Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Determinationt 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 stagesو,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, emtion regualtion,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)

Phone

+98 21 5537 6333

Email address

m.mohamadi.g@zums.ac.ir

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
Ethice 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)
Street address
Azadi Boulevard, Zanjan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
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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
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Other areas of specialty/work
Psychology
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Person responsible for updating data

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Mahdieh Mohammadi Jam
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Postal code
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m.mohamadi.g@zums.ac.ir

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