

# 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

#### City

Bushehr

#### Province

Boushehr

#### Postal code

7514633341

#### Phone

+98 77 3332 2081

#### Fax

#### Email

zahra\_rafee67@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

#### City

Bushehr

#### Province

Boushehr

#### Postal code

7514633341

#### Phone

+98 77 3345 0178

#### Fax

#### Email

zahra\_rafee67@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

#### Street address

Bushehr University of Medical Sciences, Salman Farsi  
Ave, Sabzabad,

#### City

Bushehr

#### Province

Boushehr

#### Postal code

7514633341

#### Phone

+98 77 3332 2081

#### Email

zahra\_rafee67@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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**City**

Bushehr

**Province**

Boushehr

**Postal code**

7514633341

**Phone**

+98 77 3332 2081

**Email**

msd.bahreini@yahoo.com

+98 77 3332 2081

**Email**

zahra\_rafiee67@yahoo.com

**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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