

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness of using virtual reality-based training system with routine 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

The inclusion criteria is diagnosis of attention deficit and hyperactivity in children by a psychiatrist. The exclusion criteria 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 be 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'khon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3177 1006

Email address

pakkhon.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 routine 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 routine 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 progressive matrices test Having other disorders and comorbidities diagnosed by psychiatrist based on semi-structured interview K-SAD Unwillingness to cooperate or complete treatment sessions

AgeFrom **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

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No. 2, Central Building, Golgasht St, Tabriz University of Medical Sciences

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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 methylphenedate. 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Peyman Rezaei-Hachesu

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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

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'khrou

Position

Msc Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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