Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of cognitive rehabilitation of spatial ability on improvement of executive and attentional functions in children with attention deficit hyperactivity disorder

Protocol summary

Study aim

Evaluating the Effectiveness of Spatial Cognitive Rehabilitation on Executive and Attentional Functions in Children with Attention-Deficit/Hyperactivity Disorder (ADHD)

Design

This study is a randomized parallel-group clinical trial in which participants are randomly assigned to intervention and control groups and assessed at pre-test and post-test.

Settings and conduct

The study will be conducted in child psychiatry and psychology clinics affiliated with the university. After screening and enrollment, eligible participants will undergo baseline assessments. The intervention group will participate in cognitive rehabilitation sessions, while the control group will continue routine treatment. Outcome measures will be assessed before and after the intervention period.

Participants/Inclusion and exclusion criteria

Children aged 9–12 years with ADHD and a Conners score above 40 will be included. Children with neurological disorders, autism, learning disorders, anxiety, depression, intellectual disability, sensory impairments, or lack of cooperation will be excluded.

Intervention groups

Intervention group: Methylphenidate plus the PARSA spatial cognitive rehabilitation program. Control group: Methylphenidate plus the AREF cognitive training program as a placebo control intervention.

Main outcome variables

The primary outcome variables include executive functions and attentional performance in children with ADHD. These variables will be assessed using standardized neuropsychological instruments and behavioral rating scales before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240127060825N2**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **retrospective**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

Name

Hajar Sabet

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2025-02-17, 1403/11/29

Actual recruitment start date

2024-07-10, 1403/04/20

Actual recruitment end date

2025-02-20, 1403/12/02

Trial completion date

2025-03-29, 1404/01/09

Scientific title
Effect of cognitive rehabilitation of spatial ability on improvement of executive and attentional functions in children with attention deficit hyperactivity disorder

Public title
Effect of cognitive rehabilitation of spatial ability in children with attention deficit hyperactivity disorder

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) by a child psychiatrist based on DSM diagnostic criteria. Completion of the Conners Rating Scale by the parents of the mentioned children and obtaining a score higher than 40. The child's age should be between 9 and 12 years. The child should be right-handed.

Exclusion criteria:
Lack of willingness, readiness, or cooperation of the child to participate in the study. Use of medications other than methylphenidate. Presence of neurological disorders such as seizures, cerebral palsy, visual impairments, or hearing impairments. Presence of psychological disorders such as depression, anxiety disorders, learning disorders, or autism spectrum disorder. Intelligence quotient (IQ) below the normal range.

Age
From **9 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly allocated into intervention and control groups using simple randomization at the individual level. A computer-generated random number table was used to create the random allocation sequence. The randomization sequence was generated by a researcher who was not involved in the assessment process. Allocation concealment was performed using sealed opaque envelopes to prevent prediction of group assignment before participant allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the cognitive rehabilitation intervention, blinding of participants and therapists delivering the intervention was not feasible. However, outcome assessments and data scoring procedures were conducted by an evaluator who was unaware of the participants' group allocation in order to minimize assessment bias. In addition, standardized neuropsychological measures and structured assessment procedures were used to reduce the potential influence of observer expectancy effects.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics comittees of shahid beheshti university

Street address
Shahid Beheshti University of Medical Sciences and Health Services Administrative Headquarters, Building No. 2, 6th Floor Arabi Street, Yemen Street Shahid Chamran Expressway

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Postal code
1985717443

Approval date
2024-07-06, 1403/04/16

Ethics committee reference number
IR.SBU.REC.1403.084

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder (ADHD)

ICD-10 code
F90.2

ICD-10 code description
Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description
Change in working memory assessed by the N-Back Test

Timepoint
Working memory was assessed at baseline (before the intervention) and at 40 and 70 days after the initiation of cognitive rehabilitation sessions.

Method of measurement
N-Back Test

2

Description
Change in response inhibition assessed by the Go/No-Go Test
Timepoint
Cognitive flexibility was assessed at baseline (before the intervention) and at 40 and 70 days after the initiation of cognitive rehabilitation sessions.
Method of measurement
Wisconsin Card Sorting Test

3

Description
Change in response inhibition assessed by the Go/No-Go Test
Timepoint
Response inhibition was assessed at baseline (before the intervention) and at 40 and 70 days after the initiation of cognitive rehabilitation sessions.
Method of measurement
Go/No-Go Test

4

Description
Change in attentional networks assessed by the Attention Network Test (ANT)
Timepoint
Atentional Networks were assessed at baseline (before the intervention) and at 40 and 70 days after the initiation of cognitive rehabilitation sessions.
Method of measurement
Attention Network Test

Secondary outcomes

1

Description
Spatial ability was assessed using the Spatial Ability Test of the PARSA cognitive rehabilitation software.
Timepoint
Spatial abilities were assessed at baseline (before the intervention) and at 40 and 70 days after the initiation of cognitive rehabilitation sessions.
Method of measurement
Gardner Test of Visual Perceptual Skills

Intervention groups

1

Description
Intervention group: The intervention group received 10 sessions of cognitive rehabilitation using the PARSA Spatial Ability Program. Sessions were conducted twice weekly and lasted 60 minutes each. Participants performed computerized spatial ability training exercises during each session. A cognitive rehabilitation therapist was present throughout the sessions to provide guidance and assistance whenever needed.
Category
Rehabilitation

2

Description
Control group: Participants in the control group received 10 sessions of the AREF Emotional Perception Cognitive Rehabilitation Program as an active control intervention. Sessions were conducted once weekly and lasted 15 minutes each.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Counseling Center, Shahid Beheshti University
Full name of responsible person
Hajar Sabet
Street address
Daneshjoo Blvd, Next to the Student Cultural Center, Velenjak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Reza khosroabadi
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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
Shahid Beheshti University

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
Shahid Beheshti Uni versity

Full name of responsible person
Hajar Sabet

Position
Master student

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Individual participant data will not be shared in order to protect participant confidentiality and comply with ethical considerations. The data involve children and were collected solely for the purposes of this study.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available