

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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)

##### Phone

+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**

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**Province**

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**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

#### **Street address**

Seyed Mostafa St., Farhangian Clinic

#### **City**

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Islamic Azad University

#### **Full name of responsible person**

Mohsen Bahrami

#### **Street address**

Navab Square, 3 km of Yadegar Imam Road, Imam Khomeini University Complex, Boroujerd, Iran.

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bahrami.m@malayer.iau.ac.ir  
**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  
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Psychology  
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## Person responsible for scientific inquiries

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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**

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.  
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**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**