Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Zolfaghar Hosnavydehshams
Name of organization / entity
university of medical science
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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

Street address
Zanjan University of Medical Sciences, Azadi Blvd, Zanjan.

City
Zanjan

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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Beheshti Hospital, Gate the Ark, Sadi Crossroad, Zanjan.

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Person responsible for scientific inquiries

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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