

# 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 (m<sup>2</sup>). 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

sabzevar

##### Province

Razavi Khorasan

##### Postal code

9618665737

##### Phone

+98 51 4467 5281

##### 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

##### City

sabzevar

##### Province

Razavi Khorasan

##### Postal code

9618665737

##### Phone

+98 51 4467 5281

##### Email

shokofeh.broughani@yahoo.com

#### 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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**Fax****Email**

shokofeh.broughani@yahoo.com

**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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