

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of Effectiveness of Working Memory Cognitive Rehabilitation and Methylphenidate on Emotional Processing in Children with ADHD

Protocol summary

Study aim

Comparison of Effectiveness of Working Memory Cognitive Rehabilitation with Methylphenidate Drug on Emotional Processing in Children with Attention deficit hyperactivity disorder (ADHD)

Design

Clinical trial with control group with parallel, double-blind and randomized groups, phase 3 on 30 children with ADHD. Random numbers table was used for randomization.

Settings and conduct

The study site will be the pediatric ward of Ibn Sina Psychiatric Hospital in Mashhad, Iran. This will be a double blind study that did not know the outcome of the intervention and analyzed the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 7 to 12 years old with ADHD; Conscious parental consent
Non-inclusion criteria: undergoing psychological or other medical treatment

Intervention groups

Intervention group: Doing cognitive training to strengthen and rehabilitate working memory using Captain Log software For 12 sessions, twice a week, each session will be done for 20 minutes. Captain Log software is used to develop children's cognitive skills.
Control group: Pharmacological treatment with methylphenidate tablet in the amount of 0.5 mg/kg body weight of the child in a daily dose for 45 days.

Main outcome variables

Emotional processing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210304050572N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Farah Alizadeh Jouimandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2709

Email address

alizadehj971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Working Memory Cognitive Rehabilitation and Methylphenidate on Emotional Processing in Children with ADHD

Public title

Working Memory Cognitive Rehabilitation in Children with ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 7 to 12 years Suffering from ADHD Parental informed consent

Exclusion criteria:

Chronic medical problems such as diabetes, epilepsy, etc. Psychiatric disorders other than ADHD Undergoing psychological or other medical treatment

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Write the names of 30 children from 1 to 30, respectively, and then assign them one in between in two groups using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome Assessor: The person in charge of testing and the outcome assessor does not know the type of intervention in children. Data Analyzer: The data is coded and the data analyzer does not know the type of intervention in children.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.482

Health conditions studied**1****Description of health condition studied**

Attention Deficit / Hyperactivity Disorder (ADHD)

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes**1****Description**

Emotional Processing

Timepoint

Before and after intervention

Method of measurement

CBCL Test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 15 children with Attention Deficit / Hyperactivity Disorder undergo cognitive rehabilitation exercises during 12 20-minute sessions 20 minutes for six weeks. Cognitive exercises to strengthen and rehabilitate working memory using software Captain Log will be done. Captain Log software is used to develop cognitive skills. This software is based on a range of cognitive educational research and includes 50 programs at multiple levels, which are organized into 3 training sets (attention skills training, memory skills training and problem solving and working memory) within the system. It will be used according to the age of the children by an experienced educational expert.

Category

Rehabilitation

2**Description**

Control group: Fifteen children with ADHD are treated with standard methylphenidate tablet at a dose of 0.5 mg / kg daily for 45 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn Sina Hospital

Full name of responsible person

Dr Farah Alizadeh Jouimandi

Street address

Hor Ameli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Farah Alizadeh Jouimandi

Position

Psychiatry Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Dr Farah Alizadeh Jouimandi

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable