Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Investigating the Effectiveness of Physical Activities on Balance, Cognition, and Performing Dual Tasks among Children with Autism Spectrum Disorder: A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim
Investigating the effectiveness of physical exercises on balance, cognition, and dual-task performance in 6-12 years old children with Autism Spectrum Disorder

Design
Double-blinded Randomized controlled trial of 30 patients; randomization will be via block randomization.

Settings and conduct
After receiving the code of ethics, students of the centers and schools of Tehran City will be screened to check the inclusion criteria and eligible children; After obtaining written consent from the parents, they will undergo initial evaluation and be randomly divided into two experimental and control groups. Before the implementation of the intervention, children's balance, cognitive and dual-task performance are measured by a co-evaluator who does not know which group the participants belong to. The intervention group received a 24-session occupational therapy program, and the control group received routine interventions. After completing the occupational therapy program, the variables will be re-evaluated

Participants/Inclusion and exclusion criteria
Inclusion criteria include diagnosis of high-functioning autism; obtaining a score of 55-70 in the GARS-3 questionnaire; age 6-12 years old. Exclusion criteria: using aids such as canes to maintain balance; or take medications that affect balance.

Intervention groups
Participants in the intervention group will participate in a 24-session 45-minute occupational therapy program. This program includes several categories of physical activities to improve agility, balance, central stability, and motor coordination. In this program, with the increase in the number of treatment sessions, the difficulty level of the exercises will increase. Participants in the control group receive routine rehabilitation interventions.

Main outcome variables
Balance; cognition; the ability to do cognitive-motor dual-tasks

General information

Reason for update
Due to the insufficient number of samples and the lack of access to some assessment tools in Shiraz city, the location of the study was changed to Tehran city.

Acronym

IRCT registration information
IRCT registration number: **IRCT20221214056817N1**
Registration date: **2023-05-12, 1402/02/22**
Registration timing: **prospective**

Last update: **2024-02-26, 1402/12/07**
Update count: **1**

Registration date
2023-05-12, 1402/02/22

Registrant information

Name
Mina Hashempour Alooche

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-15, 1402/02/25

Expected recruitment end date
2023-11-16, 1402/08/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effectiveness of Physical Activities on Balance, Cognition, and Performing Dual Tasks among Children with Autism Spectrum Disorder: A Double-Blind Randomized Clinical Trial

Public title
Investigating the effectiveness of physical activities on motor and cognitive skills in children with autism
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Child psychiatrists diagnose high-functioning Autism Spectrum Disorder Using the Gilliam Autism Rating Scale - Third Edition (GARS 3) to diagnose level 1 Autism Spectrum Disorder The students study in normal schools or special autism spectrum disorders schools Participants are between the ages of 6 and 12
Exclusion criteria:
Maintaining balance or walking with aids Using balance-affecting drugs Being visually and audibly impaired Having comorbidities of autism spectrum disorders with psychological disorders such as attention deficit hyperactivity disorder, obsessive compulsive disorder, etc.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Children aged 6-12 with high-functioning autism were included in the study using accessible sampling. Then the stratified randomization method will be used, and the samples will be classified based on age and body mass index. The stratified randomization method eliminates the need to control the influence of background variables. In this method, we create a separate block for each combination of contextual variables, and subjects are assigned to a suitable block of contextual variables. After all the subjects have been identified and divided into blocks, they are placed in groups that have equal sample size through the block randomization method, and considering all possible balanced combinations of assignment in the block and random selection of one of these situations are assigned to one of the experimental or control groups through a lottery for each block of people.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, each person is assigned a number, and they are randomly placed in the experimental or control groups, then the researcher performs the therapeutic intervention on the group without knowing about their attribution; The evaluator is also another colleague who is also unaware of how people are allocated; data evaluation will also be done by someone other than the research team.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Building No. 2, Shahid Beheshti University of Medical Sciences, Arabi St., Daneshjou Blvd., Valenjak
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Province
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1985717443
Approval date
2022-12-04, 1401/09/13
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.567

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Static and dynamic balance
Timepoint
Measurement of a static and dynamic balance of the samples before the start of the intervention and eight weeks after the beginning of the intervention in the test group.
Method of measurement
Using the Walking Heel to Toe test to evaluate dynamic balance and using the Force Plate device to assess static balance.

2

Description
Cognitive functions
Timepoint
Measuring the cognitive functions of the samples before the start of the intervention and eight weeks after the beginning of the intervention in the test group.
Method of measurement
Wisconsin card sorting tests, forward and backward digit span test, and executive function behavioral rating questionnaires will be used to evaluate cognitive indicators.

3

Description
Ability to perform dual tasks
Timepoint
Measuring the ability to perform dual tasks of the samples before the start of the intervention and eight weeks after the beginning of the intervention in the test group.
Method of measurement
The person performs balance tests, including the Walking Heel Toe Test and standing on the Force Plate device simultaneously with the Forward Digit Span Test.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will participate in a 45-minute exercise program. This program includes several categories of physical exercises to improve agility, balance, central stability, and motor coordination. Among the different parts of this program, we can mention jumping, walking on different surfaces, balancing activities in various positions, exercises aimed at improving central stability and bilateral coordination, eye-hand coordination, and eye-foot coordination. In this program, with the increase in the number of therapy sessions, the exercises' difficulty level will increase. It is worth noting that the intervention is conducted by an occupational therapist with experience working with children with an autism spectrum disorder in the form of 45-minute individual sessions three times a week for eight weeks.
Category
Rehabilitation

2

Description
Control group: receive routine rehabilitation program.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Exceptional school of Payambar Azam
Full name of responsible person
Mohammad Beheshti pour
Street address
No.6, Kohsar Alley, Imam Hossein st., Satari bridge, Hemmat highway
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center
Name of recruitment center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Building No. 2, Shahid Beheshti University of Medical Sciences, Arabi St., Daneshjou Blvd., Valenjak
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Email
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Web page address
https://research.sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Occupational Therapy
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Other areas of specialty/work
Occupational Therapy
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mina Hashempour Alooche
Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Email

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

information on the primary and secondary outcome measures

When the data will become available and for how long

After publishing the articles

To whom data/document is available

Researchers in this field

Under which criteria data/document could be used

1. Written permissions from the research team 2. Mention the source of information

From where data/document is obtainable

Mina Hashempour Alooche E-mail: minhashempour@gmail.com address:Rehabilitation Science School Of Shahid Beheshti University of Medical Sciences, Damavand Ave., Imam Hossein Square, Tehran

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

After sending the email to the researcher and requesting the document, the researcher will obtain the opinion of other members of the research team regarding the provision of this information and, if the members agree, the documents will be sent as soon as possible but sending the documents requires the acceptance of the criteria mentioned above.

Comments