

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

Country

Iran (Islamic Republic of)

Phone

+98 21 4425 2633

Email address

minhashempour@sbm.ac.ir

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

City

Tehran

Province

Tehran

Postal code

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

City

تهران

Province

Tehran

Postal code

1476918386

Phone

+98 21 4446 6527

Email

nikookari.kazemi@gmail.com

2

Recruitment center

Name of recruitment center

Exceptional school of Torab

Full name of responsible person

Elham Pourhasan

Street address

Shahid Akhlaghi Alley, Qanat Crossroads, Dolat St.

City

Tehran

Province

Tehran

Postal code

1939793453

Phone

+98 21 2255 8487

Email

E.dehghan@gmail.com

3

Recruitment center

Name of recruitment center

Exceptional school of Fereshtegan Asemani

Full name of responsible person

Ali Hosseini

Street address

No. 68, 17th St., Jalal Al Ahmad St., Gisha

City

Tehran

Province

Tehran

Postal code

1447733511

Phone

+98 21 8827 4864

Email

nazi.tarafdari12@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

info@sbmu.ac.ir

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

Full name of responsible person

Ali Asghar Jamebozorgi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Science School Of Shahid Beheshti University of Medical Sciences, Damavand Ave., Imam Hossein Square

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

aas.bozorg@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Asghar Jamebozorgi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Science School Of Shahid Beheshti University of Medical Sciences, Damavand Ave., Imam Hossein Square

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

aas.bozorg@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Hashempour Alooshe

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

Rehabilitation Science School Of Shahid Beheshti
University of Medical Sciences, Damavand Ave., Imam
Hossein Square

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

minhashempour@gmail.com

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