

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

investigating the effect of environment based on virtual reality exposure therapy on psychological,cognitive_ behavioral symptoms and physiological symptoms of social anxiety disorder

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determination of efficacy of exposure therapy -based on virtual reality on reducing the physiological, cognitive-behavioral symptoms in people with social anxiety disorder

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

Registration date

2018-03-04, 1396/12/13

Design

According to the inclusion criteria, 20 patients with social anxiety disorder diagnosis based on social anxiety scale (SPIN) and structured clinical interview for dsm (SCID) are selected and randomly divided into two groups of intervention and control.

Registrant information

Name

Hoda Nazemi

Name of organization / entity

Semnan university

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

The statistical population of the study consisted of all students of Semnan University in the academic year of 97-96. These clients are volunteered and selected according to entry and exit criteria.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

The criteria for entering the study include age between 20 to 45, diagnostic criteria for social anxiety disorder based on DSM5 and exit criteria including history of certain mental and physical illnesses, alcohol or drug dependence

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: A group of patients undergoing exposure therapy -based on virtual reality. Control group: A group of patients who do not undergo any intervention.

Main outcome variables

physiological symptoms, cognitive-behavioral symptoms

Scientific title

investigating the effect of environment based on virtual reality exposure therapy on psychological,cognitive_ behavioral symptoms and physiological symptoms of social anxiety disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171227038106N1**

Registration date: **2018-03-04, 1396/12/13**

Public title

design and evaluation environment based on virtual reality exposure therapy in treatment of social anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 20 to 45 years old that have a diagnosis criteria for social anxiety disorder according to DSM5

Exclusion criteria:

alcoholism drug dependency History of physical or mental illness

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study has been used random allocation rules. Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomization gives each participant equal chance for being placed in each of the groups. A number of students from Semnan University participated volunteering using public call. Of these, 20 people who received social anxiety disorder were randomly assigned to experimental and control groups using a draw container.

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**

Ethics committee of semnan University of Medical Sciences

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No.142, west erfaneh avenue, baharestan town, semnan, iran

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Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

ir.semums.rec.1396,170

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**

psychological symptoms of social anxiety disorder,

Timepoint

Measurement of physiological symptoms social anxiety disorder such as heart rate oscillation, skin temperature, respiratory distress, muscle tension at the beginning of the study and during treatment based on exposure virtual reality sessions and two months after the end of the intervention.

Method of measurement

physiological symptoms assessment device (CAPTIV)

2**Description**

cognitive behavioral symptoms of social anxiety disorder

Timepoint

Measurement of cognitive behavioral symptoms of social anxiety disorder such as avoidance, fear of negative evaluation, social turmoil at the beginning of the study and during treatment based on exposure virtual reality sessions and two months after the end of the intervention.

Method of measurement

Conner social anxiety questionnaire and Watson & Trend's Avoidance Social turmoil Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Patients with social anxiety disorder are subjected to virtual reality-based exposure therapy sessions, which

consists of 12 sessions, which first comes from the patient's anxiety hierarchy, and according to virtual scenes designed with social anxiety content in each patient's session, The weakest hierarchy of content faces up to the harshest anxiety content of the hierarchy and During the sessions, the patient's physiological and cognitive-behavioral symptoms are recorded and measured.

Category

Treatment - Other

2**Description**

Control group: patients with social anxiety disorder who do not receive any intervention.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Semnan University

Full name of responsible person

Hoda Nazemi

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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

Semnan 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**

Semnan university

Full name of responsible person

Hoda nazemi

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Faculty of Psychology and Educational Sciences,
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Other areas of specialty/work

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