Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Physical Activity–Based Cognitive Behavioral Play Therapy on Attention and Emotion Regulation in Children with Attention-Deficit/Hyperactivity Disorder (ADHD)

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of physical activity-based play therapy on reducing the symptoms of Attention-Deficit/Hyperactivity Disorder (ADHD) in children aged 5 to 7 years.

Design

This randomized quasi-experimental study uses a pretest-posttest control group design. 30 children with ADHD (convenience sampling) are randomly assigned into two groups of 15. Following a pretest, the intervention group completes 12 weekly 60-minute sessions of cognitive-behavioral play therapy (physical activity-based), while the control group receives no intervention. Both groups then undergo a posttest.

Settings and conduct

This study involves children with ADHD. Participants are selected through convenience sampling and randomly assigned to intervention and control groups after the pretest. The intervention group attends 12 weekly 60-minute cognitive-behavioral play therapy sessions based on physical activity, while the control group receives no intervention. The study is conducted in psychological service centers.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Confirmed ADHD diagnosis; age 5–7; parental consent; ability to perform physical play therapy; no concurrent similar treatments. **Exclusion Criteria:** Severe psychiatric/neurological disorders; physical/motor disability; withdrawal of consent; missing >2 sessions.

Intervention groups

Intervention Group: Participate in 12 weekly 60-minute cognitive-behavioral play therapy sessions focused on physical activity to reduce ADHD symptoms and enhance attention, impulse control, and hyperactivity. **Control Group:** No intervention; only involved in pre-test and post-test assessments.

Main outcome variables

Score of Attention-Deficit/Hyperactivity Disorder (ADHD) based on the Conners Parent Rating Scale and emotion regulation score based on the Emotion Regulation Checklist (ERC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260426069174N1**
Registration date: **2026-07-12, 1405/04/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-12, 1405/04/21**
Update count: **0**

Registration date

2026-07-12, 1405/04/21

Registrant information

Name

Shekufeh Morshedzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3390 6154

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Physical Activity–Based Cognitive Behavioral Play Therapy on Attention and Emotion Regulation in Children with Attention-Deficit/Hyperactivity Disorder (ADHD)

Public title
The effect of a play therapy program with physical activity on improving attention and emotional control in children with ADHD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
• Diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) by a psychologist or psychiatrist. Age range of 5 to 7 years. Ability to participate in physical activity–based play therapy sessions (no significant motor limitations). No concurrent participation in similar therapeutic programs. Informed consent obtained from parents for the child's participation in the study. Ability to attend and regularly participate in the treatment sessions. Normal or near-normal intellectual functioning based on psychological evaluation.
Exclusion criteria:
Diagnosis of autism spectrum disorder Moderate to severe intellectual disability Presence of serious neurological disorders (e.g., uncontrolled epilepsy) Physical illness or motor impairment that prevents participation in physical activity sessions Receiving similar psychological interventions during the study period Initiation of a new medication or change in medication dosage within the past month Lack of parental informed consent Parents' unwillingness to participate in the study
Age
From **5 years** old to **7 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After confirming eligibility criteria and obtaining informed consent from the parents, eligible participants will be randomly allocated to the intervention and control groups. The allocation sequence will be generated using computer-generated random numbers. Based on this sequence, each participant will be assigned to one of the two groups. Group allocation will be performed by the researcher without participant involvement.
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 Islamic Azad University, Ahvaz Branch
Street address
Kiyan pars Movahedin
City
Ahvaz
Province
Khouzestan
Postal code
6155616587
Approval date
2026-01-10, 1404/10/20
Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.667

Health conditions studied

1

Description of health condition studied
Attention-Deficit/Hyperactivity Disorder (ADHD)
ICD-10 code
F90.0
ICD-10 code description
Attention-deficit hyperactivity disorder, predominantly inattentive type

Primary outcomes

1

Description
ADHD symptom score based on the Conners Parent Rating Scale and emotion regulation score based on the Emotion Regulation Checklist (ERC).
Timepoint
Assessments are conducted at two time points: 1. Pre-test (before the intervention sessions start), 2. Post-test (immediately after completing the 12 intervention sessions).
Method of measurement
Outcomes are measured using the Conners Parent Rating

Scale and the Emotion Regulation Checklist (ERC), completed by parents or caregivers. The final score for each variable is calculated by summing the scores of all items based on a 4-point Likert scale.

Secondary outcomes

1

Description

Child's emotion regulation capacity, assessed using the 'Emotion Regulation Checklist (ERC).' This 24-item tool consists of two subscales (Emotion Regulation and Lability/Negativity) and is completed by parents or caregivers. Higher scores on the Emotion Regulation subscale indicate better regulatory capacity

Timepoint

Pre-test: Before the start of the intervention sessions.Post-test: Immediately after completing the 12 intervention sessions.

Method of measurement

This variable is measured using the Emotion Regulation Checklist (ERC), completed by the child's parents or caregivers. The total score for each subscale (Emotion Regulation and Lability/Negativity) is calculated by summing the scores of the items, based on a 4-point Likert scale (1 = Never, 4 = Almost Always).

Intervention groups

1

Description

Control group: The control group receives no intervention (physical activity-based play therapy) during the study period. This group only participates in the pre-test and post-test stages (simultaneously with the intervention group), and the questionnaires are completed by their parents. For ethical considerations, educational materials or brief sessions will be offered to this group after the study's conclusion.

Category

Behavior

2

Description

Intervention group: Participants in this group receive physical activity-based cognitive-behavioral play therapy over 12 sessions (one 60-minute session per week). The sessions include purposeful games designed to enhance executive functions, physical exercises to improve motor coordination, and age-appropriate CBT techniques for children aged 5 to 7. The intervention focuses on increasing response inhibition, improving sustained attention, and strengthening self-control through high-activity physical tasks and structured rule-based games.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Asyabi Psychology and Counseling Clinic

Full name of responsible person
Shekufeh Morshed zadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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
Islamic Azad University

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Shekufeh Morshed Zade

Position
M.SC. Student in Psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
Intervention protocol and study implementation documents Shareable documents include the intervention protocol, parental informed consent form, and study implementation guide. These documents will be provided without participants' identifying information, and raw individual data will not be shared.

When the data will become available and for how long
From study completion and publication of the results, the study documents (protocol and forms) will be available for 5 years.

To whom data/document is available
Qualified researchers and relevant professionals may access the non-identifiable study documents upon reasonable research or educational request and with approval from the principal investigator.

Under which criteria data/document could be used
The documents may be used for research and educational purposes only, provided that the IRCT registration is properly cited and authorship rights are respected. Commercial use or any attempt to identify participants is not permitted.

From where data/document is obtainable
Requests for access to the study documents should be submitted to the principal investigator/corresponding investigator through the contact information provided in the IRCT registration.

What processes are involved for a request to access

data/document

Intervention protocol and study implementation documents Shareable documents include the intervention protocol, parental informed consent form, and study implementation guide. These documents will be provided without participants' identifying information, and raw individual data will not be shared.

Comments