Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of virtual reality as an adjunctive intervention in the treatment of Attention-Deficit/Hyperactivity Disorder: a clinical trial design

Protocol summary

Study aim

Effectiveness of virtual reality as an adjunctive intervention in the treatment of Attention-Deficit/Hyperactivity Disorder

Design

A controlled, double-blind, randomized on 30 patient children and adolescents. A random number table will be used for randomization.

Settings and conduct

30 children and adolescents with attention-deficit/hyperactivity disorder visiting Razi Hospital in Tabriz will be enrolled in the study after providing informed consent and will be randomly assigned to either the intervention or control group. The study will be conducted in a double-blind manner, meaning that neither the outcome assessor nor the data analyst will be aware of the intervention assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ADHD diagnosis confirmed by a child and adolescent psychiatry subspecialist in accordance with the Diagnostic and Statistical Manual of Mental Disorders, Absence of any comorbid psychiatric disorders, No history of receiving virtual reality-based interventions during the preceding six months, Provision of written informed consent by the participants and legal guardians. Exclusion criteria: Disorders that fundamentally impair the ability to participate in the research or require immediate intervention that renders the use of the virtual reality headset impossible, Worsening of symptoms or the need to modify the treatment during the study period.

Intervention groups

Intervention group: Participants in the intervention group, comprising children and adolescents, will receive a fully immersive virtual reality intervention over an 8-week period, consisting of two 30-minute sessions per week. The virtual reality program will include exercises targeting attention, impulse control, and executive functioning.

Main outcome variables

Academic performance; Severity of attention deficit symptoms; Sustained attention; Impulsivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260822070753N1**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date

2026-09-17, 1405/06/26

Registrant information

Name

Niloofar Babazadeh

Name of organization / entity

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-09-23, 1406/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of virtual reality as an adjunctive intervention in the treatment of Attention-Deficit/Hyperactivity Disorder: a clinical trial design

Public title
Effectiveness of virtual reality in the treatment of Attention-Deficit/Hyperactivity Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ADHD diagnosis confirmed by a child and adolescent psychiatry subspecialist in accordance with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria. Absence of any comorbid psychiatric disorders. No history of receiving virtual reality-based interventions during the preceding six months. Provision of written informed consent by the participants and, for participants below the legal age of consent, by their parents or legal guardians.
Exclusion criteria:
Disorders that substantially impair the participant's ability to take part in the study or require immediate clinical intervention, including serious suicidal risk, active psychotic disorders, autism spectrum disorder requiring substantial support, or sensory–motor impairments that preclude the use of a virtual reality headset. Worsening of symptoms or the need to modify the standard treatment during the study period.
Age
From **8 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying eligible patients based on the inclusion and exclusion criteria, a list of eligible individuals will be prepared. If the number of eligible individuals exceeds the required sample size, each individual will be assigned a unique identification number, and the required sample will be selected from this list using a table of random numbers. For this purpose, a starting point will be selected randomly from the table, and the numbers will be read in a prespecified direction, namely [by row/by column]. Numbers outside the range of the assigned identification numbers and duplicate numbers will be excluded, and this process will continue until the required sample size has been selected. After sample selection and obtaining informed consent, participants will be allocated to the intervention and control groups using simple randomization with a 1:1 allocation ratio. In this study, the individual patient will be considered the unit of randomization, and cluster randomization will not be used; that is, each patient will be assigned independently and separately to either the intervention or control group. In addition, given the objectives of the study, stratified randomization will not be used, and no strata will be defined based on variables such as age, sex, disease severity, or other clinical characteristics. To generate the random allocation sequence, after determining the final sample size, each participant will be assigned a numerical code according to the order of entry into the study. A starting point will then be selected from the table of random numbers, and the numbers will be read in the predetermined direction. For each participant, group allocation will be determined based on the random number obtained, such that even numbers will be assigned to the intervention group and odd numbers to the control group [or vice versa]. Duplicate numbers and numbers outside the required range will be excluded during the sequence-generation process. This procedure will continue until the allocation sequence for all required participants has been completed. Therefore, the tool used to generate the random sequence in this study will be a table of random numbers; no statistical software, lottery method, or sealed envelopes will be used. The random allocation sequence will be prepared before the enrollment of patients begins and will be maintained by [a research assistant/an individual who will not be involved in participant recruitment, assessment, or intervention delivery]. After final confirmation of the eligibility criteria, obtaining informed consent, and recording each patient's baseline information, group allocation will be performed according to the first unused code in the random allocation sequence. The researcher responsible for identifying and initially assessing the patients will not be aware of their group allocation before their enrollment in the study is finalized and will not have access to the subsequent allocation codes. Accordingly, the allocation sequence will not be predictable before the definitive enrollment of participants, thereby reducing the possibility of selection or modification of group assignments by the researcher. This procedure will be implemented to ensure allocation concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will implement a single-blind design where participants and outcome assessors will be blinded to group allocation, while therapists will remain unblinded due to the psychological nature of the intervention. All medical personnel and data analysts will maintain blinding regarding treatment assignments until completion of outcome assessments.
Placebo
Not used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2026-07-13, 1405/04/22
Ethics committee reference number
IR.TBZMED.REC.1405.225

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Academic performance
Timepoint
Before the intervention began, after the final intervention session, and three months after the intervention
Method of measurement
Objective report card grades in core subjects and the parent-report questionnaire on academic performance

2

Description
Severity of attention deficit symptoms
Timepoint
Before the intervention began, after the final intervention session, and three months after the intervention
Method of measurement
Conner's Parent Rating Scaled-Revised Questionnaire

3

Description
Sustained attention
Timepoint
Before the intervention began, after the final intervention session, and three months after the intervention
Method of measurement
Integrated Visual and Auditory Continuous Performance Test–Second Edition

4

Description
Impulsivity
Timepoint
Before the intervention began, after the final intervention session, and three months after the intervention
Method of measurement
Integrated Visual and Auditory Continuous Performance Test–Second Edition

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Will continue standard Psychiatric care only, with identical assessments but no additional psychological intervention during the study period.
Category
Treatment - Other

2

Description
Intervention group: Participants in the intervention group, comprising children and adolescents, will receive a fully immersive virtual reality intervention over an 8-week period, consisting of two 30-minute sessions per week. The intervention will be delivered using wearable, head-mounted Meta Quest devices. The virtual reality program will include exercises targeting attention, impulse control, and executive functioning. Each session will comprise interactive scenarios with progressively increasing levels of difficulty.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Psychiatric Hospital

Full name of responsible person
Shahrokh Amiri
Street address
Tabriz Razi Psychiatric Hospital, Building Number 1, Golshahr Street, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Sciences
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
Tabriz University of Medical Sciences
Full name of responsible person
Shahrokh Amiri
Position
Professor
Latest degree
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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