

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The Effect of selected exercise training on physical fitness indices and social interaction in children with autism spectrum disorders.

Protocol summary

Study aim

The aim of this study was to investigate the effect of a selected exercise program on physical fitness and social interaction indices in children with autism.

Design

A clinical trial with a control group (n = 8) and an intervention group (n = 8), single-blind, randomized, was used to randomize the rand function of Excel software.

Settings and conduct

The training program of the present study included combined aerobic resistance exercises that were performed three sessions per week for eight weeks in the environment of Sabzevar Autism School. The test taker and data analyst did not know the groups.

Participants/Inclusion and exclusion criteria

Admission requirements: Children with autism, age 5 to 10 years, clinical examination by a physician to perform physical activity, no history of cardiorespiratory disease, written consent of parents or legal guardian of the child, no severe mobility restrictions. Exclusion criteria: inability to perform exercise, not attending regular exercise sessions (3 consecutive sessions and 5 non-consecutive sessions, injury, illness and any other obvious disorders other than autism that can be considered as the main diagnosis, personal reasons

Intervention groups

The experimental group participated in a selective exercise program consisting of hand-held play, rhythmic movements by rhythmic song and resistance training with stretching for 8 weeks (3 sessions per week). The control group engaged in normal daily activities

Main outcome variables

: cardio-respiratory endurance, lower body explosive power, upper body muscle power, back muscle flexibility, balance, claw strength, coordination, agility, social interactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220103053616N1**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **retrospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Shokofeh Broughani

Name of organization / entity

Hakim Sabzevari University

Country

Iran (Islamic Republic of)

Phone

+98 51 4467 5281

Email address

shokofeh.broughani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-06-03, 1398/03/13

Actual recruitment start date

2019-04-04, 1398/01/15

Actual recruitment end date

2019-06-03, 1398/03/13

Trial completion date

2019-06-03, 1398/03/13

Scientific title

The Effect of selected exercise training on physical fitness indices and social interaction in children with autism spectrum disorders.

Public title

The Effect of selected exercise training on physical fitness indices and social interaction in children with autism spectrum disorders.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children with autism Age 5 to 10 years Clinical examination by a specialist doctor for physical activity No history of cardiorespiratory disease Written consent of the child's parent or legal guardian No severe movement limitations

Exclusion criteria:

Inability to perform the exercise Absence from regular training sessions (3 consecutive sessions and 5 non-consecutive sessions) Injury Illness and any other obvious disorder other than autism that can be considered as the main diagnosis. personal reasons

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **21**

Actual sample size reached: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software was used for randomization tools and to hide allocation concealment from opaque envelopes sealed with random sequence. In this method, each of the random sequences created was recorded on a card and the cards were placed in the envelopes of the letter, respectively. In order to maintain a random sequence, the envelopes were numbered in the same way on the outer surface. Finally, the letter envelopes were glued and placed in a box, respectively. Eligible participants, one of the envelopes was opened in order, and the group assigned to that participant was revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessors and data analysts did not know which individual belonged to the control group or the experimental group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research OF Hakim Sabzevari University

Street address

Hakim Sabzevari University, Tohid Shahr, Sabzevar, Khorasan Razavi

City

SABZEVAR

Province

Razavi Khorasan

Postal code

9617976487

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.HSU.REC.1398.004

Health conditions studied

1

Description of health condition studied

AUTISM spectrum disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

social interaction

Timepoint

At the beginning of the study (before the intervention) and eight weeks after the start of the exercise program

Method of measurement

Gilliam Autism Test (GARZ)

2

Description

physical fitness Indices (Anthropometric tests, cardiopulmonary endurance, leg and trunk explosive power, hand muscle strength, flexibility, static balance, agility, hand grip strength, coordination)

Timepoint

At the beginning of the study (before the intervention) and eight weeks after the start of the exercise program

Method of measurement

For anthropometric evaluation, height and weight were measured by meters and scales. Body mass index was calculated by dividing weight (kg) by height squared (m²). Evaluation of cardiorespiratory fitness (20-meter

shuttle run test), explosive power (sergeant test), trunk explosive power (medical ball throwing test), static balance (strok test), agility (T test), hand grip strength (hand dynamometer), flexibility (Wells test) and coordination of the Nelson selective response motor test were used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group participated in a selective exercise program consisting of hand-held play, rhythmic movements by rhythmic song and resistance training with stretching for 8 weeks (3 sessions per week).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Autism School

Full name of responsible person

Education

Street address

No. 15, Eram 19, Eram st, sabzevar

City

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9618665737

Phone

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Email

shokofeh.broughani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hakim Sabzevari University

Full name of responsible person

Mohammad Ibrahim Hajiabadi

Street address

No. 15, Eram19, Eram ST, Sabzevar

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hakim Sabzevari University

Proportion provided by this source

10

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

Hakim Sabzevari University

Full name of responsible person

shokofeh broughani

Position

Student

Latest degree

Master

Other areas of specialty/work

Physical Education

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Person responsible for scientific inquiries

Contact

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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

Only part of the data, such as information about the main outcome, and its results are shared

When the data will become available and for how long

Access started from 2021

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To carry out research projects

From where data/document is obtainable

sending email

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

Send email and the purpose and reason for the request

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hakim Sabzevari University

Full name of responsible person

Shokofeh Broughani

Position

Student

Latest degree

Master

Other areas of specialty/work

Physical Education

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