Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Individual and Group Exercise Interventions on Social Skills and Physical Fitness in Children with Autism Spectrum Disorder

Protocol summary

Study aim

The aim of this study is to investigate the effect of a 12-week karate and basketball training program on social skills and physical fitness in preschool children with autism spectrum disorder (ASD).

Design

Three-arm randomized controlled trial (karate, basketball, control) with pre- and post-intervention assessments.

Settings and conduct

This study was conducted as a clinical trial across three specialized autism treatment centers in Tehran, involving 51 children aged 3–6 years diagnosed with autism spectrum disorder. Participants were randomly and evenly assigned to three groups: karate, basketball, and control. The karate and basketball groups underwent 12 weeks of training, with three 60-minute sessions per week. Social skills and physical fitness were assessed before and after the intervention. No blinding was applied.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of Autism Spectrum Disorder (ASD) based on DSM-IV-TR criteria, Age between 3 to 6 years, No prior participation in formal karate or basketball training, Medically cleared for physical activity participation, Parental consent for participation Exclusion Criteria: Presence of severe psychiatric or neurological disorders, Severe visual or auditory impairments preventing participation in exercise, Medical conditions restricting physical activity, Use of medications affecting motor or cognitive function, Severe behavioral issues preventing cooperation in training sessions

Intervention groups

The karate, basketball, and control groups. The karate and basketball groups performed 12 weeks of specific exercise training (three 60-minute sessions per week), while the control group did not participate in any physical activity.

Main outcome variables

Social Responsiveness Scale (SRS-2); balance; cardiorespiratory endurance; speed; handgrip strength; long jump.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241205063953N3**
Registration date: **2025-03-25, 1404/01/05**
Registration timing: **prospective**

Last update: **2025-03-25, 1404/01/05**
Update count: **0**

Registration date

2025-03-25, 1404/01/05

Registrant information

Name

akram jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 547 9267

Email address

jafari.akm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-20, 1404/02/30

Expected recruitment end date

2025-08-21, 1404/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Individual and Group Exercise Interventions on Social Skills and Physical Fitness in Children with Autism Spectrum Disorder

Public title

Effectiveness of Karate and Basketball Training on Social Skills and Physical Fitness in Children with Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Autism Spectrum Disorder (ASD) based on DSM-IV-TR criteria Age between 3 to 6 years No prior participation in formal karate or basketball training Physical ability to participate in exercises, confirmed by a physician Parental consent for the child's participation in the study

Exclusion criteria:

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization was used to assign participants to study groups. The randomization unit was individual, meaning that each child was independently assigned to one of the three groups: karate, basketball, or control. The randomization tool was EXECL software which generated the random sequence before the study began to prevent allocation bias. Allocation concealment was ensured using sealed and numbered opaque envelopes containing the group assignment for each participant. These envelopes were opened only after a participant's eligibility was confirmed by an independent researcher not involved in the randomization process. Stratified randomization was applied based on age and autism severity to ensure balance across groups for these key variables.

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

Islamic Azad University Shahrekord Branch

Street address

Rahmatieh, Islamic Azad University Shahrekord Branch

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

881863003

Approval date

2024-06-05, 1403/03/16

Ethics committee reference number

IR.IAU.SHK.REC.1403.058

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

social communication

Timepoint

48 hours before and after 12 weeks of research

Method of measurement

Social Responsiveness Scale Second Edition (SRS-2)

2

Description

Balance

Timepoint

48 hours before and after 12 weeks of research

Method of measurement

one leg balance test

3

Description

Cardiorespiratory Endurance

Timepoint

48 hours before and after 12 weeks of research

Method of measurement
10 × 20 m endurance test

4

Description
Sprint
Timepoint
48 hours before and after 12 weeks of research
Method of measurement
20 m sprint test

5

Description
handgrip strength
Timepoint
48 hours before and after 12 weeks of research
Method of measurement
hand grip dynamometer

6

Description
standing broad jump
Timepoint
48 hours before and after 12 weeks of research
Method of measurement
standing broad jump test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Karate group. This group practiced karate under the supervision of instructors for 12 weeks, 3 sessions per week, 60 minutes per session.
Category
Treatment - Other

2

Description
Intervention group: Basketball group. This group practiced basketball under the supervision of instructors for 12 weeks, 3 sessions per week, 60 minutes per session.
Category
Treatment - Other

3

Description
Control group: No sports activities were involved during the research.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University Shahrekord Branch
Full name of responsible person
Farshid Khairi
Street address
Rahmatieh, Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8818630003
Phone
+98 912 547 9267
Email
jafari.akm@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshid Khairi
Street address
Rahmatieh, Islamic Azad University Shahrekord Branch
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8818630003
Phone
+98 38 3336 1001
Email
jafari.akm@gmail.com
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
Private
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
Akram Jafari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
sport physiology

Street address
Rahmatieh, Islamic Azad University Shahrekord Branch

City
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Email
jafari.akm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Jafari

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
sport physiology

Street address
Rahmatieh, Islamic Azad University Shahrekord Branch

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8817630003

Phone
+98 38 3336 1001

Email
jafari.akm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Akram Jafari

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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 data without participant names

When the data will become available and for how long
6 months after publication of the article

To whom data/document is available
University students and professors

Under which criteria data/document could be used
For future research

From where data/document is obtainable
To the researchers of this study

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

Comments