

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Efficacy of cognitive behavioral therapy (CBT) and virtual reality exposure therapy (VRET) on fear of negative evaluation and social anxiety disorder symptoms among adolescents

Protocol summary

Study aim

Efficacy of cognitive behavioral therapy with virtual reality exposure therapy on the social anxiety disorder symptoms and fear of negative evaluation in adolescents

Design

A clinical trial with a control group, parallel groups, blinded and nonrandomized, on 51 patients.

Settings and conduct

If eligible, patients with a social anxiety disorder referred to the Atieh Clinic in Bushehr City will be included in the study and assigned to experimental and control groups.

Participants/Inclusion and exclusion criteria

Inclusion: 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; Do not receive other current psychological treatment; Age between 14 - 18. Exclusion: Having hearing or visual impairment such as stereoscopy blindness or nystagmus; Presence of specific physiological illnesses such as heart, lung, and respiratory diseases, epilepsy and seizures, developmental or intellectual disability, cognitive impairment, known balance disorders such as vertigo; Receiving other psychological treatment.

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

Social anxiety disorder symptoms and Fear of negative evaluation

General information

Reason for update

I noticed that when registering the virtual reality group sessions, I wrote 8 sessions, while both treatments were 12 sessions. Also, the information related to randomization and blinding was updated more accurately and the sample size was updated to the previous state. Also, in the intervention section 3, I made mistakes in entering the information of the control group, which was due to copying, and I deleted the extra information

Acronym

CBT, VRET

IRCT registration information

IRCT registration number: **IRCT20210213050343N2**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **prospective**

Last update: **2024-11-16, 1403/08/26**

Update count: **2**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Parisa Azimisefat

Name of organization / entity

Persian Golf University

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Email address

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2023-09-22, 1402/06/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of cognitive behavioral therapy (CBT) and virtual reality exposure therapy (VRET) on fear of negative evaluation and social anxiety disorder symptoms among adolescents

Public title

Efficacy of cognitive behavioral therapy (CBT) and virtual reality exposure therapy (VRET) on social anxiety disorder symptoms

Purpose

Education/Guidance

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 hearing or visual impairment such as stereoscopy blindness or nystagmus. Presence of specific physiological illnesses such as heart, lung, and respiratory diseases, epilepsy and seizures, developmental or intellectual disability, cognitive impairment, and known balance disorders such as vertigo. Receiving other psychological treatment.

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

The participants were assigned to different groups based on a randomized, balanced block method using a random number table: VRE + CBT (n = 17), CBT (n = 17), and WLCC (n = 17). The randomization method was simple and the randomization unit was individual. Using Excel software, the consultant epidemiologist designed and drew a table of four balanced blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

Neither the therapist nor participants were blinded. However, data analysts and outcome assessors were blinded to the participants' group assignments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Bushehr Province
University of Medical Sciences

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Bushehr University of Medical Sciences ,Moalem St.,
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Postal code

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Approval date

2023-08-25, 1402/06/03

Ethics committee reference number

IR.BPUMS.REC.1402.124

Health conditions studied**1****Description of health condition studied**

Social anxiety disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes**1****Description**

Fear of negative evaluation

Timepoint

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

Method of measurement

Brief Fear of Negative Evaluation Scale (FNES-B)

2

Description

Social anxiety disorder symptoms

Timepoint

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

Method of measurement

The Social Phobia Inventory (SPIN)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cognitive-behavioral therapy: cognitive-behavioral therapy sessions will be held 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 problem conceptualization. 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 maintaining 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 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 be held according to its standard protocol for social anxiety disorder (including eight 60-minute sessions twice weekly). 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 safely. 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, and fear of negative evaluation 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 and fear of negative evaluation will be measured again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Atiyeh Bushehr Clinic

Full name of responsible person

Dr. Yosef Dehghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Persian Gulf University

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

Persian Gulf University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Persian Golf University

Full name of responsible person

Parisa Azimisefat

Position

Master Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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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 social anxiety disorder symptoms, and fear of negative evaluation questionnaires in the pre-test, post-test, and follow-up will be analyzed 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

Parisa Azimisefat, Department of Psychology, Persian Gulf University, Bushehr, Iran. parisa0730@gmail.com 0098184025128

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

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

Comments