Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of cognitive behavioral therapy in fear of negative evaluation, self-criticism, and self-focused attention in adolescents with social anxiety symptom

Protocol summary

Study aim

A review of the effectiveness of cognitive-behavioral therapy on the fear of negative evaluation, self-focused attention and self-criticism in adolescents with social anxiety syndrome.

Design

A clinical trial with a control group was conducted in a non-random and available manner on 30 patients who were randomly assigned to two groups, an experimental group of 15 people and a control group of 15 people.

Settings and conduct

After approving the proposal and obtaining the code of ethics and permission from the 2nd district education and school principals and by attending several girls' high schools, Lajarka questionnaire was taken from the students to confirm the diagnosis, and those who obtained high grades were given a clinical interview. It was done and the number of 30 people It was selected non-randomly and those people were randomly assigned in two groups of 15 people, control and experimental.

Participants/Inclusion and exclusion criteria

Inclusion criteria : age between 13 and 15 Completion of the informed consent form by the parents and the teenager to participate in the research project have symptoms of social anxiety (based on the Lajerka questionnaire and structured clinical interview by a psychiatrist) exclusion criteria: Absence of more than one treatment session Failure to do homework in more than one time

Intervention groups

After completing the questionnaires, the experimental group received cognitive behavioral therapy in eight sessions. Then they completed the questionnaires again. The control group also completed the questionnaires but did not receive treatment, then they completed the questionnaire again after two months

Main outcome variables

With the treatment, the mental condition and social communication of the students improved and the anxiety in social situations decreased, which increased the quality of life of the students.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240616062146N1**
Registration date: **2024-08-03, 1403/05/13**
Registration timing: **retrospective**

Last update: **2024-08-03, 1403/05/13**
Update count: **0**

Registration date

2024-08-03, 1403/05/13

Registrant information

Name

fatemeh zahra sedaghat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3339 0832

Email address

sedaghatfatem9@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-13, 1402/11/24

Expected recruitment end date

2024-02-23, 1402/12/04

Actual recruitment start date

2024-01-21, 1402/11/01

Actual recruitment end date

2024-02-03, 1402/11/14

Trial completion date

2024-06-01, 1403/03/12

Scientific title

The effectiveness of cognitive behavioral therapy in fear of negative evaluation, self-criticism, and self-focused attention in adolescents with social anxiety symptom

Public title

The effectiveness of cognitive behavioral therapy in adolescents with social anxiety symptom

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 13 and 15 completing the informed consent agreement regarding participation in the research project not having a substance use disorder have social anxiety symptoms (based on the Lajerka adolescent anxiety questionnaire and structured clinical interview based on DSM 5 criteria by a psychiatrist Not suffering from psychiatric disorders based on a structured clinical interview based on DSM 5 criteria by a psychiatrist. Not suffering from vision and hearing problems so that the person cannot participate in the treatment process and complete the questionnaires. Absence of acute and chronic physical diseases.

Exclusion criteria:

Absence of more than one treatment session - Failure to do homework in more than one session Unwillingness to continue participating in the treatment process for any reason.

Age

From **13 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Available selection and random assignment by lottery method in two blocks of experimental group and control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University

Street address

No, 481567896. shamshirband20 Ave. Shamshirband Blvd , Sari town

City

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Province

Mazandaran

Postal code

4815678596

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

187. 1402.IR.IAU.SARI.REC

Health conditions studied

1

Description of health condition studied

Social anxiety disorder

ICD-10 code

F40.1

ICD-10 code description

Social anxiety disorder

Primary outcomes

1

Description

fear of negative evaluation

Timepoint

Measuring the fear of negative evaluation at the beginning of the study (before the start of the intervention) and after the end of the cognitive behavioral therapy sessions

Method of measurement

Brief Fear of Negative Evaluation Scale Leary (1983)

2

Description

Self _focused attention

Timepoint

Measuring self-focused attention at the beginning of the study (before the start of the intervention) and after the end of the cognitive behavioral therapy sessions

Method of measurement

In the focus of attention questionnaire of Woody, Chambless and Glass (1997)

3

Description
self-criticism
Timepoint
Measuring self-criticism at the beginning of the study (before the start of the intervention) and after the end of the cognitive behavioral therapy sessions
Method of measurement
The Levels of Self-Criticism Scale (LOSC; Thompson & Zuroff, 2004)

Secondary outcomes

1

Description
Fear score of negative evaluation
Timepoint
The time periods of measuring the fear of negative evaluation at the beginning of the study and after the end of the intervention
Method of measurement
12-item short form questionnaire (FNES-B)

2

Description
Self-focused attention score
Timepoint
The time periods of measuring the amount of self-focused attention at the beginning of the study and after the end of the intervention
Method of measurement
A 10-question questionnaire is the focus of attention

3

Description
self-criticism
Timepoint
The time periods of measuring the amount of self-criticism at the beginning of the study and after the end of the intervention
Method of measurement
22-question questionnaire (LOSC)

Intervention groups

1

Description
Intervention group: The experimental group of 15 adolescent girls with symptoms of social anxiety disorder in Sari city was selected in a non-random and accessible manner based on the inclusion criteria. Before implementing the intervention, three questionnaires of fear of negative evaluation, self-focused attention and self-criticism were taken from them. Then they received eight 90-minute sessions of cognitive behavioral therapy based on the Heimberg and Becker protocol.
Category
Behavior

2

Description
Control group: The control group of 15 teenage girls with symptoms of social anxiety disorder in Sari city was selected in a non-random and accessible manner based on the inclusion criteria. At the beginning of the work, at the same time as the experimental group, three questionnaires of fear of negative evaluation, self-focused attention and self-criticism were taken from them, and this group did not receive any intervention. After the experimental group received the intervention, questionnaires were taken again from both the control group and the experimental group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbari School
Full name of responsible person
Fatemeh zahra sedaghat
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Recruitment center
Name of recruitment center
Shahid Falahi School
Full name of responsible person
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Recruitment center

Name of recruitment center
School of Islamic Sciences and Education

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fatemeh zahra sedaghat

Street address
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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 sedaghat

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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 outcome or the like, can be shared
When the data will become available and for how long
Access starts 6 months after results are published
To whom data/document is available
Researchers working in academic and scientific institutions can access the data
Under which criteria data/document could be used
We have not considered other conditions.
From where data/document is obtainable
Dr. Maede Bagheri 09113546226 Mbagheri66.mb@gmail.com
What processes are involved for a request to access data/document
The applicant can receive the documents by submitting the code of ethics and sending her request to the mentioned email.
Comments