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

8

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Insomnia Severity

Timepoint

Before intervention, after intervention and 3-month follow-up

Method of measurement

Insomnia Severity Index

2

Description

Sleep-related beliefs

Timepoint

Before intervention, after intervention and 3-month follow-up

Method of measurement

Sleep-related beliefs scale

3

Description

Emotion Regulation

Timepoint

Before intervention, after intervention and 3-month follow-up

Method of measurement

Difficult Emotion Regulation Scale

Secondary outcomes

1

Description

Sleep Quality

Timepoint

Before intervention, after intervention and 3-month follow-up

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

bedtime procrastination

Timepoint

Before intervention, after intervention and 3-month follow-up

Method of measurement

bedtime procrastination scale

Intervention groups

1

Description

intervention group: treatment, Barlow Unified protocol - 18 sessions of 60 minutes on the intervention group

Category

Behavior

2

Description

Control group: The control group was without action and no therapeutic intervention was performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Omid Saed (PhD)

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Omid Saed

Position

P.H.D

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

I have not made a decision yet

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available