

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparing the efficacy of Specific Cognitive Behavioral Protocol and Unified Protocol in reducing student's anxiety sensitivity, anxiety, depression and negative affect: Double Blind Randomized Clinical Trial

Protocol summary

Study aim

comparing the efficacy of Specific Cognitive Behavioral Protocol and Unified Protocol in reducing student's anxiety sensitivity, anxiety, depression and negative affect.

Design

This double blind randomized clinical trial has two parallel intervention groups and a control group.

Settings and conduct

The study will be done at Zanjan University of Medical Sciences. Also in this study, participants and data analyzer will not be aware of the randomization process.

Participants/Inclusion and exclusion criteria

The participants must be students of Zanjan University of Medical Sciences, and also residence in Zanjan city and tending to participate in research.

Intervention groups

First group will receive specific cognitive behavioral therapy, second group will receive transdiagnostic therapy and third group will not receive any intervention.

Main outcome variables

Anxiety sensitivity, anxiety, depression and negative affect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180501039497N1**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Reza Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 4001

Email address

ahmadi.reza@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparing the efficacy of Specific Cognitive Behavioral Protocol and Unified Protocol in reducing student's anxiety sensitivity, anxiety, depression and negative affect: Double Blind Randomized Clinical Trial

Public title

The comparing the efficacy of Specific Cognitive Behavioral Protocol and Unified Protocol in reducing anxiety sensitivity, anxiety, depression and negative affect

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being a student Residence in the Zanjan city Tending to participate in research

Exclusion criteria:
Drug abuse Personality disorders Cardiovascular diseases More than two sessions of absenteeism during the intervention Not attending in any of the evaluation sessions

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized block; Individual; Stratified; Random allocation software

Blinding (investigator's opinion)
Double blinded

Blinding description
After sampling, any of participant will not aware from randomization and allocation to groups. The data analyzer is selected outside of the study and all of datas will be given to him as a code.

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
Zanjan University of Medical Sciences, Azadi Square

City
Zanjan

Province
Zanjan

Postal code
45156-13191

Approval date
2018-04-18, 1397/01/29

Ethics committee reference number

IR.ZUMS.REC.1396.306

Health conditions studied

1

Description of health condition studied

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

2

Description of health condition studied

Major depressive disorder

ICD-10 code

F33.0

ICD-10 code description

Major depressive disorder, recurrent, mild

3

Description of health condition studied

Emotional problems

ICD-10 code

R45

ICD-10 code description

Symptoms and signs involving emotional state

Primary outcomes

1

Description

Anxiety sensitivity

Timepoint

Pre-test, Post-test and follow up (two month after post-test)

Method of measurement

Anxiety Sensitivity Index- 3 (ASI-III)

Secondary outcomes

1

Description

Anxiety

Timepoint

Pre-test, Post-test and Follow up (Two month after post-test)

Method of measurement

Beck Anxiety Inventory (BAI)

2

Description

Depression

Timepoint

Pre-test, Post-test and Follow up (Two month after post-

test)
Method of measurement
Beck Depression Inventory-II (BDI-II)

3

Description

Negative affect

Timepoint

Pre-test, Post-test and Follow up (Two month after post-test)

Method of measurement

Positive and Negative Affect Schedule-Negative (PANAS-NA)

Intervention groups

1

Description

First intervention group: Cognitive behavioral Therapy by Margo and Stewart's Protocol

Category

Behavior

2

Description

Second intervention group: Transdiagnostic of emotional disorders by Unified Protocol

Category

Behavior

3

Description

Control group: Without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences

Full name of responsible person

Omid Saed

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ahmadi.reza@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=en&sid=1

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Soghrat Faghihzadeh

Street address

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s.faghihzadeh@zums.ac.ir

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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Department of Clinical Psychology, Beheshti Hospital, Besat Ave, Arg Square

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o.saed@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Reza Ahmadi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All of information related to main outcome will be published.

When the data will become available and for how long

Start the access period from 2019

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Access to documents is possible to inform other researchers. Access to documents is possible to work with the researcher.

From where data/document is obtainable

DR. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr Omid Saed, Mobile: 09128425270 Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Reza Ahmadi, Mobile: 09142828221

What processes are involved for a request to access data/document

Documents will be shared only when the reason for the request is announced by phone or e-mail.

Comments