Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Attention Training with BARAN Cognitive Rehabilitation Program on executive functions and behavioral problems in Preschool Children with ADHD Symptoms

Protocol summary

Study aim

To determine the effectiveness of the BARAN cognitive rehabilitation package on executive functions (inhibitory control, working memory, and cognitive flexibility) and behavioral problems in preschool children with Attention Deficit/Hyperactivity Disorder symptoms

Design

A randomized controlled trial with an active control group, parallel group design, non-blinded, without placebo, conducted on 30 preschool children with ADHD symptoms (15 per group). Simple randomization at the individual level was performed using SPSS version 27. No pharmacological intervention was involved.

Settings and conduct

Children were randomly assigned to receive either the BARAN cognitive-balance rehabilitation program or storytelling sessions (active control) at Atieh Occupational Therapy Clinic, Isfahan. Outcomes were assessed at baseline, post-intervention, and 1-year follow-up using the Day/Night Stroop, Corsi Block Task, Shape Trail Test, and a behavioral questionnaire.

Participants/Inclusion and exclusion criteria

Children aged 60 to 72 months with Attention Deficit/Hyperactivity Disorder symptoms, normal intelligence quotient, and parental consent. Children with confirmed physical impairment preventing participation in balance exercises were excluded.

Intervention groups

Intervention group: BARAN cognitive rehabilitation package consisting of balance-cognitive tasks in 10 sessions of 45 minutes, three times per week Active control group: Storytelling sessions in 10 sessions of 45 minutes, three times per week

Main outcome variables

Inhibitory control (Day/Night Stroop Task); Working memory (Corsi Block Task); Cognitive flexibility (Shape Trail Test-Child Version); Behavioral problems (Behavior Rating Inventory of Executive Function-Preschool Version, BRIEF-P)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260618069861N1**
Registration date: **2026-10-19, 1405/07/27**
Registration timing: **retrospective**

Last update: **2026-10-19, 1405/07/27**
Update count: **0**

Registration date

2026-10-19, 1405/07/27

Registrant information

Name

Zahra Khaki Bakhtiarvand

Name of organization / entity

Institute for Cognitive Science Studies

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-17, 1404/01/28

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

2025-04-21, 1404/02/01

Actual recruitment end date
2025-05-24, 1404/03/03
Trial completion date
2026-06-14, 1405/03/24

Scientific title
Effectiveness of Attention Training with BARAN Cognitive Rehabilitation Program on executive functions and behavioral problems in Preschool Children with ADHD Symptoms

Public title
Effectiveness of BARAN Cognitive Rehabilitation in Preschool Children with ADHD Symptoms
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having symptoms of Attention Deficit/Hyperactivity Disorder Age between 60 and 72 months Having normal intelligence quotient Completion of parental consent form Child's willingness and cooperation to participate in the study
Exclusion criteria:
Having a confirmed physical impairment that prevents performing balance exercises
Age
From **60 months** old to **72 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization was performed at the individual level. After compiling the list of eligible participants, each participant was assigned a unique identifier and entered into SPSS version 27. Using the Select Cases option in the Data menu, the Random Sample of Cases feature was applied to randomly select 50% of participants (n=15). Those selected were allocated to the intervention group, while the remaining 15 participants were assigned to the active control group. A random seed was set in SPSS to ensure complete randomization. Allocation concealment was maintained by keeping the allocation list with the principal investigator, ensuring that the session facilitator was unaware of group assignments.
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
Ethics Committee of the Institute for Cognitive Science Studies
Street address
Shahid Qasem Soleimani Blvd., Cognitive Science Blvd., Pardis City
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Province
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Postal code
1658344575
Approval date
2025-03-18, 1403/12/28
Ethics committee reference number
IR.UT.IRICSS.REC.1404.003

Health conditions studied

1

Description of health condition studied
Attention-deficit hyperactivity disorder
ICD-10 code
F90.9
ICD-10 code description
Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description
The child's inhibitory control score, measured using the Day/Night Stroop task, was assessed before and after the intervention. The child's working memory score, measured using the Corsi Block Task, was assessed before and after the intervention. The child's cognitive flexibility score, measured using the Shape Trail Test+ (Child Version), was assessed before and after the intervention. The child's executive function-related behavioral problems score, completed by parents on the Behavior Rating Inventory of Executive Function–Preschool Version (BRIEF-P), was assessed before and after the intervention.
Timepoint
Outcomes (inhibitory control, working memory, cognitive flexibility, and behavioral problems) were measured at baseline (before the start of the intervention) and immediately after completion of the intervention (after 10 sessions, 45 minutes each, three times per week, over approximately 3–4 weeks).
Method of measurement

Day/Night Stroop Task for assessment of inhibitory control/ Corsi Block Task for assessment of working memory/ Shape Trail Test, Child Version, for assessment of cognitive flexibility/ Behavior Rating Inventory of Executive Function, Preschool Version, for assessment of executive function-related behavioral problems

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children in this group (n=15) received the Balance-based Attentive Rehabilitation of Attention Networks (BARAN) cognitive-balance rehabilitation program. This program is based on a dual-task paradigm, involving the simultaneous performance of balance tasks and verbal-cognitive tasks. Balance tasks were graded according to 4 factors: base of support size (5 levels), upper limb position (5 levels), surface stability (2 levels), and quality of sensory information (eyes open/closed, 2 levels), yielding a total of 200 possible balance positions. Cognitive tasks comprised 10 progressive difficulty levels (e.g., naming categories, letters, and random numbers under specific conditions). The therapist first determined the child's baseline balance position (the ability to maintain balance for 30 to 60 seconds), after which the cognitive task was performed simultaneously while maintaining that balance position. Task difficulty was adjusted individually based on the child's performance in each session, with the aid of a computer program that displayed the target position and recorded performance. The intervention was delivered over 10 sessions, 45 minutes each, three times per week (approximately 3–4 weeks in total), administered by a master's student in cognitive rehabilitation at Atieh Occupational Therapy Clinic, Isfahan.

Category

Rehabilitation

2

Description

Control group: Children in this group (n=15) served as the active control group and, instead of the BARAN cognitive rehabilitation program, participated in storytelling sessions. These sessions were also held over 10 sessions, 45 minutes each, three times per week (approximately 3–4 weeks in total), matching the same frequency and duration as the intervention group, but without any balance-related or dual-task cognitive content, at the same clinic.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Atieh Occupational Therapy Clinic

Full name of responsible person
Zahra Khaki Bakhtiarvand

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No. 81, Before Laleh Dead End, Mirza Kouchak Khan Bypass

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zahra Khaki Bakhtiarvand (Researcher)

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Zahra Khaki Bakhtiarvand
Position
Master's Student in Cognitive Rehabilitation
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The complete de-identified individual participant dataset from this study, after full removal of identifying information (name, surname, and other identifying details), will be available for sharing. This dataset includes pre- and post-intervention and follow up scores for all 4 primary outcome variables (inhibitory control score on the Day/Night Stroop task, working memory score on the Corsi Block Task, cognitive flexibility score on the Shape Trail Test, and behavioral problems score on the Behavior Rating Inventory of Executive Function–Preschool Version), along with baseline demographic variables (age, sex, and allocated group: intervention or control). No identifying information about the children or their parents (such as name, address, or contact number) will be included in any part of the shared data.
When the data will become available and for how long
The access period will begin 6 months after publication of the resulting article and will continue for 3 years thereafter.
To whom data/document is available

Researchers affiliated with academic and scientific institutions who submit a reasonable and justified request for research purposes.

Under which criteria data/document could be used

Data and documents may be used solely for research purposes (such as meta-analysis, re-analysis, or secondary studies) with proper citation of the source. Commercial use of the data is not permitted.

From where data/document is obtainable

Requests should be sent via email to the corresponding author (Zahra Khaki Bakhtiarvand) at [khaki_z@icss.ac.ir]. Postal address: No. 81, Before Laleh Dead End, Mirza Kouchak Khan Bypass, Isfahan, Iran.

What processes are involved for a request to access data/document

Upon receipt of a request via email, the request will be reviewed by the corresponding author within 2 weeks. If approved, a Data Use Agreement will be sent to the requester, and upon signing, the data/documents will be provided within 1 month.

Comments