

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of cognitive-behavioral group therapy and training of relaxation techniques on students' anxiety

Protocol summary

on Students' Anxiety; Comparing Two Methods of Study

Study aim

Comparison of Cognitive-Behavioral Group Therapy and training of relaxation techniques on students' anxiety

Design

The study is an interventional, prospective, and randomized study. The randomization method will be performed with the help of the Excel random number table. The completion of the three stages of the Spielberger questionnaire will be completed by 40 students. The first step is before the implementation of the training process. Then group therapy sessions will be held for one group and training for relaxation exercises will be held for the other group. After the sessions are completed, the questionnaires will be completed simultaneously for two weeks and then three months later by both groups. And a group will also be considered as a control, which will complete the questionnaire three times without attending classes

Settings and conduct

This study will be conducted on students living in Bushehr Medical Sciences Dormitories. In this way, the Spielberger questionnaire will be provided to the students and then, according to the students' anxiety scores, the study will be done in three groups.

Participants/Inclusion and exclusion criteria

Entry Requirements: Moderate to severe anxiety based on Spielberger questionnaire Residence in girls' dormitory as a student of Bushehr University of Medical Sciences The desire to participate in the study Non-arrival conditions: Student not being at the time of the study

Intervention groups

1- A group for whom Cognitive-Behavioral Group Therapy is taught. 2. A group for whom training is given to relaxation techniques. 3. Control group that does not receive any training.

Main outcome variables

The Effect of Group Therapy Training on Students 'Anxiety; The Effect of Teaching Relaxation Techniques

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141102019780N2**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **retrospective**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4436 1156

Email address

zahra_rafiiee67@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-10-02, 1393/07/10

Expected recruitment end date

2014-11-01, 1393/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cognitive-behavioral group therapy and training of relaxation techniques on students' anxiety

Public title

Comparison of two methods of Cognitive-Behavioral group Therapy and relaxation techniques on reducing student anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate to severe anxiety scores based on Spielberger questionnaire Residence in girls' dormitory as a student of Bushehr University of Medical Sciences The desire to participate in the study

Exclusion criteria:

Student not being at the time of the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

How to randomize this research include the following steps At first, the researcher randomly and voluntarily selected the students of the dormitory living in the dormitory in order to complete the Spielberger's anxiety questionnaire. Then, after examining the scores of each student, they would enter the study among those who had a moderate to severe anxiety score. Became In the next step, randomly and with the numbering of each questionnaire, the students will be divided into three groups. The first group, which is numbered 1 to 15, is called the first intervention group and the second group is from 15 to 30. The second intervention group and the third group, from 30 to 40, will be called the control group. Subsequently, with the help of the spss software, the information of each student related to the completion of the questionnaire at different stages of the research, according to the number assigned by the researcher to the student Finding will arrive in the software.

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

Ethics Committee of Bushehr University of Medical Sciences

Street address

bushehr. sabzabad. University of Medical Sciences

City

bushehr

Province

Boushehr

Postal code

7514633341

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

B-93-16-10

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Student anxiety

Timepoint

Before intervention / two weeks after intervention / three months after intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The "first intervention group" includes 15 people attending cognitive-behavioral group therapy training sessions. The intervention is that in the course of eight sessions, regular training will be given to the group members by the psychologist.

Category

Treatment - Other

2

Description

The "second intervention group" includes 15 people attending training sessions on relaxation techniques. The intervention is that six sessions will be regularly provided by the psychologist to the members of the group

Category

Treatment - Other

3

Description

The "control group" includes 10 people who will not receive any training and will not intervene.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr University of Medical Sciences

Full name of responsible person

Zahra Rafiee

Street address

University of Medical Sciences, Salman Farsi Ave.
Sabz Abad, Bushehr

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Phone

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Fax

Email

zahra_rafiiee67@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Afshin Ostovar

Street address

Bushehr University of Medical Sciences, Pardis site,
Rishehr St ,Bushehr

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Email

zahra_rafiiee67@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Boushehr University of Medical Sciences

Proportion provided by this source

30

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

Boushehr University of Medical Sciences

Full name of responsible person

Zahra Rafiee

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Bushehr University of Medical Sciences, Salman Farsi
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zahra_rafiiee67@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Masoud Bahreini

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information that relates to student anxiety score can be shared

When the data will become available and for how long

Three months after the results are published

To whom data/document is available

All researchers have permission to receive information

Under which criteria data/document could be used

If necessary, use the data of their publication and publication, after obtaining consent from the participants in the study

From where data/document is obtainable

Email your request by email: zahra_rafiee67@yahoo.com

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

After sending the email and reviewing the request if it is mentioned in the terms of the terms, it will be answered by email within a maximum of one month

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Zahra Rafiee

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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