Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effect of Functional Exercise Along with online Nutritional Education on Inflammatory-Oxidative and Metabolic Profile in Children with Autism Spectrum Disorder during Covid-19 Pandemic

Protocol summary

Study aim

Effect of Functional Exercise Along with online Nutritional Education on Inflammatory-Oxidative and Metabolic Profile in Children with Autism Spectrum Disorder during Covid-19 Pandemic

Design

Randomized clinical trial with parallel groups on 80 children with autism spectrum disorder

Settings and conduct

This study will be recruited in selected autism and rehabilitation centers in Tehran. Participants will be randomly allocated in one of 4 study groups.this study will last for 8 weeks. Functional training group will recruit training including warm-up, sits-to-stand with weight and stairs up and down training ends with stretch and cool down. Online nutritional education groups will participate in online educational sessions for 8 weeks, 3 sessions per week for 15-30 minutes in each session training+education groups will receive both interventions. Control groups will only participate in pre-test and post-test.

Participants/Inclusion and exclusion criteria

Participants of this study will be included 8-12 years old children (boys) with autism spectrum disorder diagnosed and approved by neurologist from selected centers in Tehran city. Participants will not enter the study in case of: reaching to puberty according to specialist approval, any inhibition from physical activity and any medical condition or disease which inhibit participant from physical activity.

Intervention groups

1) functional exercise group, 2) online nutritional education group, 3) functional exercise and online nutritional education group and 4) control group

Main outcome variables

Lipid profile Insulin resistance indiator waist to hip ratio (WHR) body mass index (BMI) fat mass Physical fitness indicators White blood cells (neutrophil, basophils, eusinophil) C-reactive protein Super oxide dismutase (SOD) Glutathione peroxidase (GPx) Catalase (CAT) Lactate dehydrogenase (LDH)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201211049678N1**
Registration date: **2021-07-29, 1400/05/07**
Registration timing: **retrospective**

Last update: **2021-07-29, 1400/05/07**
Update count: **0**

Registration date

2021-07-29, 1400/05/07

Registrant information

Name

Kimia Moiniafshari

Name of organization / entity

Science and research branch islamic azad university

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 4170

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Functional Exercise Along with online Nutritional Education on Inflammatory-Oxidative and Metabolic Profile in Children with Autism Spectrum Disorder during Covid-19 Pandemic

Public title
Exercise and nutrition effect on Autism
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Autism spectrum disorder diagnosis approved by neurologist No inhibition for physical activity No experience of physical activity within past 6 month Not reaching maturity according to specialist diagnosis
Exclusion criteria:
Reaching to puberty according to specialist approval Any prohibition from physical activity Any medical conditions or disease which inhibits physical activity
Age
From **8 years** old to **12 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a clinical trial with pre-test and post-test and participants will be children diagnosed with autism spectrum disorder approved by neurologist. Targeted sampling with available participants will be recruited for participants selection. Among 100 eligible individuals, 80 participants will be selected according to Morgan chart. Then, participants will randomly receive specific codes by using random allocation software, without researches awareness. Participants will be divided into 4 groups according to their random codes as following: 1) functional exercise, 2) online nutritional education, 3) functional exercise+ online nutritional education and 4) control group. Participants with codes 1-20 will be allocated in functional exercise group, participants who received codes 21-40 will be allocated in online nutritional education group and allocation for functional exercise+ online nutritional education and control group will be for codes 41-60 and 61-80 respectively. In order to prevent from any bias, all sampling process, participants selection, specific codes allocation and participants grouping will be without researcher awareness. Moreover, the intervention process will be done under occupational therapist, physiotherapist and nutritionist super vision and via their assistance
Blinding (investigator's opinion)
Double blinded
Blinding description
Each candidate will randomly receive specific codes using random allocation software without researcher involvement or awareness. Participants will be allocated in one of the for groups according to their codes. All the sampling, randomized code allocation and grouping, will be recruited without researcher awareness and with occupational therapist, physiotherapist and nutritionist supervision and assistance.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad university- science and research branch
Street address
13th floor, Block A, ministry of health and medical education head quarter, Simaye Iran street, between South Falamak and Zarafshan street, Shahrake-e-Gharb, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۹۴۳۴۷۱
Approval date
2021-06-16, 1400/03/26
Ethics committee reference number
IR.IAU.SRB.REC.1400.003

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Lower limb strength

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Sits to stand test

2

Description

Upper limb strength

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

1 kilogram dumbbell press

3

Description

Abdominal strength

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Push ups test

4

Description

Flexibility

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Modified sit and reach test

5

Description

Cardio-respiratory endurance

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

6 minutes walking test

6

Description

Lipid profile

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

7

Description

Insulin resistance indicator

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

8

Description

Waist to hip circumference ratio (WHR)

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Waist and hip circumference measurement and division to each other

9

Description

Fat mass

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Caliper

10

Description

C-reactive protein (CRP)

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

11

Description

White blood cells (WBC)

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

12

Description

Superoxide dismutase enzyme (SOD)

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

13

Description

Lactate dehydrogenase enzyme

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital veil blood sample

14

Description
Glutathione peroxidase enzyme
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Anterior cubital vein blood sample

15

Description
Catalase enzyme
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Anterior cubital vein blood sample

16

Description
Speed
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
10 minutes walking test

17

Description
Balance
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Flamingo and Time-Up-and-GO tests

Secondary outcomes

1

Description
Lower limb muscle strenght
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Sit-to-stand test

2

Description
Upper limb muscle strenght
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
1 kilogram dumbbell press

3

Description
Abdominal muscle strenght
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Push-ups test

4

Description
Flexibility
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Modified sit-and-reach test

5

Description
Cardio-respiratory endurance
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
6 minutes walking test

6

Description
Lipid profile indicators
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Anterior cubital vein blood sample

7

Description
Insulin resistance indicator
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Anterior cubital vein blood sample

8

Description
Waist-to-hip ratio
Timepoint
Before the study as pre-test and at the end of 8 weeks intervention as post-test
Method of measurement
Waist and hip circumference measurement and division to each other

9

Description

Fat mass

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Caliper

10

Description

C-reactive protein

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

11

Description

White blood cells

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

12

Description

Superoxide dismutase enzyme

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

13

Description

Lactate dehydrogenase enzyme

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

14

Description

Gluthatione peroxidase enzyme

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital vein blood sample

15

Description

Catalase enzyme

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Anterior cubital blood vein sample

16

Description

Speed

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

10 minutes walking test

17

Description

Balance

Timepoint

Before the study as pre-test and at the end of 8 weeks intervention as post-test

Method of measurement

Flamingo and Time-Up-and-Go (TUGT) test

Intervention groups

1

Description

Functional group, will participate in 8 weeks functional training including warm up, going up and down the stairs, sit-to-stand using weight and cool down at the end of the sessions for 3 times per week for 60 minutes each session.

Category

Other

2

Description

Online nutritional education group will participate in online nutritional education sessions for 3 time per week and 30 minutes in each session.

Category

Other

3

Description

Functional exercise and online nutritional education group will participate in exercise and online education session for 8 weeks, 3 session per week for 90 minutes.

Category

Other

4

Description

Control group will not receive any exercise or online nutritional education intervention and only will participate in pre-test and post-test

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabesh Rehabiliation Center

Full name of responsible person
Mohammad Mohebi Rad

Street address
Yousefabad Street

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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Islamic Azad University Science And Research Branch

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
Islamic Azad University

Full name of responsible person
Mandana Gholami

Position
Associate professor

Latest degree
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Other areas of specialty/work
Physiology

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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Data from variables and their outcomes will be available after Unidentifiabling
When the data will become available and for how long
6 month after results publication
To whom data/document is available
Researchers
Under which criteria data/document could be used
Researchers can use study design and its results for future studies
From where data/document is obtainable
Researcher
What processes are involved for a request to access data/document
Researchers can contact for future information for future studies after results publication via kimia.moiniafshari@srbiau.ac.ir
Comments