

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 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

#### Province

Guilan

#### Postal code

4199613776

#### Phone

+98 13 3375 3395

#### 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

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Bachelor

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## Person responsible for updating data

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**Email**

malihesharifi6971@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

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