Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of mindfulness-based cognitive therapy and virtual reality-based anxiety exposure therapy on cognitive avoidance, emotional capital, hyper-emotion, and social self-efficacy in adolescents with social anxiety

Protocol summary

Study aim
Comparing the effectiveness of mindfulness-based cognitive therapy and virtual reality-based anxiety exposure therapy on cognitive avoidance, emotional capital, hyper-emotion, and social self-efficacy in adolescents with social anxiety

Design
A clinical trial with a control group, with parallel groups, double-blind, selected by purposive randomization and then placed into three groups of 15 people by simple randomization.

Settings and conduct
In this study, a field experimental research method and an extensive pre-test and post-test design with a follow-up phase will be used. All information is confidential and no one knows.

Participants/Inclusion and exclusion criteria
1- Be in the age range of 15-17 years. 2- Participate in the research with informed consent. 3- Having social anxiety disorder. 4- Not have other concurrent clinical disorders and not be dependent on alcohol or drugs. 1- Absent more than two sessions. 2- Participants withdraw from continuing therapy sessions. 3- Severe stressful life events. 4- Suffering from a physical disorder .

Intervention groups
Mindfulness-based cognitive therapy, by focusing on increasing awareness and acceptance of negative emotions and thoughts, helps adolescents cope with their anxiety in a healthier way. Virtual reality-based anxiety exposure therapy, by creating simulated situations, allows adolescents to face challenging social situations in a controlled manner. These innovative approaches can help reduce cognitive avoidance, increase emotional capital, improve hyperarousal, and strengthen social self-efficacy in adolescents with social anxiety, while the control group receives no therapy.

Main outcome variables
Mindfulness-based cognitive therapy, virtual reality-based anxiety exposure therapy, cognitive avoidance, emotional capital, hyperemotion , social self-efficacy, social anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250215064731N1**
Registration date: **2025-02-23, 1403/12/05**
Registration timing: **prospective**

Last update: **2025-02-23, 1403/12/05**
Update count: **0**

Registration date
2025-02-23, 1403/12/05

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-03-05, 1403/12/15

Expected recruitment end date
2025-06-05, 1404/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of mindfulness-based cognitive therapy and virtual reality-based anxiety exposure therapy on cognitive avoidance, emotional capital, hyper-emotion, and social self-efficacy in adolescents with social anxiety

Public title
Comparing the effectiveness of two therapy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being in the age range of 15-17 years. Participate in the research with informed consent. Having social anxiety disorder based on a diagnostic interview and the Social Anxiety Scale questionnaire (achieving a minimum score of 50 on the test). No concurrent clinical disorders and no dependence on alcohol or drugs. Not receiving any other concurrent treatment.
Exclusion criteria:
Absent more than two meetings. Participants may withdraw from continuing treatment sessions. The occurrence of severe stressful events in life (such as divorce or death of a first-degree relative). Suffering from a physical disorder that requires hospitalization. The presence of certain physical diseases such as heart, lung and respiratory diseases, epilepsy and seizures.
Age
From **15 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Experimental and control groups: After selecting the sample, the next step is to divide the people into experimental and control groups. For this, a simple random method can be used. How to perform randomization: Step 1: After selecting the purposive sample, all the selected people are placed in a list. Step 2: From among these people, using a random method (such as drawing lots or using randomization software), people are divided into two experimental groups and a control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the study in question, all participants and clinical caregivers and evaluators who interpret and analyze the data are blinded, and the participants are unaware of each other, and an abbreviation is considered for each participant.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University, Ahvaz
Street address
No. 718, Khansari Street, Zand Street
City
ahvaz
Province
Khouzestan
Postal code
6195655344
Approval date
2025-01-23, 1403/11/04
Ethics committee reference number
IR.IAU.AHVAZ.REC.1403.408

Health conditions studied

1

Description of health condition studied
Anxiety disorder in adolescents
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Social anxiety is a specific and persistent fear of being embarrassed or negatively evaluated (scrutinized) in social situations or when performing an activity in front of others.
Timepoint
It takes two months before and after the study begins.
Method of measurement
The Adolescent Social Anxiety Scale was developed by

Lajerka (1999).

2

Description

Experiential cognitive avoidance refers to an individual's attempt to get rid of unwanted personal experiences by avoiding or suppressing them.

Timepoint

It takes two months before and after the study begins.

Method of measurement

Cognitive avoidance is the score that the subject obtains from the Cognitive Avoidance Questionnaire, Sexton and Dagas (2004).

3

Description

Emotional capital is a state of inner positive emotional energy and vitality that can be directed and transformed, which, with purposeful focus, has the ability to have a relatively lasting impact on human behaviors and choices, and is capable of expanding individuals' capacities and skills, promoting mental health, and psychological well-being.

Timepoint

It takes two months before and after the study begins.

Method of measurement

Emotional capital is the score that the subject obtains from the Emotional Capital Questionnaire (Golparvar, 2016).

4

Description

Literally, metaemotion means awareness of emotion, and figuratively, it means organizing a group of thoughts, feelings, and emotions about emotions.

Timepoint

It takes two months before and after the study begins.

Method of measurement

Hyperemotion is the score that the subject obtains from the Hyperemotion Questionnaire, Mittmannsgruber et al. (2009).

5

Description

Social self-efficacy is the belief and expectation that an individual has about their ability to succeed in social situations and interpersonal behavior.

Timepoint

It takes two months before and after the study begins.

Method of measurement

Social self-efficacy is the score that the subject obtains from the Social Self-Efficacy Scale, Gaudiano and Herbert (2003).

6

Description

Mindfulness-based cognitive therapy allows a person to engage with negative thoughts and feelings in a nonjudgmental, accepting manner, rather than reacting automatically to them. This approach is particularly effective for treating depression, anxiety, and stress-related disorders, and focuses on enhancing present-moment awareness, accepting emotional experiences, and reducing psychological distress.

Timepoint

It takes three months before and after the study begins.

Method of measurement

The content of mindfulness-based cognitive therapy is introduced based on the educational protocol of Williams, Segal, and Tizdel (2002). This intervention is designed in the form of 8 90-minute sessions. It will be carried out on the experimental group during 8 90-minute sessions. In Iran, this protocol has been used by Mohammad Gholizadeh (2015; quoted from Mousavi et al., 2010).

7

Description

Anxiety is a type of worry about the future and negative events. It triggers intense mental-verbal activity. Virtual reality is a relatively new technology that enables people to immerse themselves in a virtual world. This method has many advantages, including a more or less real-life environment that allows patients to forget that they are being tested and provides the opportunity for them to participate better.

Timepoint

It takes three months before and after the study begins.

Method of measurement

In this study, virtual reality-based anxiety exposure therapy refers to therapy sessions that will be conducted on the experimental group over 8 45-minute sessions based on the protocol (North et al., 2015). Virtual reality in which the individual is confronted with anxiety-provoking scenes in socially fearful subjects.

Secondary outcomes

empty

Intervention groups

1

Description

Mindfulness-based cognitive therapy Mindfulness can help prevent anxiety due to its underlying mechanisms, such as acceptance, increased awareness, desensitization, presence in the moment, nonjudgmental observation, daydreaming, and letting go.

Category

Behavior

2

Description

Virtual Reality-Based Exposure Therapy for Anxiety Virtual reality exposure therapy is a standardized, exposure-based treatment approach that has been introduced as an alternative to classic cognitive-

behavioral therapy. Virtual reality is defined as a situation in which sensory information is provided by a computer instead of the natural environment.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Counseling Center

Full name of responsible person
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Sponsors / Funding sources

1

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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
solmaz choheili

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
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Position
PhD student

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participant data is completely confidential and I do not intend to publish it.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Participant data is completely confidential and I do not intend to publish it.
When the data will become available and for how long
I don't have a timeframe for publishing the data.
To whom data/document is available
I do not intend to publish the data.
Under which criteria data/document could be used
I do not intend to publish the data.
From where data/document is obtainable
I do not intend to publish the data.
What processes are involved for a request to access data/document
I do not intend to publish the data.
Comments