

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of Perceptual-motor Exercises along with music and Vitamin D3 Supplementation on Nerve Growth Factor, Attention, motor proficiency and GARS-2 in children with high-functioning autism

Protocol summary

Study aim

This study aims to investigate the effect of perceptual motor Exercises along with music and Vitamin D3 Supplementation on Nerve Growth Factor (NGF), Attention, motor proficiency and GARS-2 in 6 to 9 years old children suffering from autism disorder.

Design

Among children with autism in autistic children care centers in Isfahan, 150 children were selected using screening tests. The children with autism spectrum disorders were randomly selected from the Autism Center. Then, They were randomly assigned to one of the four study groups and receive the special intervention. They were randomly divided into Four groups: group 1= perceptual-motor Exercises along with music; Group 2= Vitamin D3 supplementation; Group 3= perceptual-motor Exercises along with music and Vitamin D3; and Group 4= Placebo.

Settings and conduct

Participants were screened by an experienced physician and were found eligible to participate in Perceptual-motor Exercises and Vitamin D Supplementation. Participants of the group 1 received perceptual-motor exercises along with music instruction 1 session/day, 3 days/week for 12 weeks. The sessions were carried out in a therapy room located at the Center of Autism. The intervention related to the group 2 includes intake of Vitamin D tablets (300 IU/ day not to exceed 5,000 IU/day). In Group 3, both interventions of Groups 1 and 2 were conducted for 3 months (Perceptual-motor Exercises along with music was 36 sessions (3 months) + receive vitamin D3 drops, 300 IU/ day not to exceed 5,000 IU/day for 3 months.). Children with ASD in Group 4 also received placebos during the investigation period. The placebo consisted of a combination of polysorbate 20, which is the same fragrance ingredient used in vitamin D drops in addition to glycerin, disodium edetate,

and b-cyclodextrin in purified water. Finally, all subjects were subjected to post-test using the research kit of the NGF, stroop test, Bruininks-Oseretsky Test of Motor Proficiency, GARS-2.

Participants/Inclusion and exclusion criteria

Inclusion criteria: an autism diagnosis confirmed by a psychologist along with a medical team and based on diagnostic criteria DSM-5; Children with high-functioning autism disorder; obtaining consent from parents; Vitamin D serum level less than 30 ng/ml. Exclusion criteria: Subjects who had associated gastrointestinal problems; neurological diseases and children with malnutrition.

Intervention groups

Intervention group 1: The protocol of Perceptual-motor Exercises along with music was 36 sessions at 12 weeks (3 months) and three sessions per week, with each session lasting 60 minutes. They included stretching and jogging (10 minutes), main perceptual-motor exercises (45 minutes), and cool down (5 minutes). Intervention group 2: The intervention related to the group 2 includes intake of Vitamin D tablets (300 IU/ day not to exceed 5,000 IU/day). Intervention group 3: In Group 3, both interventions of Groups 1 and 2 were conducted for 3 months (Perceptual-motor Exercises along with music was 36 sessions (3 months) + receive vitamin D3 drops, 300 IU/ day not to exceed 5,000 IU/day for 3 months). Control group: Children with ASD in Group 4 also received placebos during the investigation period. The placebo consisted of a combination of polysorbate 20, which is the same fragrance ingredient used in vitamin D drops in addition to glycerin, disodium edetate, and b-cyclodextrin in purified water.

Main outcome variables

Nerve Growth Factor Attention Motor Proficiency
Stereotypic Behaviors Communication Social

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022323N2**

Registration date: **2017-12-16, 1396/09/25**

Registration timing: **retrospective**

Last update: **2017-12-16, 1396/09/25**

Update count: **0**

Registration date

2017-12-16, 1396/09/25

Registrant information

Name

Hadi Moradi

Name of organization / entity

Ferdowsi University Of Mashhad

Country

Iran (Islamic Republic of)

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+98 38 3422 8893

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

2016-11-20, 1395/08/30

Actual recruitment end date

2017-03-19, 1395/12/29

Trial completion date

empty

Scientific title

The effect of Perceptual-motor Exercises along with music and Vitamin D3 Supplementation on Nerve Growth Factor, Attention, motor proficiency and GARS-2 in children with high-functioning autism

Public title

The effect of Perceptual motor Exercises along with music and Vitamin D3 Supplementation in children with autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

An autism diagnosis confirmed by a psychologist along with a medical team and based on diagnostic criteria DSM-5 Children with high-functioning autism disorder Vitamin D serum level less than 30 ng/ml Chronological age between six and nine years IQ more than 70 Sound sense of sight and hearing Obtaining consent from parents

Exclusion criteria:

Children with autoimmune disorders Subjects who had associated gastrointestinal problems Children with

neurological diseases Children with malnutrition Children with anemia Children with orthopedic and respiratory disorders Seizure attacks in the last two years

Age

From **6 years** old to **9 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The children with autism spectrum disorders were randomly selected from the Autism Center. Then, They were randomly assigned to one of the four study groups and receive the special intervention.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University Of Medical Sciences, Azadi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUMS.REC.1396.129

Health conditions studied

1

Description of health condition studied

autism

ICD-10 code

F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description

Nerve Growth Factor

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

The research kit of the Nerve Growth Factor

2

Description

Attention

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

Stroop test

3

Description

Motor proficiency

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

Bruininks-Oseretsky Test of Motor Proficiency

4

Description

Stereotypic behaviors

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

Gilliam Autism Rating Scale-Second Edition (GARS-2)

5

Description

Communication

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

Gilliam Autism Rating Scale-Second Edition (GARS-2)

6

Description

Social

Timepoint

Before Intervention, 12 Weeks After Intervention

Method of measurement

Gilliam Autism Rating Scale-Second Edition (GARS-2)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The protocol of Perceptual-motor Exercises along with music was 36 sessions at 12 weeks (3 months) and three sessions per week, with each session lasting 60 minutes. They included stretching and jogging (10 minutes), main perceptual-motor exercises (45 minutes), and cool down (5 minutes).

Category

Rehabilitation

2

Description

Intervention group 2: The intervention related to the group 2 includes intake of Vitamin D tablets (300 IU/ day not to exceed 5,000 IU/day).

Category

Treatment - Drugs

3

Description

Intervention group 3: In Group 3, both interventions of Groups 1 and 2 were conducted for 3 months (Perceptual-motor Exercises along with music was 36 sessions (3 months) + receive vitamin D3 drops, 300 IU/ day not to exceed 5,000 IU/day for 3 months).

Category

Treatment - Other

4

Description

Control group: Children with ASD in Group 4 also received placebos during the investigation period. The placebo consisted of a combination of polysorbate 20, which is the same fragrance ingredient used in vitamin D drops in addition to glycerin, disodium edetate, and b-cyclodextrin in purified water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Autism Center

Full name of responsible person

Mojtaba Gashool

Street address

Jomhuri-e-Eslami Square

City

Esfahan

Province

Isfahan

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8871796545

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Email

Hadimoradi_85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ferdowsi University Of Mashhad, Mashhad

Full name of responsible person

Mehdi Sohrabi

Street address

Ferdowsi University Of Mashhad, Paradise
Daneshgah, Azadi Square

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Email

sohrabi@um.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ferdowsi University Of Mashhad, Mashhad

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

Ferdowsi University Of Mashhad

Full name of responsible person

Hadi Moradi

Position

Ph.D Student Of Motor Development

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable