Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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)

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alizadehjf971@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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
Psychiatiy Resident
Latest degree
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Other areas of specialty/work
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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
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