

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of an 8 week multimodal exercise program (SPARK) on walking mechanics in boys with autism spectrum disorder

Protocol summary

Study aim

The aim of this study was to evaluate the effects of a multimodal exercise program entitled Sports, Play, and Active Recreation for Kids (SPARK) on variables of walking mechanics in boys with autism spectrum disorder (ASD).

Design

A double blind randomized controlled trial

Settings and conduct

Both participants and examiners were unaware of group allocation. During pre and post-tests, children were instructed to walk barefoot along a 15-m walkway. Walking mechanics were measured using foot scan system, motion analysis system, and electromyography system. SPARK was conducted over a period of 8 weeks with three weekly sessions. SPARK included aerobic dance, running games, and jump rope exercises.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the scores of the children with ASD according to the "Gilliam Autism Rating Scale-2" ranged between 62 and 123. Exclusion criteria: Neuromotor or orthopedic disorders or medication that could affect the central nervous system

Intervention groups

SPARK was conducted over a period of 8 weeks with three weekly sessions. SPARK included aerobic dance, running games, and jump rope exercises.

Main outcome variables

Plantar pressure variables; Kinematic analysis; Muscle activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035517N4**

Registration date: **2021-11-08, 1400/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-08, 1400/08/17**

Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

AmirAli Jafarnezhadgero

Name of organization / entity

University of Mohaghegh Ardabili

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 0903

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of an 8 week multimodal exercise program (SPARK) on walking mechanics in boys with autism spectrum disorder

Public title

Effects of an 8 week multimodal exercise program (SPARK) on walking mechanics in boys with autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The scores of the children with autism spectrum disorder according to the “Gilliam Autism Rating Scale-2” ranged between 62 and 123 Age range between 7-12 years old

Exclusion criteria:
Neuromotor or orthopedic disorders or medication that could affect the central nervous system

Age
From **7 years** old to **13 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method (block size=4) will be used to allocate study participants into experimental groups. During the randomization procedure, a set of sealed, opaque envelopes will be used to ensure the concealment of the allocation. Each envelope will be contained a card stipulating to which group the participant would be allocated to.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be blinded to group allocation. One examiner will determine whether a participant will eligible for inclusion, while the other will carried out gait analyses of the eligible participants. Both examiners will be unaware of group allocation. Another naïve examiner (i.e., physiotherapist with 10 years professional experience) will be responsible for delivering the treatment to both groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethical Committee of the University of Mohaghegh Ardabili

Street address
University street

City
Ardabil

Province
Ardabil

Postal code
5618953141

Approval date
2021-11-01, 1400/08/10

Ethics committee reference number
IR.UMA.REC.1400.019

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

Platar presuure variables

Timepoint

before and after 8 weeks

Method of measurement

A plantar pressure plate (RsScan International, Belgium, 0.5 m × 0.5× 0.02 m, 4363 sensors)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: SPARK training

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabili city

Full name of responsible person

AmirAli Jafarnezhadgero

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Mohaghegh Ardabili
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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

University of Mohaghegh Ardabili

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
University of Mohaghegh Ardabili
Full name of responsible person
AmirAli Jafarnezhadgero
Position
Associate professor
Latest degree

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Other areas of specialty/work

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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

Plantar pressure data

When the data will become available and for how long

after publication process

To whom data/document is available

Experts in this field

Under which criteria data/document could be used

Experts in this field

From where data/document is obtainable

by e-mail

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

by e-mail

Comments

Experts in this field