Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Mindfulness training based on virtual reality and comparing its effectiveness with mindfulness therapy on the main symptoms, emotional dysregulation and executive functions of male adolescents with attention deficit hyperactivity disorder

Protocol summary

Study aim
train mindfulness based on virtual reality and compare its effectiveness with mindfulness therapy on the main symptoms, emotion dysregulation, and executive functions of adolescent boys with attention deficit hyperactivity disorder.

Design
The clinical trial has three groups: mindfulness with virtual reality, mindfulness, and control. The group assignment was simple randomization, and the sample size was 65 patients.

Settings and conduct
First, after obtaining the necessary coordination with the relevant authorities, a visit will be made to a boys' high school located in Karaj. After obtaining informed consent, the SNAP questionnaire will be delivered to the students. Then, 65 students will be selected according to the entry and exit criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Presence of symptoms of attention deficit hyperactivity disorder since childhood Having normal vision and no serious vision problems Age between 13 and 18 years No neurological disorders such as epilepsy or brain injuries Parental consent for their child to participate in the study Not receiving concurrent treatment (medication and other psychological treatment) Exclusion criteria: Lack of commitment to doing home exercises Irregularity in attending sessions and absence of more than two sessions of therapy sessions Participant withdrawal during the training course Emergence of severe psychological disorders in the sample during the training course (anxiety, depression, severe academic problems) Inability to use a virtual reality headset

Intervention groups
Intervention group 1: Mindfulness training using virtual reality. Intervention group 2: Mindfulness training. Group 3: Control

Main outcome variables
Core symptoms (attention deficit and hyperactivity-impulsivity), dysregulation of emotion and executive functions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250517065776N1**
Registration date: **2025-05-31, 1404/03/10**
Registration timing: **prospective**

Last update: **2025-05-31, 1404/03/10**
Update count: **0**

Registration date
2025-05-31, 1404/03/10

Registrant information

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Fereshteh Parsapour

Name of organization / entity
Khalije fars university

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-10, 1404/03/20
Expected recruitment end date
2025-08-22, 1404/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Mindfulness training based on virtual reality and comparing its effectiveness with mindfulness therapy on the main symptoms, emotional dysregulation and executive functions of male adolescents with attention deficit hyperactivity disorder

Public title
Mindfulness training based on virtual reality and comparing its effectiveness with mindfulness therapy on attention deficit hyperactivity disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of attention deficit hyperactivity disorder symptoms since childhood Having normal vision and no serious vision problems Age between 13 and 18 years old Absence of neurological disorders such as epilepsy or brain injuries Parental consent for their child to participate in the study Failure to receive concurrent treatment (medication and other psychological treatment)
Exclusion criteria:
Inability to use a virtual reality headset
Age
From **13 years** old to **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
A cluster (a high school) was randomly selected from among the high schools in Karaj. Then, all the students of this high school were considered as a cluster and the SNAP questionnaire was distributed among the students. Students whose average SNAP questionnaire scores were higher than the total average plus one standard deviation were selected as research subjects. These subjects included 65 people. Then, these subjects were randomly assigned to three groups in such a way that each person was assigned an identification code. Then, using random number generation software and the block randomization method, the subjects were divided into three groups: the first experimental group including mindfulness with virtual reality (25 people), the second experiment including traditional mindfulness (25 people), and the control group (15 people). The randomization process was carried out by an independent researcher, and the group assignment will remain secret until the intervention begins to prevent bias.
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 Bushehr University of Medical Sciences
Street address
Bushehr University of Medical Sciences and Health Services, opposite the Friday prayer place, Moallem Street, Bushehr.
City
Bushehr
Province
Boushehr
Postal code
7514633341
Approval date
2025-04-27, 1404/02/07
Ethics committee reference number
IR.BPUMS.REC.1404.061

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder (ADHD)
ICD-10 code
F90.0
ICD-10 code description
Attention deficit: disorder with hyperactivity

Primary outcomes

1

Description
Attention Deficit and Hyperactivity-Impulsivity
Timepoint
Pre-test - post-test - after two months
Method of measurement

SNAP questionnaire

2

Description
Emotion dysregulation
Timepoint
Pre-test - Post-test - After two months
Method of measurement
Gratz and Romer's Difficulty in Emotion Regulation Scale Questionnaire

3

Description
executive function
Timepoint
Pre-test - post-test - after two months
Method of measurement
Executive Functions Questionnaire Brief

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group will receive 8 sessions of mindfulness training using virtual reality, one session per week. In this study, mindfulness exercises will be designed based on the book Mindfulness Prescription for Adults (Attention Deficit Hyperactivity Disorder) and in the virtual reality space. This book consists of 8 steps, and each step includes exercises that aim to improve the problems of people with attention deficit/hyperactivity disorder.
Category
Rehabilitation

2

Description
Intervention group: Second intervention: They will receive 8 mindfulness training sessions, one session per week. In this study, mindfulness exercises are based on the book Mindfulness Prescription for Adults (Attention Deficit Hyperactivity Disorder). This book consists of 8 steps, and each step includes exercises that aim to improve the problems of people with attention deficit/hyperactivity disorder.
Category
Rehabilitation

3

Description
Control group: They do not receive any intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahimi High School
Full name of responsible person
Parviz Solgi
Street address
beginning of Shohada Blvd, Hafeziyeh intersection, , Fardis, Alborz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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, Bushehr
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
Khalije fars university

Full name of responsible person
Fereshteh Parsapour

Position
Phd candidate

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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