Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of vestibular and motor coordination on cognitive function in children with autism spectrum disorder

Protocol summary

Study aim
Determining the effect of vestibular exercises and motor coordination on the cognitive functions of autistic children

Design
Clinical trial with control group, with parallel groups, unblinded, randomized, on 30 patients. for randomization used lottery method.

Settings and conduct
In this research, will be sampled 30 children age between 6 to 15 years with autism spectrum disorder level one from autism center and Besharat and Omidanejat schools in Semnan city, and will be randomly divided into 3 groups: vestibular exercises, motor coordination exercises and control group. they do exercises for 8 weeks and three sessions each week and each session lasts for one hour.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed parental consent The gender of boys and girls Autism with level 1 Age between 6 and 15 years Exclusion criteria: Attend other therapy sessions

Intervention groups
The intervention group includes two groups of vestibular and motor coordination exercises. The control group received no intervention.

Main outcome variables
Cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240603061993N1**
Registration date: **2024-07-31, 1403/05/10**
Registration timing: **retrospective**
Last update: **2024-07-31, 1403/05/10**
Update count: **0**

Registration date
2024-07-31, 1403/05/10

Registrant information

Name
mona gorji

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3333 6678

Email address
mona.grj5144@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date
2024-04-29, 1403/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of vestibular and motor coordination on cognitive function in children with autism spectrum disorder

Public title
The impact of vestibular and motor coordination on cognitive function in children with autism spectrum disorder

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Informed parental consent The gender of boys and girls Autism with level 1 Age between 6 and 15 years

Exclusion criteria:

Age

From **6 years** old to **15 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

In simple random sampling, the selection of participants is completely based on chance and probability. Each participant has an equal chance of entering the sample. The randomization method is done by lottery. In this way, one number is given to each person. Numbers are randomly taken from the container and placed in three groups. Therefore, one group is randomly selected as the "control group" and the other two groups as the "intervention group". In this way, to randomly determine the "control group" and "intervention group", we put the list of each group in three separate envelopes and put them in a container. Then we randomly take one envelope from the container and assign it to the "control group" and then the second and third group of envelopes are assigned to the "control group".

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

Research Ethics Committee of Islamic Azad University - Semnan branch

Street address

Kilometer 5 of Semnan-Damghan road,

City

Semnan

Province

Semnan

Postal code

۳۷۱۱۱۳۵۱۳۱

Approval date

2024-05-21, 1403/03/01

Ethics committee reference number

IR.IAU.SEMNAN.REC.1403.023

Health conditions studied

1

Description of health condition studied

Autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Cognitive function

Timepoint

The cognitive function of the clients is measured before and after the intervention of vestibular exercises and motor coordination.

Method of measurement

Cognitive-diagnostic test kay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The vestibular training group consists of 10 people who receive vestibular training for 8 weeks.

Category

Rehabilitation

2

Description

Intervention group: The motor coordination training group which includes 10 people who receive motor coordination training for 8 weeks.

Category

Rehabilitation

3

Description

Control group: This group includes 10 people who do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Zehn ziba Autism Center
Full name of responsible person
Mona gorji
Street address
No. 27, East12 Taavon Ave., Modares Blv
City
Semnan
Province
Semnan
Postal code
3514847940
Phone
+98 23 3344 8330
Email
mona.grj5144@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Shahab Moradi
Street address
Kilometer 5 of Semnan-Damghan road
City
Semnan
Province
Semnan
Postal code
۳۷۱۱۱۳۵۱۳۱
Phone
+98 23 3333 7866
Email
mona.grj5144@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Mona Gorji
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 8, Saadi Ave., Saadi7
City
Semnan
Province
Semnan
Postal code
3518694793
Phone
+98 23 3333 7866
Email
mona.grj5144@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mona Gorji
Position
studdent
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 8, Saadi Ave., Sadi 7
City
Semnan
Province
Semnan
Postal code
3518694793
Phone
+98 23 3333 7866
Email
mona.grj5144@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
mona gorji
Position
Student

Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 8, Saadi Ave., Saadi7
City
Semnan
Province
Semnan
Postal code
3518694793
Phone
023337866
Email
mona.grj5144@gmail.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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Results and data can be shared after de-identifying individuals.
When the data will become available and for how long
It is possible to access the data after the thesis and article are published.
To whom data/document is available
Psychologists, counselors, rehabilitation activists
Under which criteria data/document could be used
Non-manipulation and change of data
From where data/document is obtainable
Mona Gorji mona.grj5144@gmail.com
What processes are involved for a request to access data/document
The applicant must explain the topic, statistical sample and working method in the email and after checking it will be available to the applicant within one to two days.
Comments