

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effectiveness of cognitive behavioral group intervention on insomnia, bedtime procrastination and negative affect in student.

Protocol summary

Summary

Brief implementation method: The research method of this study is a clinical trial. First, according to the statistical population of this study, which will include all students of Zanjan University of Medical Sciences, a sample of 160 people will be available, then a questionnaire for insomnia (ISI) and symptoms of mental disorders, 25 questions (SCL-25) They will be implemented. Of those who scored ISI scores above 15 and SCL-25 scores below 45, and who have been suffering from insomnia for at least one month, a sample of 32 subjects was selected in a simple random manner and divided into two groups of 16 and control will be made. In the next step and in the pretest, a negligible questionnaire for BTPS, PANAS's positive and negative affective questionnaire will be implemented. In order to implement cognitive-behavioral insomnia for insomnia, the experimental group will use the protocol of Edinger and Carney (2008) as a group therapy, in the form of a 8-week 90-minute intervention, put a sleep hygiene leaflet to the control group to influence the cognitive domain. To be after performing group therapy intervention, the questionnaires are re-implemented and eventually follow-up one month after the intervention by re-running the questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061834608N2**

Registration date: **2017-10-10, 1396/07/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-10, 1396/07/18

Registrant information

Name

Zolfaghar Hosnavydehshams

Name of organization / entity

university of medical science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive behavioral group intervention on insomnia, bedtime procrastination and negative affect in student.

Public title

The effectiveness of cognitive behavioral group intervention on insomnia, bedtime procrastination and negative affect.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion major conditions: sleep quality score higher than 15; less than 45 in test score of SCL-25; volunteered

to participate in the plan satisfied Exclusion major conditions: sleep quality score below 15; score higher than 45 on tests of mental disorder symptoms SCL-25.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Zanjan University of Medical Sciences Ethics Committee

Street address

Zanjan University Of Medical Sience, Azadi Blvd, Zanjan

City

Zanjan

Postal code

4515613191

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

ZUMS.REC.1396.35

Health conditions studied

1

Description of health condition studied

INSOMNIA

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep

Primary outcomes

1

Description

Insomnia

Timepoint

Pre test, Post test and one month Follow up

Method of measurement

Insomnia severity index

Secondary outcomes

1

Description

Negative affect

Timepoint

Pre test, Post test and one month Follow up

Method of measurement

Positive and Negative Affect Scale

2

Description

Bedtime procrastination

Timepoint

Pretest, Posttest and one month Follow up

Method of measurement

Bedtime Procrastination Scale

Intervention groups

1

Description

The implementation of the cognitive-behavioral group therapy for insomnia using the Edinger-Carney protocol in 8 sessions of 90 minutes on the experimental group includes the following sessions: 1. First and second sessions: Measures and therapeutic preparations (psycho-education) a. assessing the nature of sleeplessness and the suitability of the patient for cognitive-behavioral therapy, b. Review sleep baseline report. 2. Third and fourth sessions: Performing behavioral therapy component. a. Describe the logic of treatment and sleep training plan, b. Working on sleep rules, c. Calculating the initial time prescribed for bedding, d. assign homework. 3. Fifth and sixth sessions: using cognitive therapy strategies. a. review and comment on the results of a sleep report, b. explaining cognitive logic to the patient, c. discussing constructive worries. C. discussing the method of the memo of thoughts, d. assign homework. 4. Seventh and eighth sessions: principles of relapse prevention and problem-solving techniques. a. recommendations for adjusting the time spent in bed, b. reviewing and reinforcing compliance with treatment, c. resolving the difficulty of behavioral components, d. resolving the difficulty of cognitive components, e. terminating the treatment

Category

Other

2

Description

There is no treatment for the control group at the same time as working on the experimental group. But at the end of the work on experimental group, the same treatment will be performed on the control group.

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

Zanjan University of Medical Sciences, Azadi Blvd,
Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zanjan University of
Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

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Zanjan University of Medical Sciences, Azadi Blvd,
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City

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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

Vice chancellor for research, Zanjan University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Zolfaghar Hosnavy Dehshams

Position

M.Sc.candidate in clinical psychology

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty