Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness of using virtual reality-based training system with routin treatment of ADHD in improving attention and impulsivity of seven to eleven years old children with ADHD

Protocol summary

Study aim

Evaluation of the improvement of symptoms of children with ADHD after using a virtual reality-based system compared to routine treatment

Design

In the evaluation phase 30 samples, which include 7-11-year-old children with ADHD will be tested. The samples will be divided into two groups and according to the psychiatrist's diagnosis, the first group will be given the virtual reality-based system and the second group will be given routine treatment as the control group.This trial will be non-randomized and not blind. Before and after the intervention in both groups, the patients will be evaluated in terms of factors of inattention, impulsivity and hyperactivity.

Settings and conduct

The sample size is selected based on the available sample method which are among those who refer to the educational counseling center for children and adolescents and the psychological counseling service center Rasta in Sari. Due to the nature of the work, it is not possible to blind the researcher, and the samples. But in the data analysis stage, blinding will be implemented.

Participants/Inclusion and exclusion criteria

TThe inclusion criteria is diagnosis of attention deficit and hyperactivity in children by a psychiatrist.The Exclusion critera is having an IQ lower than normal or having comorbidities which was diagnosed by a psychiatrist. Also, patients who did not want to cooperate or complete the treatment sessions will also excluded from the study.

Intervention groups

The samples will divide into two groups and according to the psychiatrist's diagnosis, the first group will be given the system based on virtual reality, and the second group will be given the routine treatment .

Main outcome variables

Auditory and Visual :Attention, Vigilance, Focus, Sustained Attention, Response Control, Consistency, Stamina, Speed, Prudence and Fine Motor Hyperactivity

General information

Reason for update

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT20231218060451N1**
Registration date: **2023-12-31, 1402/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-31, 1402/10/10**
Update count: **0**

Registration date

2023-12-31, 1402/10/10

Registrant information

Name

Saba Pak'khou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3177 1006

Email address

pakkhou.s@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-31, 1402/10/10

Expected recruitment end date

2024-03-10, 1402/12/20

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

Scientific title
Comparison of the Effectiveness of using virtual reality-based training system with routin treatment of ADHD in improving attention and impulsivity of seven to eleven years old children with ADHD

Public title
Investigating the effectiveness of the virtual reality system compared to routin therapy in the treatment of children with ADHD
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of attention deficit and hyperactivity in 7 to 11 years old children by a psychiatrist based on semi-structured K-SAD interview and the diagnostic and statistical criteria of DSM v mental disorders
Exclusion criteria:
Having an IQ lower than normal and a score of less than 70 in the Ravan pogressive matrices test Having other disorders and comorbidities diagnosed by psychiatrist based on semi-structured interview K-SAD Unwillingness to cooperate or complete treatment sessions
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
The ethics committee of Tabriz university of Medical Science (consultative committee for the protect
Street address
No. 2, Central Building, Golgasht St, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number
IR.TBZMED.REC.1400.223

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
Attention : This index, which includes visual attention and auditory attention, its overall score is calculated based on the scores of alertness, concentration, and speed indicators, and its value is obtained from performing an integrated visual and auditory test.
Timepoint
60 Days
Method of measurement
Integrated visual and auditory test-2

2

Description
Vigilance : Ability to maintain and direct attention to the classification of target or non-target stimuli and appropriate response to them. In this study, vigilance is the evaluation of attention, which includes the omission error, and is the average scores obtained from the answers to the questions of the IVA-2 test.
Timepoint
60Days
Method of measurement
Integrated Visual and Auditory test 2

3

Description
Focus: sustained and stable attention during the test, which indicates the change in the variance of the

reaction speed to the correct answers. The evaluation of the variance of the response speed and also the average scores obtained from the answers to the questions of the IVA-2 test

Timepoint

60Days

Method of measurement

Integrated Visual and Auditory test 2

4

Description

Speed: It is the reaction time to the correct answers and the speed of mental processing. It is the average reaction time for the correct answers and also the average scores obtained from answering the questions of the IVA-2 test.

Timepoint

60Days

Method of measurement

Integrated Visual and Auditory test 2

5

Description

Response control: This index, which includes visual response control and auditory response control, is calculated based on the scores of Prudence, Stamina and consistency indicators.

Timepoint

60Days

Method of measurement

Integrated Visual and Auditory test 2

6

Description

Prudence: Measuring impulsivity and poor response control compared to non-target stimuli. Evaluation of impulsivity/response control, which includes three types of committing errors, and is the average score obtained from the answers to the questions of the IVA-2 test.

Timepoint

60Days

Method of measurement

Integrated Visual and Auditory test 2

7

Description

Stamina: A measure of overall reliability and variability of response times. It also measures the ability to stay active.

Timepoint

60 Days

Method of measurement

Integrated Visual and Auditory test 2

8

Description

Consistency: average reaction times to correct answers. Assessment of sustained attention. Average reaction time compares correct responses during the first 200 trials with the last 200 trials. This score is used to identify problems with sustaining attention and effort over time.

Timepoint

60 Days

Method of measurement

Integrated Visual and Auditory test 2

9

Description

Fine Motor Hyperactivity : The Fine Motor Regulation scale provides additional information by recording off-task behaviours with the mouse, including multiple clicking, spontaneous clicks during instruction periods, anticipatory clicks and holding the mouse button down. In behavioural terms, the Fine Motor Regulation scale quantifies fidgetiness and restlessness associated with small motor hyperactivity.

Timepoint

60Days

Method of measurement

Integrated Visual and Auditory test 2

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15 boys and girls will receive virtual reality-based therapy once or twice a week, each session lasting between 60 and 90 minutes and supervised by a psychiatrist. Study for each person will be in 8 sessions for about 2 months. The timing of the sessions is approximately such that the first 10 to 20 minutes are for educating and informing the child and his companion about the therapy sessions, and then another 60 minutes are devoted to performing cognitive behavioral therapy exercises based on virtual reality. Between these exercises, times are considered for rest and children are tested during virtual reality sessions to discover and challenge the power of concentration and attention and control of impulsive behaviors. In this way, in the virtual environment, the child is asked to use his attention and concentration to try to overcome challenges and obstacles, to overcome the stages and to control his impulsive behaviors. Participants are also asked not to do any home exercises between sessions so that the effects of virtual reality therapy can be investigated without the influence of other factors. Then, the effectiveness of each of the treatment methods before and after the intervention will be compared and analyzed in each group and between the two groups.

Category

Treatment - Devices

2

Description
Control group: 15 boys and girls will receive routine treatment of attention deficit disorder and impulsivity by a psychiatrist. According to the psychiatrist's diagnosis, the control group, which includes 15 subjects aged 7 to 11 years, will be given a standard dosage of half to one mg/kg methylphenedaite. Subjects will be monitored by a psychiatrist for 8 weeks, once a week.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasta Clinic

Full name of responsible person
Dr. Samane Fernia Child and adolescent psychiatry specialist

Street address
3rd floor, Sina Bank Building, Taleghani Blvd, intersection of Moalem St, Rasta Clinic , Sari, Mazandaran, Iran

City
Sari

Province
Mazandaran

Postal code
5166614711

Phone
+98 11 3310 7212

Email
pakkhou.s@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Peyman Rezaei-Hachesu

Street address
Next to Shahid Madani Medical Education Center, University Street,Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3177 1006

Email
rezaeip@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
50

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
Saba Pak'khou

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Next to Shahid Madani Medical Education Center, TabrizUniversity Street,

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3177 1006

Email
pakkhou.s@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Saba Pak'khou

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Next to Shahid Madani Medical Education Center, University Street, Tabriz

City

Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3177 1006

Email
pakkhou.s@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Saba Pak'khou

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

Street address
Next to Shahid Madani Medical Education Center, University Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3177 1006

Email
pakkhou.s@gmail.com

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
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

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