

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effectiveness of Cognitive Group Therapy on Fear of Negative Evaluation, Cognitive Flexibility and State-Trait Anxiety of Anxious Adolescents

Protocol summary

Study aim

Determining the Effectiveness of Cognitive Therapy Group on Fear of Negative Evaluation, Cognitive Flexibility and State-Trait Anxiety of Anxious Adolescents

Design

Non-randomized clinical trial with control group, parallel group, no blinding, on 30 patients. The intervention and comparison groups were studied in a period of time.

Settings and conduct

The venue was Ayatollah Hashemi Rafsanjani High School for Girls, Sari city, and the sample was selected in a non-random and purposeful manner, they were assigned to an experimental group of 15 people and a control group of 15 people, and all three tests were performed on the experimental and control groups. However, the experimental group underwent 12 sessions of cognitive group therapy, then the questionnaire was re-administered for both groups, after 45 days after the post-test, the tests were re-administered for the follow-up period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Obtaining a score of at least 43 in the Spielberger Trait-Trait Anxiety Questionnaire 2. Age between 13 and 16 years Exclusion criteria: 1.Absence of more than two sessions in treatment

Intervention groups

The intervention group includes anxiety patients who receive cognitive therapy group. The control group is the anxiety patients who do not receive the cognitive therapy group.

Main outcome variables

Effect on the level of fear of negative evaluation, cognitive flexibility, trait state anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230524058277N2**

Registration date: **2023-06-11, 1402/03/21**

Registration timing: **retrospective**

Last update: **2023-06-11, 1402/03/21**

Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Bahram Mirzaian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2022-12-18, 1401/09/27

Actual recruitment start date

2022-12-25, 1401/10/04

Actual recruitment end date

2023-03-12, 1401/12/21

Trial completion date

2023-04-25, 1402/02/05

Scientific title

The Effectiveness of Cognitive Group Therapy on Fear of

Negative Evaluation, Cognitive Flexibility and State-Trait Anxiety of Anxious Adolescents		Street address km 7 Darya road, Sari, Mazandaran province	
Public title The Effectiveness of Cognitive Group Therapy on Anxious Adolescents		City Sari	
Purpose Supportive		Province Mazandaran	
Inclusion/Exclusion criteria Inclusion criteria: Obtaining a score of at least 43 in the Spielberger State-Trait-Anxiety Questionnair Age between 13 and 16 years He has not taken any psychiatric medication during the last three months Do not suffer from an incurable physical disease such as cancer, MS, Alzheimer's and the like. Do not suffer from a serious psychiatric illness such as psychotic or the like Be literate at least up to the fifth grade Completion of the informed consent agreement regarding participation in the research project Do not undergo treatment or other psychological interventions during the research Exclusion criteria: Absence of more than two sessions in treatment It should be determined that he has taken psychoactive drugs or drugs during the last 5 months Suffering from mania or a psychotic disorder The lack of inclusion criteria led to the exclusion of the research		Postal code 48164194	
		Approval date 2023-02-15, 1401/11/26	
		Ethics committee reference number IR.IAU.SARI.REC.1401.232	
Health conditions studied			
1			
Description of health condition studied anxiety			
ICD-10 code			
ICD-10 code description			
Primary outcomes			
1			
Description Anxiety score in Spielberger Trait State Anxiety Questionnaire			
Timepoint At the beginning of the study (before the start of the intervention), the end of the intervention and 45 days after the end of the intervention.			
Method of measurement Spielberger Trait State Anxiety Questionnaire			
Secondary outcomes empty			
Intervention groups			
1			
Description Intervention group:The first session of the pre-test, welcoming and getting to know the group members with each other, the relevant rules and regulations, thinking and feeling training, providing homework in the field of concern formulation; The second session review and review the homework of the previous session, teaching negative spontaneous thoughts, practicing negative spontaneous thoughts related to group therapy, guided visual relaxation exercise, presenting homework in the field of compiling spontaneous thoughts in the A-B-C chain; The third session review and check the homework of the previous session, teaching the behavioral consequences of beliefs, practicing thought induction, teaching the downward arrow technique, practicing the downward arrow, presenting homework in the field of developing thought induction and analyzing the downward arrow by chain A- B-C; The fourth session is			
Ethics committees			
1			
Ethics committee Name of ethics committee Research Ethics Committee of Islamic Azad University, Sari Branch			

review and review of the homework of the previous session, continuation of the downward arrow technique, belief classification training, practice of belief classification, providing homework in the field of compilation of belief classification and downward arrow; The fifth session review and review the homework of the previous session, preparing the main list of beliefs and concerns, practicing the main list of beliefs and concerns, teaching cognitive map, preparing cognitive map, using the rating scale of mental discomfort, presenting homework in the field of classification classifying beliefs and practicing cognitive mapping; The sixth session review and check the homework of the previous session, teaching the list of beliefs and concerns, teaching objective analysis, practicing objective analysis, providing homework in the field of compiling objective analysis of beliefs; The seventh session review and check the homework of the previous session, standard analysis training, standard analysis practice, efficiency analysis training, efficiency analysis practice, providing assignments in the field of standard and efficiency analysis compilation; The 8th session review and check the homework of the previous session, teach logical analysis, practice and implement logical analysis, continue logical analysis, present homework in the field of logical analysis; The ninth session review and check the homework of the previous session, building a hierarchy of beliefs, practice building a hierarchy of beliefs, teaching opposition, practicing opposition, providing homework in the field of compiling opposition to beliefs; 10th session, reviewing and checking the homework of the previous session, training on perception change, filling in perception change forms, presenting homework on the field of perception change formulation; The eleventh and twelfth sessions review and check the homework of the previous session, self-discipline-self-reward training, sustainable change, use of mental imagery, closing ceremonies, appointments for follow-up and evaluation after treatment, post-test execution

Category

Rehabilitation

2

Description

Control group: It has not received any intervention. In addition, if interested, the members of the control group could receive the intervention done for the experimental group in the same treatment sessions after the completion of the plan.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Hashemi Rafsanjani High School

Full name of responsible person

Zahra Mostashtrikh

Street address

Ayatollah Hashemi Rafsanjani High School, at the beginning of Qaran St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ali Abbaszadeh Mousavi

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Khazar Square, km 7 of Darya Road (Farahabad), Islamic Azad University Complex, Sari branch

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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

Islamic Azad University

Full name of responsible person

Fatemeh Zahra Khayati Ghasem Kheyli

Position
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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

Only a part of the data, such as the information related to the main result or the like, can be shared

When the data will become available and for how long

One month after the end of the study

To whom data/document is available

There is no limit

Under which criteria data/document could be used

There is no limit

From where data/document is obtainable

Fz.khayati2022@gmail.com To receive the documents, send your request to the email provided

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

After sending the request to obtain the documents to the e-mail address, the documents will be sent after 10 working days

Comments