Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Adding standard Core Stability Exercises to Standard Sensorimotor Training on Balance Indices and Quality of Life in Children with Autism Spectrum Disorder: A Clinical Trial”

Protocol summary

Study aim

The aim of this study is to investigate the effect of adding core stability exercises to standard sensorimotor exercises on balance and quality of life in children with Autism Spectrum Disorder (ASD). In addition, this study will compare the outcomes between the intervention and control groups to evaluate the effects of the intervention on static balance, dynamic balance, and quality of life in children with ASD.

Design

This is a randomized, controlled, parallel-group clinical trial involving 34 children with Autism Spectrum Disorder (ASD). Participants will be recruited through convenience sampling and randomly allocated (1:1) to the intervention or control group using computer-generated block randomization. This is a non-pharmacological rehabilitation trial

Settings and conduct

This is a randomized controlled trial in children with Autism Spectrum Disorder (ASD). The intervention group will receive core stability plus standard sensorimotor exercises for 8 weeks, while the control group will receive standard sensorimotor exercises only. Balance and quality of life will be assessed before and after the intervention. Open-label study

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 8–12 years with Autism Spectrum Disorder (ASD) and written parental consent. Exclusion Criteria: More than two absences, medical contraindications, or withdrawal from the study.

Intervention groups

Participants in the intervention group will receive standard sensorimotor exercises in addition to a standard core stability exercise program for 8 weeks, 3 sessions per week, with each session lasting 35–40 minutes. The exercise program will be conducted under the supervision of the researcher or a trained therapist according to a standardized protocol.

Main outcome variables

Static balance; dynamic balance; quality of life in children with Autism Spectrum Disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260622069918N1**
Registration date: **2026-07-07, 1405/04/16**
Registration timing: **prospective**

Last update: **2026-07-07, 1405/04/16**
Update count: **0**

Registration date

2026-07-07, 1405/04/16

Registrant information

Name

Shamim Fadakar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Adding standard Core Stability Exercises to Standard Sensorimotor Training on Balance Indices and Quality of Life in Children with Autism Spectrum Disorder: A Clinical Trial”

Public title

The Effect of Sensorimotor and Core Stability Exercises on Balance and Quality of Life in Children with Autism Spectrum Disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

confirmed diagnosis of Autism Spectrum Disorder (ASD) by a child and adolescent psychiatrist or a pediatric neurologist based on DSM-5 diagnostic criteria. Ability to understand simple instructions Ability to participate in the exercise program Ability to walk independently without the use of assistive devices. No participation in a structured core stability exercise program during the previous 3 months No participation in a structured sensorimotor exercise program during the previous 3 months. Written informed consent provided by a parent or legal guardian.

Exclusion criteria:

Age younger than 8 years or older than 12 years No confirmed diagnosis of Autism Spectrum Disorder (ASD) based on DSM-5 criteria Presence of neurological, musculoskeletal, cardiovascular, or other medical conditions that would preclude safe participation in the exercise program. Inability to walk independently without assistive devices. Inability to understand or follow simple instructions. Failure to obtain written informed consent from a parent or legal guardian.

Age

From **8 years** old to **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate participants to the study groups, block randomization will be employed. This method will be used to ensure a balanced distribution of participants between the study groups throughout the recruitment process and to minimize selection bias and the influence of potential confounding variables. First, each eligible child with Autism Spectrum Disorder (ASD) who meets the inclusion criteria will be assigned a unique identification code. Subsequently, the randomization process will be performed using a web-based randomization program, and participants will be randomly allocated to one of the two study groups. Given the total sample size of 30 participants, the participants will be organized into five blocks of six participants each. Within each block, three participants will be assigned to the intervention group and three participants to the control group according to a computer-generated random allocation sequence. At the completion of the randomization process, two groups of 15 participants each will be formed. The intervention group will receive a combined core stability and sensorimotor training program, whereas the control group will receive sensorimotor training only. The use of block randomization will ensure balanced group sizes and minimize the risk of allocation bias throughout the study.

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

Faculty of Medicine, Islamic Azad University – Mashhad Medical Sciences Branch, Iran

Street address

No. 4, 4th Floor, Kolahdooz 14, Kolahdooz Street, Ahmadabad District, Mashhad, Iran.

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9183846898

Approval date

2026-06-01, 1405/03/11

Ethics committee reference number

IR.IAU.MSHD.REC.1405.043

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

1. Static balance:Static balance was assessed using the Tandem Stance Test, measured as the duration of maintaining the tandem stance in seconds.2. Dynamic balance:Dynamic balance was assessed using the Tandem Walk Test, Measured based on performance during the tandem walking task.3. Quality of life:Quality of life was assessed using the Pediatric Quality of Life Inventory (PedsQL), Measured by the total questionnaire score.

Timepoint

Measurements will be performed at baseline (prior to the intervention) and immediately after completion of the 8-week intervention.

Method of measurement

Tendom walk,tendom stance,test quality of lif(peal)

Secondary outcomes

empty

Intervention groups

1

Description

Control GroupChildren aged 8–12 years with Autism Spectrum Disorder (ASD) in the control group will participate in a standard sensorimotor exercise program. All training sessions will be conducted face-to-face under the direct supervision of the principal investigator or a corrective exercise specialist. The program consists of sensorimotor exercises designed to improve balance, postural control, motor coordination, and proprioception. The exercises will be performed using standard rehabilitation equipment, including balance pads, balance boards, therapy balls, obstacles, and training cones. The intervention will be delivered for 8 weeks, 3 sessions per week, with each session lasting 45–60 minutes. Exercise intensity and difficulty will be progressively increased according to each child's functional abilities to ensure safety and optimize training effectiveness.

Category

Treatment - Other

2

Description

Intervention group: Intervention GroupChildren aged 8–12 years with Autism Spectrum Disorder (ASD) in the intervention group will participate in a play-based core stability exercise program in addition to the standard sensorimotor exercise program. All training sessions will be conducted face-to-face under the direct supervision of the principal investigator or a corrective exercise specialist. The intervention consists of play-based exercises designed to strengthen the trunk and pelvic stabilizing muscles and improve postural control, balance, motor coordination, and proprioception. The exercises will be performed using therapy balls, BOSU balls, and balance boards, with activities progressively adapted to each child's functional abilities. The intervention will be delivered over 8 weeks, with three sessions per week, and each session lasting 45–60 minutes. Exercise intensity and difficulty will be progressively increased throughout the intervention to ensure safety, promote active participation, and maximize the effectiveness of the program.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Navid Zendegi

Full name of responsible person
Elham Mosapor

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Sponsors / Funding sources

1

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Name of organization / entity
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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?
No

Title of funding source
Azad Islamic

Proportion provided by this source
1

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
Islamic Azad University

Full name of responsible person
Shamim Fadakar

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Sport Medicine

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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
All information generated from this research will be made freely and openly available to researchers and interested individuals through university databases and reputable scientific publications, at no cost.

When the data will become available and for how

long

months after the completion of the research project.

To whom data/document is available

All researchers, clinicians, and specialists.

Under which criteria data/document could be used

To facilitate the advancement of academic research and improve patient care by clinicians, researchers, and specialists.

From where data/document is obtainable

Faculty of Physical Education, University of Tehran

Islamic Azad University, Mashhad Branch Faculty of Humanities Complex Ostad Yousefi Street, Mashhad, Iran

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

Upon publication of the scientific articles, all relevant findings and data that may contribute to the advancement of research and the improvement of therapeutic approaches will be made available to the scientific community

Comments