Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effects of a SPARK Training Program on Balance and Motor Performance in Adolescents with Autism

Protocol summary

Study aim
An Investigation of the Effects of SPARK Training on Balance and Motor Performance in Adolescents with Autism

Design
Clinical trial with control group, parallel groups, single-blind, randomized.

Settings and conduct
Adolescents with autism who refer to Akhtar Hospital in Tehran will be enrolled in the study if they meet the eligibility criteria. Participants will then be randomly assigned to the intervention and control groups using block randomization. The study will be conducted as a single-blind trial, in which the intervention provider and participants are aware of the assigned intervention; however, the outcome assessor and data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adolescents with high-functioning autism. Exclusion criteria: History of lower-limb surgery, unwillingness to participate in the study, or engagement in concurrent training programs outside the study protocol.

Intervention groups
Intervention group (SPARK): The intervention will be conducted over 6 weeks, with three 60-minute sessions per week. The training program includes overhead ball throws, striking movements, hoop jumping, tug-of-war, hopping through hoops, heel-to-toe walking, free dribbling, and passing drills using equipment such as balls and ropes. Control group: The control group will receive no intervention during the 6 weeks.

Main outcome variables
Static Balance, Dynamic Balance, Motor Performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260321069007N3**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date
2026-06-13, 1405/03/23

Registrant information

Name
Razieh Yousefian Molla

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of a SPARK Training Program on Balance and Motor Performance in Adolescents with Autism

Public title

The Effects of SPARK Training on Adolescents with Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Autism Spectrum Disorder based on DSM-5 criteria Having Autism Spectrum Disorder with moderate to high functioning based on medical records and specialist evaluation Ability to participate in the SPARK training program

Exclusion criteria:

No history of injury or surgery Participation in similar training programs during the past 3 months Lack of consent to participate in the study

Age

From **15 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after identifying eligible participants based on the inclusion and exclusion criteria and obtaining written informed consent from parents or legal guardians, participants will be randomly assigned to either the “SPARK training group” or the “control group.” The unit of randomization in this study is the individual. To ensure balance in the number of participants between the two groups, simple randomization will be used based on a random number table. The random allocation sequence will be generated using Random Allocation Software or a random number table. In this method, each participant will be assigned a code, and based on the software output, individuals will be randomly allocated to one of the two study groups. The allocation sequence will be generated by an independent person who is not involved in the implementation of the study, and the researcher will have no role in the sequence generation or group assignment process. To ensure allocation concealment, the group assignment for each participant will be placed in sealed, opaque, and sequentially numbered envelopes. After completion of the baseline assessments (pre-test), the envelope corresponding to each participant will be opened by the responsible person, and the participant’s group allocation will be revealed. This procedure ensures that the allocation process cannot be predicted or manipulated by the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding will be implemented in a limited manner and only at the level of outcome assessment. Due to the nature of the intervention (the SPARK exercise program), full blinding of participants and the intervention provider is not feasible; therefore, participants will be aware of the type of training program they receive, and blinding of participants will not be possible. In addition, the principal investigator and the exercise instructor will be informed of group allocation and will have a direct role in delivering the intervention; thus, blinding is not applied to them. In contrast, the outcome assessor (the individual responsible for measuring balance and motor function) will be blinded to participants’ group allocation and will have no access to information regarding the type of intervention. All assessments will be conducted using anonymized numerical codes, and the assessor will not be aware of whether participants belong to the control or SPARK training group. Where possible, the data analyst will also use de-identified coded data and perform statistical analyses without knowledge of group allocation in order to minimize potential bias in interpretation of the results. In this study, there is no independent Data Safety and Monitoring Committee (DSMC), and study oversight will be provided by the academic supervisor. The manuscript preparation and final reporting will also be based on coded datasets, and group allocation will remain concealed from unauthorized personnel until completion of the primary analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University- Karaj Branch

Street address

Amir al-Mu’minin (A.S.) University Complex, Moazen Boulevard, Esteghlal Street Junction Rajaei Shahr (End), Karaj Alborz Province Iran

City

Karaj

Province

Tehran

Postal code

3149968111

Approval date

2026-05-23, 1405/03/02

Ethics committee reference number

IR.IAU.K.REC.1405.037

Health conditions studied

1

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

Primary outcomes

1

Description
Static Balance
Timepoint
Outcome measures were assessed in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program.
Method of measurement
Strok Balance Test

2

Description
Dynamic Balance
Timepoint
Outcome measures were assessed in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program.
Method of measurement
Walking Heel to Toe Test

3

Description
Motor Performance
Timepoint
Outcome measures were assessed in two stages: a pre-test conducted before the start of the intervention and a post-test administered immediately after the completion of the 6-week training program
Method of measurement
Bruininks–Oseretsky Test of Motor Proficiency (BOT-2)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: SPARK Training Intervention Group. Participants in this group will undergo a structured SPARK-based training program for a period of 6 weeks. Training sessions will be conducted regularly (3 sessions per week, approximately 60 minutes per session) under the supervision of the researcher. The program is designed to improve physical fitness, motor performance, balance, and fundamental movement skills through structured, dynamic, and activity-based exercises. The main component of the intervention includes moderate-to-vigorous aerobic activities, agility training, group-based movement games, and fundamental movement skill exercises such as running, jumping, hopping, directional changes, and throwing/catching a ball. These activities will be progressively developed in terms of intensity, duration, and complexity over the 6 weeks. The exercises are designed to enhance active participation, motivation, and motor engagement while simultaneously improving neuromuscular coordination and motor control. During the sessions, simple equipment such as balls, cones, and low hurdles will be used to facilitate training tasks. Training load (including intensity, volume, and movement complexity) will be progressively increased throughout the intervention, starting with simpler and less demanding activities in the initial weeks and advancing toward more complex, faster-paced, and higher motor-control-demanding activities in the final weeks.
Category
Rehabilitation

2

Description
Control group: Participants in the control group will not engage in any structured exercise, rehabilitation program, or corrective training during the 6-week study period. They will be instructed to continue their usual daily activities and to refrain from initiating any new exercise programs, including strength training, balance training, stretching routines, or regular sports participation.To control for potential confounding factors, participants will be asked to maintain their habitual level of physical activity and avoid performing any targeted lower-limb exercise throughout the study period. No therapeutic intervention, training equipment, or rehabilitation procedures will be provided to this group. Baseline and post-intervention assessments will be conducted for these participants in the same manner as the intervention groups; however, no supervised training sessions will be held during the study period.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Aliasghar Jamebozorgi
Street address
Akhtar Hospital, Shariati St., Rumi Bridge, Sharifi

Manesh St., Azar Dead End, Tehran
City
Tehran
Province
Tehran
Postal code
1964714960
Phone
+98 21 2200 1072
Email
akhtarhospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Shabnam Mirnezami
Street address
Amir Al-Momenin (A.S.) University Complex, Intersection of Moazen Blvd. and Esteghlal St., Rajaei Shahr
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3149968111
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karaj@iau.ece.ir
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
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
Razieh Yousefian Molla
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Occupational Therapy
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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 potential data can be shared after de-identifying individuals
When the data will become available and for how long
Access period starts after publication of results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers at universities, such as faculty members, will be allowed to conduct any statistical and clinical analysis
From where data/document is obtainable
Applicants can contact the responsible researcher by sending an email (razieh.yousefianmolla@iau.ac.ir) or calling (0098 9122022730).
What processes are involved for a request to access data/document
The researcher will receive the items within a maximum of two weeks after sending the email or making the phone call
Comments