Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the Effectiveness of Cognitive Behavioral Therapy with Eye Movement Desensitization and Reprocessing Therapy on Anxiety Sensitivity, Fear of Negative Evaluation, Social Self-Efficacy and Quality of Life in Teenager with Social Anxiety Disorder

Protocol summary

Study aim

The purpose of this study is to compare the effectiveness of Cognitive Behavioral Therapy (CBT) with Eye Movement Desensitization and Reprocessing (EMDR) therapy on anxiety sensitivity, fear of negative evaluation, social self-efficacy and quality of life in adolescents with social anxiety disorder.

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 2 on 51 patients. A table of random numbers was used for randomization.

Settings and conduct

Following randomization and assignment of individuals in the study groups, patients are treated approximately twice a week using CBT or EMDR. This study will run at the Farhangian Clinic in Karaj city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A SPIN greater score than or equal to 40, fulfilling all diagnostic criteria of social phobia based on the SCID-5, providing written informed consent for participation in the study by participants and their parents, No presence of any other mental disorders No history of mental illness No dependence on alcohol or drugs Do not receive other current psychological treatment, and age between 14 - 18 Exclusion criteria: Having suicidal thoughts and beliefs More than 2 absences in treatment sessions

Intervention groups

CBT group (n= 17) EMDR group (n= 17) Control group (n= 17)

Main outcome variables

Anxiety sensitivity: Fear of anxiety-related emotions. Fear of negative evaluation: It means fear, worry and avoidance of being judged negatively by others. Social self-efficacy: refers to a person's self-confidence about his or her ability to behave in a certain way that leads to a favorable perception of oneself in others. Quality of Life: an individual's perception of their position in life in the context of the culture and value systems.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220502054725N1**
Registration date: **2022-05-17, 1401/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-17, 1401/02/27**
Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

Farnaz Moghbeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 4262 3959

Email address

f.moghbeli71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-13, 1401/02/23

Expected recruitment end date

2022-06-13, 1401/03/23

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the Effectiveness of Cognitive Behavioral Therapy with Eye Movement Desensitization and Reprocessing Therapy on Anxiety Sensitivity, Fear of Negative Evaluation, Social Self-Efficacy and Quality of Life in Teenager with Social Anxiety Disorder

Public title
Investigation of the Effectiveness of Cognitive Behavioral Therapy with Eye Movement Desensitization and Reprocessing Therapy in Teenager with Social Anxiety Disorder
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having suicidal thoughts and beliefs More than 2 absence in treatment sessions
Exclusion criteria:
A SPIN greater score than or equal to 20 Fulfilling all diagnostic criteria of social phobia based on the SCID-5 Providing written informed consent for participation in the study by participants and their parents No presence of any other mental disorders No history of mental illness No dependence on alcohol or drugs Do not receive other current psychological treatment Age between 14 - 18
Age
From **14 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will run by using the Software Allocation Random. Since the total number of samples predicted for the present study is small (n=45), we will use the simple randomization method to assign subjects to three study groups. We will assign a unique number to every member of our study's sample (from 1 to 45). An independent researcher makes random allocation codes using computer-generated random numbers. Then, we will use the random allocation generator software to randomly assign each number to experimental (CBT and EMDR) and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind study in that the researcher and participants are aware of the allocating intervention, but the data analyst and the person conducting the assessments will be blind to the specific participant's group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Islamic Azad University - Boroujerd Branch
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
City
Boroujerd
Province
Lorestan
Postal code
6915136335
Approval date
2022-04-19, 1401/01/30
Ethics committee reference number
IR.IAU.B.REC.1401.002

Health conditions studied

1

Description of health condition studied
Social phobias
ICD-10 code
F40.1
ICD-10 code description
Social phobias

Primary outcomes

1

Description
Anxiety sensitivity: Fear of anxiety which are related to their thoughts
Timepoint
One week before the intervention, one week after the last intervention session, one month after the last intervention session.
Method of measurement
Questionnaire

2

Description
Fear of negative evaluation: It means fear, worry and avoidance of being judged negatively by others.
Timepoint
One week before the intervention, one week after the last intervention session, one month after the last intervention session.
Method of measurement
Questionnaire

3

Description
Social self-efficacy: refers to a person's self-confidence about his or her ability to behave in a certain way that leads to a favorable perception of oneself in others.
Timepoint
One week before the intervention, one week after the last intervention session, one month after the last intervention session.
Method of measurement
Questionnaire

4

Description
Quality of Life: an individual's perception of their position in life in the context of the culture and value systems.
Timepoint
One week before the intervention, one week after the last intervention session, one month after the last intervention session.
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Cognitive-behavioral therapy: In the present study, twelve 60-minute sessions of cognitive-behavioral therapy weekly according to the standard protocol of cognitive-behavioral therapy for social anxiety disorder.
Timepoint
In each treatment session
Method of measurement
Behavior

2

Description
Eye Movement Desensitization and Reprocessing Therapy: In the present study, eight 90-minute sessions of eye movement desensitization and reprocessing therapy weekly according to the standard protocol of cognitive-behavioral therapy for social anxiety disorder.
Timepoint
In each treatment session
Method of measurement
Behavior

Intervention groups

1

Description
Intervention group: Cognitive-behavioral therapy: In the present study, twelve 60-minute sessions of cognitive-behavioral therapy weekly according to the standard protocol of cognitive-behavioral therapy for social anxiety disorder.
Category
Behavior

2

Description
Intervention group: Eye Movement Desensitization and Reprocessing Therapy: In the present study, eight 90-minute sessions of eye movement desensitization and reprocessing therapy weekly according to the standard protocol of cognitive-behavioral therapy for social anxiety disorder.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhangian Boroujerd Clinic
Full name of responsible person
Parviz Khorshidifard
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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
Islamic Azad University

Full name of responsible person
Farnaz Moghbeli

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Other areas of specialty/work
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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

Data from participants' responses to anxiety sensitivity, fear of negative evaluation, social self-efficacy, quality, and social anxiety disorder questionnaires in pre-test, post-test and follow up will analyze using SPSS software, and the results, without mentioning the names of the participants, were shared as study results.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data of this study will be provided for use by researchers in review or comparative studies.

From where data/document is obtainable

Farnaz Moghbeli, Department of Psychology, Islamic Azad University, Boroujerd Branch, Iran. f.moghbeli71@gmail.com, +989163992924

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

The applicant provides information about their application via email. Up to two weeks after the request, if accepted, documents or data files will be sent.

Comments