Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Cognitive - Behavioral Therapy (CBT) with Virtual Reality Exposure Therapy (VRET) on Cognitive Emotion Regulation, Fear of Negative Evaluation, Anxiety Sensitivity, and Quality of Life in Adolescents with Symptoms of Social Anxiety Disorder

Protocol summary

Study aim

To compare the effectiveness of cognitive behavioral therapy with virtual reality exposure therapy on cognitive emotion regulation, fear of negative evaluation, anxiety sensitivity, and quality of life in adolescents with social anxiety disorder.

Design

A clinical trial with a control group, parallel groups, not blinded and nonrandomized, on 51 patients.

Settings and conduct

If eligible, patients with a social anxiety disorder who refer to the Hadaf Bartar Clinic in Qaemshahr city will be included in the study and assigned to experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A Social Phobia Inventory score greater than or equal to 40, Fulfilling all diagnostic criteria of social phobia based on the Structured Clinical Interview for DSM-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. Exclusion criteria: Having suicidal thoughts and beliefs.

Intervention groups

Intervention group 1: cognitive-behavioral therapy: includes twelve 60-minute sessions twice per week of cognitive-behavioral therapy according to the standard protocol of Clark and Wells. Intervention group 2: virtual reality exposure therapy: includes eight 60-minute sessions twice per week of virtual reality therapy according to the standard protocol of exposure therapy for specific phobias. Control group: Participants will be evaluated one week before the intervention, one week after, and three months after the last intervention session.

Main outcome variables

Cognitive Emotion Regulation; Fear of negative evaluation; Anxiety sensitivity; Quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220905055887N1**
Registration date: **2022-11-18, 1401/08/27**
Registration timing: **retrospective**

Last update: **2022-11-18, 1401/08/27**
Update count: **0**

Registration date

2022-11-18, 1401/08/27

Registrant information

Name

Nazila Razaghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Cognitive - Behavioral Therapy (CBT) with Virtual Reality Exposure Therapy (VRET) on Cognitive Emotion Regulation, Fear of Negative Evaluation, Anxiety Sensitivity, and Quality of Life in Adolescents with Symptoms of Social Anxiety Disorder

Public title

Comparison of the Effectiveness of Cognitive - Behavioral Therapy (CBT) with Virtual Reality Exposure Therapy (VRET) on Social Anxiety Disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A Social Phobia Inventory (SPIN) score greater than or equal to 40 Fulfilling all diagnostic criteria of social phobia based on the Structured Clinical Interview for DSM-5 (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

Exclusion criteria:

Having suicidal thoughts and beliefs

Age

From **14 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Not randomized

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 Committee of Islamic Azad University - Boroujerd Branch

Street address

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

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Province

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Approval date

2022-08-13, 1401/05/22

Ethics committee reference number

IR.IAU.B.REC.1401.017

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

Cognitive Emotion Regulation

Timepoint

One week before the intervention, one week after the last intervention session, three month after the last intervention session.

Method of measurement

Cognitive Emotion Regulation Questionnaire (CERQ)

2

Description

Fear of negative evaluation

Timepoint

One week before the intervention, one week after the last intervention session, three month after the last intervention session.

Method of measurement

Brief Fear of Negative Evaluation Scale (FNES-B)

3

Description

Anxiety sensitivity

Timepoint

One week before the intervention, one week after the last intervention session, three month after the last intervention session.

Method of measurement

Anxiety Sensitivity Index (ASI-R)

4

Description

Quality of Life

Timepoint

One week before the intervention, one week after the last intervention session, three month after the last intervention session.

Method of measurement

Quality of Life questionnaire (QOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cognitive-behavioral therapy: cognitive-behavioral therapy sessions will hold according to its standard protocol for social anxiety disorder (including twelve 60-minute sessions twice per week). This therapy is based on the Clark and Wells model, which emphasizes self-focused attention because social anxiety disorder is associated with reduced processing of social cues (Tsitsas & Paschali, 2014). The content of cognitive behavioral therapy sessions is described below: Session 1 aims to evaluate and conceptualize the problem and create a therapeutic alliance. In Session 2, the focus is on psycho-education, goal setting, and conceptualization of the problem. Participants are primarily informed about the general structure of the sessions and agenda setting. Then, the objectives that the participants want to achieve at the end of the process are determined. In Session 3, the focus is on how the participants' automatic thoughts, cognitive distortions, and safety behaviors relate to their problem and their effect on the maintenance of this issue. In Session 4, a specific memory of early negative life experiences related to the participants' problem, the meaning they ascribe to this memory, and images are identified and reevaluated using the empty chair technique. In Sessions 5, 6, and 7, the participants' beliefs about their problems will be determined based on the agenda, and cognitive interventions will be carried out for the determined beliefs. During these interventions, what the participants will learn in the fourth session is also utilized. In Session 8, the avoidance and safety behaviors of the participants are discussed, and the rationality of exposure and habituation, its place, and its importance in coping with the problem is evaluated. In Sessions 9, 10, and 11, cognitive and behavioral interventions are carried out simultaneously. Cognitive and behavioral techniques are used together to intervene on the agenda items determined together with the participants. In these sessions, participants are exposed to these situations they avoid that are related to their problems during the session and daily life. In Session 12, the process will end.

Category

Behavior

2

Description

Intervention group 2: Virtual reality exposure therapy: Virtual reality exposure therapy sessions will hold according to its standard protocol for social anxiety disorder (including eight 60-minute sessions twice per week). We will conduct virtual reality therapy sessions with a Desktop Computer with the specifications; Graphics Card: ASUS NVIDIA GEFORCE GTX 1060 6GB GDDR5, CPU: Core i7-4,790 (8 M Cache, up to 4.00 GHz), RAM: 8 GB DDR4, and an Oculus Rift Dk2 Virtual Reality Headset. These tools enable us to create a virtual environment and provide virtual reality stimuli to the patient in a safe manner. We will use the Unity platform for creating virtual reality experiences and scenarios. Patients will move within the virtual environment with a virtual reality gamepad. The therapist will explain how to use the app and conduct therapeutic sessions by following the standard protocols of cognitive behavioral therapy for specific phobias (Scozzari and Gamberini, 2011). Four different virtual reality scenarios are offered. Patients are confronted with one virtual reality scenario in each session. Depending on how fast the user wanted to pass the scenarios, each session took an average of 60 min to complete. In the final session, all virtual reality scenarios were presented one after another. The therapist will provide the content of cognitive-behavioral therapy using the six modules below: Module 1: The therapist will describe social phobic anxiety and provide information about the possibility of retaining safety. At the same time, in social phobic situations, educate the patient about how social phobic anxiety develops in a virtual reality environment and explain how the patient can overcome it. Module 2: The therapist will inform and educate the patient about the fear curve and how to set realistic goals to overcome his or her social phobic fears. Module 3: Immersion will take between twenty minutes. As exposure to virtual reality scenarios may provoke anticipatory fear, the therapist will explain to the patient that this is a normal response and that exposure to a virtual environment is not, in fact, dangerous. Module 4: The therapist will explain how automatic, catastrophic thoughts affect a patient's fear and anxiety. Also, the patient is encouraged to reflect on how realistic her catastrophic thoughts are .Module 5: The therapist will invite the patient to think about his or her unrealistic thoughts about the fear, explain why these thoughts are unrealistic, and help the patient formulate more realistic thoughts. Module 6: The therapist will encourage the patient to apply the new knowledge so that she can start practicing exposure to social situations in the real world.

Category

Behavior

3

Description

Control group: One week after entering the study, the patients in this group will be tested on the symptoms of social anxiety disorder, cognitive regulation of emotion, fear of negative evaluation, anxiety sensitivity, and quality of life through questionnaires. Also, one week after the last treatment session of participants in cognitive behavioral therapy group and virtual reality therapy, symptoms of social anxiety disorder, cognitive regulation of emotion, fear of negative evaluation, anxiety sensitivity, and quality of life will be measured again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hadaf Bartar Clinic

Full name of responsible person

Zeynab Valian

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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?

No

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

Nazila Razaghi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Full name of responsible person

Davood Jafari

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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 cognitive emotion regulation, anxiety sensitivity, fear of negative evaluation, quality of life, and social anxiety disorder questionnaires in the pre-test, post-test, and follow-up will analyze using SPSS software. The results (without mentioning the names of the participants) will be shared.
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
Nazila Razaghi, Department of Psychology, Islamic Azad University, Boroujerd Branch, Iran. naazil.razzaghi@gmail.com 00989333917995
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