

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of a group aerobic exercise program on body composition, physical and cognitive performance in children with pervasive developmental disorders: a randomized clinical trial

Protocol summary

Summary

Objective: we aim to assign the children with Autism Spectrum Disorder (ASD) to a group exercise intervention in a controlled trial, regard to effect on physical and cognitive factors. 30 autistic children (aged 7-14 years old) are recruited through the special schools of Tehran, Iran; subjects are selected from a database which prepared from autism schools by research center of sport medicine, 2009-10. They are divided in two equal groups of intervention and control. All subjects are included if they have definite clinical and instrumental (ADI-R) diagnosis of ASD by the specialists. Any orthopedic disorder which may interrupt with the exercise ability of the children will result in exclusion. Intervention is applied for 15 subjects as a group exercise on a weekly schedule (2 times a week) up to 20 sessions and each session is 45 minutes. Another group will be with no intervention. Outcome measures include physical activity level and cognitive factors in children.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904204264N3**

Registration date: **2010-11-01, 1389/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-01, 1389/08/10

Registrant information

Name

Amirhossein Memari

Name of organization / entity

Sport Medicine Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy, Tehran University of Medical Sciences

Expected recruitment start date

2010-07-03, 1389/04/12

Expected recruitment end date

2010-07-10, 1389/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of a group aerobic exercise program on body composition, physical and cognitive performance in children with pervasive developmental disorders: a randomized clinical trial

Public title

Physical education effects in autistic children

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 7-14 years old and high function participants with DSMIV based diagnosis of ASD which confirmed by ADI-R; Capable to walk independently; Allowed to exercise due to physician opinion. Exclusion criteria: orthopedics and musculoskeletal impairment

that contradict to exercise, epilepsy.

Age

From **7 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Tehran University of Medical Sciences Ethic Committee

Street address

Central University Building, Ghods st, Keshavarz Blv

City

Tehran

Postal code

14395-578

Approval date

empty

Ethics committee reference number

89-01-53-8641

Health conditions studied**1****Description of health condition studied**

pervasive developmental disorder

ICD-10 code

F84.0

ICD-10 code description

childhood autism

Primary outcomes**1****Description**

Physical factors

Timepoint

Before and after the intervention period

Method of measurement

BOTMP test

2**Description**

physical activity

Timepoint

before and after intervention

Method of measurement

accelerometry

Secondary outcomes**1****Description**

Cognitive and social factors

Timepoint

Pre and Pos intervention period

Method of measurement

WCST, ATEC tests

Intervention groups**1****Description**

An adapted aerobic group exercise for intervention group; 20 sessions under coach instruction of 1 : 1 and weekly basis education (twice a week) is presented. Each session includes 45 minutes of adapted physical education which prompted by certified physical educators in an adapted rich context.

Category

N/A

2**Description**

Control group: subjects are in waiting list with no adapted physical intervention

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Research Center of Sport Medicine , Tehran University of Medical Sciences

Full name of responsible person

Memari, Amir Hossein

Street address

Jalale Ale Ahmad
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy, Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotoohi
Street address
Central University Building, Ghods st, Keshavarz Blv
City
Tehran

Grant name

Grant code / Reference number

89-01-53-8641

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

Yes

Title of funding source

Research Deputy, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty