

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effectiveness of cognitive-behavioral stress management training on emotion regulation strategies, life expectancy, mental well-being and Social Adjustment in students with generalized anxiety disorder

Protocol summary

Study aim

Evaluating the impact of cognitive-behavioral stress management training on emotion regulation strategies, life expectancy, mental well-being, and social adjustment in students with generalized anxiety disorder

Design

This research includes pre-test, post-test, and follow-up assessments in both the experimental and control groups

Settings and conduct

This study, set to take place in the Education Department of Region 1 in Sanandaj, will involve the selection of 30 female students diagnosed with generalized anxiety disorder. Subsequently, they will be divided into two groups: an experimental group that will undergo a 10-session intervention, and a control group that will not receive any intervention after obtaining the necessary permits

Participants/Inclusion and exclusion criteria

This research will be conducted for middle school students who have generalized anxiety disorder

Intervention groups

intervention group: In this research, the stress management protocol based on the cognitive-behavioral approach by Antony et al. (2007) and other sources will be used for the experimental group. The sessions are outlined as follows: 1. Description of stressors and responses, 2. The impact of stress on thoughts 3. Exploring the connection between thoughts and emotions, 4. Identification of negative thoughts 5. Substituting logical thoughts for irrational ones, 6. Training in effective stress coping, 7. Implementing effective coping responses, 8. Anger management training, 9. Teaching assertiveness in interpersonal relationships, 10. Social support and social network maintenance techniques. Control group: In this study, the control group participated in the pre-test, post-test

and follow-up, but no educational or psychological intervention was implemented for this group

Main outcome variables

Emotion Regulation Strategies, Life Expectancy, Mental Well-Being and Social Adjustment

General information

Reason for update

Acronym

انریختشی آموزش مدیریت استرس به شیوه شناختی رفتاری

IRCT registration information

IRCT registration number: **IRCT20230417057932N2**

Registration date: **2024-01-10, 1402/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-10, 1402/10/20**

Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

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Anvar Dastbaz

Name of organization / entity

The University of Kurdistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral stress management training on emotion regulation strategies, life expectancy, mental well-being and Social Adjustment in students with generalized anxiety disorder

Public title

The effectiveness of cognitive- behavioral stress management training on emotion regulation strategies, life expectancy, mental well-being and Social Adjustment in students with generalized anxiety disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Middle school student and attendance at school during the research period being between the ages of 14-18 years Having generalized anxiety disorder (diagnosed based on the Spitzer Generalized Anxiety Disorder Questionnaire by Spitzer Et al. (2006) and an interview conducted by an experienced psychologist according to the criteria of DSM-5-TR).

Exclusion criteria:

presence of a chronic and disabling disease presence of concurrent mental disorders Participation in similar courses with an independent variable in the past or concurrently. Consumption of Psychiatric Medications

AgeFrom **14 years** old to **18 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

N/A

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**

Research Ethics Committees of Islamic Azad University-Sanandaj Branch

Street address

Sanandaj - Adab St. - central site of Islamic Azad University, Sanandaj branch

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.IAU.SDJ.REC.1402.019

Health conditions studied**1****Description of health condition studied**

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Emotion Regulation Strategies

Timepoint

Pre-test (before the intervention), post-test (after the intervention), follow-up (2 months after the intervention)

Method of measurement

Emotion regulation scale (Gross and Jones, 2003)

2**Description**

Life Expectancy

Timepoint

Pre-test (before the intervention), post-test (after the intervention), follow-up (2 months after the intervention)

Method of measurement

Miller Hope Scale (1988)

3**Description**

Mental Well-Being

Timepoint

Pre-test (before the intervention), post-test (after the intervention), follow-up (2 months after the intervention)

Method of measurement

Mental well-being questionnaire (Keyes & Magyar-Moe, 2003)

4

Description

Social Adjustment

Timepoint

Pre-test (before the intervention), post-test (after the intervention), follow-up (2 months after the intervention)

Method of measurement

California Social Adjustment Questionnaire (Clark et al., 1993)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this study, the cognitive-behavioral stress management training protocol is used for the intervention group. The first session: description of stressors and responses to them, awareness of possible health consequences, introduction of the protocol to the participants, awareness of the physical effects of stress, muscle relaxation for 16 muscle groups. The second session: the effect of stress on emotions and behavior, awareness of the effect of stress on thoughts, muscle relaxation for 8 muscle groups. Third session: communication of thoughts and emotions, awareness of imaging technique, diaphragmatic breathing, muscle relaxation for 4 muscle groups. The fourth session: identifying negative thoughts and cognitive distortions, solutions to challenge negative thoughts, visualization and passive muscle relaxation, the fifth session: replacing logical thoughts with illogical ones, spontaneous training to feel heaviness and warmth. Sixth session: training to cope effectively with stress, spontaneous training for heart rate, breathing, abdomen and forehead. Seventh session: Implementation of effective countermeasures of self-generated training along with visualization and self-induction. Session 8: Anger management training and mantra meditation, repetition and meditation practice. Ninth session: Teaching expressiveness in interpersonal relationships, breathing counting meditation. Session 10: Social support and social network maintenance techniques, creating a personal stress management plan.

Category

Behavior

2

Description

Control group: In this study, the control group participated in the pre-test, post-test and follow-up, but no educational or psychological intervention was implemented for this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling center of Sanandaj city education

Full name of responsible person

Ali Soleimani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Islamic Azad University

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
University of Kurdistan
Full name of responsible person
Anvar Dastbaz
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Person responsible for updating data

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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

In this study, an intervention program, including sessions accompanied by grade margins, is presented during the pre-test, post-test, and follow-up stages without specifying the participants' names. Additionally, the final results are disclosed.

When the data will become available and for how long

After one month from the publication of the results.

To whom data/document is available

for everyone

Under which criteria data/document could be used

It is not necessary conditions.

From where data/document is obtainable

email

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

1 Month

Comments