

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Vestibular Stimulation Exercises on Balance and some Motor skills of Intellectual Disability Children with balance impairment

Protocol summary

Study aim

The Effect of Vestibular Stimulation Exercises on Balance and some Motor skills of Intellectual Disability Children with balance impairment

Design

a randomized single-blind clinical trial with intervention and control groups. parallel group, according to the centralized and computerized study

Settings and conduct

The study is conducted at the Khazaeli School of Rasht city, as well as single-blind design

Participants/Inclusion and exclusion criteria

Imbalance performance- an intellectual disability-The age group is 7-12 years old

Intervention groups

intervention group: Vestibular Stimulation Exercises - control group: without training program.

Main outcome variables

vestibular-balance

Country

Iran (Islamic Republic of)

Phone

+98 34 3411 4622

Email address

malihesharifi6971@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vestibular Stimulation Exercises on Balance and some Motor skills of Intellectual Disability Children with balance impairment

Public title

effect of motor training on balance in intellectual disability

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

being in the group of intellectual disability did not have visual and hearing impairment having a balance function disorder

Exclusion criteria:

having any physical and motor impairment having other disability use of special medication

Age

From 12 years old to 7 years old

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043393N1**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **prospective**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

Malihe Sharifi

Name of organization / entity

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

subject are randomly assigned with help of a random number table in one of the two group and receive related intervention

Blinding (investigator's opinion)

Single blinded

Blinding description

The selected training sessions of intervention group were blinded without knowledge of being in intervention or control groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of guilan university of medical sc

Street address

shahid siadaty ave, namjoo str, rasht

City

rasht

Province

Guilan

Postal code

4188794755

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.GUMS.REC.1397.478

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

intellectual disability patient

ICD-10 code

F71

ICD-10 code description

Moderate intellectual disabilities

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

balance

Timepoint

measurement of balance tests before and after of 6 week intervention

Method of measurement

functional test of balance

2**Description**

Coarse motor skills

Timepoint

measurement of balance tests before and after of 6 week intervention

Method of measurement

Subtest of Bruninks Oseretsky Test

3**Description**

fine motor skills

Timepoint

measurement of balance tests before and after of 6 week intervention

Method of measurement

Subtest of Bruninks Oseretsky Test

4**Description**

The Timed Up and Go

Timepoint

measurement of balance tests before and after of 6 week intervention

Method of measurement

The duration of this test

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

"intervention group 1"

Timepoint

"Measure relevant tests after 6 weeks"

Method of measurement

" Bruninks Oseretsky Test "

2**Description**

"control group"

Timepoint

"Measure relevant tests after 6 weeks"

Method of measurement

" Bruninks Oseretsky Test "

Intervention groups

1

Description

"Intervention group"

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

KHazaeli's exceptional school

Full name of responsible person

GHazalgeh Tahereh

Street address

KHazaeli's exceptional school-Higher than the police station 15-Modares freeway-Pirklauchai

City

Rasht

Province

Guilan

Postal code

4189845353

Phone

+98 13 3381 0081

Email

k.azarnoosh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mirhoseini Seyed Ziaaedin

Street address

5th Kilometer Gazvin rote,KHalije farse Highway,Rasht down

City

Rasht

Province

Guilan

Postal code

4199613776

Phone

+98 13 0338 3369

Email

szmirhoseini@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Rasht University of Medical Sciences

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

Rasht University of Medical Sciences

Full name of responsible person

SHarifi Malihe

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Sport injury and corrected exercise

Street address

Faculty of physical education and sport science.5th Kilometer Gazvin-Tehran rot,Rasht

City

Rasht

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4199613776

Phone

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Email

malihesharifi6971@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht university of medical sciences

Full name of responsible person

SHarifi Malihe

Position

Msc student

Latest degree

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Other areas of specialty/work

sport injury and corrected exercised

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

All data of variables measured after unidentifiable
individuals can be shared.

When the data will become available and for how long

Starting the access period from 2020

To whom data/document is available

Only for scholars working in academic and scientific
institutions

Under which criteria data/document could be used

Scientific use in improving and comparing with other
research is allowed

From where data/document is obtainable

E-mail address for correspondence

What processes are involved for a request to access data/document

Applicants should send the reason for using the
documentation to an e-mail

Comments