

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The Effect of Vestibular Stimulation Exercises on Motor Function and Balance in Children with Hearing Impairment

#### Protocol summary

##### Study aim

The Effect of Vestibular Stimulation Exercises on Motor Function and Balance in Children with Hearing Impairment

##### Design

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

##### Settings and conduct

The study is conducted at the preschool school and Ghotbzadeh primary school of Rasht city, as well as single blind design

##### Participants/Inclusion and exclusion criteria

Hearing-impaired subjects with a hearing loss of about 80 dB are selected. Complete satisfaction and willingness to participate in research. Have no visual impairment

##### Intervention groups

Intervention group: Vestibular stimulation based on motor exercises. Control group: Do not participate in any exercise program.

##### Main outcome variables

vestibular, balance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190427043392N1**

Registration date: **2019-06-02, 1398/03/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-02, 1398/03/12**

Update count: **0**

##### Registration date

2019-06-02, 1398/03/12

##### Registrant information

##### Name

vahideh sadat mousavi zadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3411 9618

##### Email address

v.s.mousavizadeh@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 Motor Function and Balance in Children with Hearing Impairment

##### Public title

effect of motor exercises on the balance of children with hearing impairment

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Hearing-impaired subjects with a hearing loss of about 80 dB are selected. Complete satisfaction and willingness to participate in research. No visual impairment. Children aged 5 to 8 years old

###### Exclusion criteria:

Beyond the age range of 5 to 8 years. Subjects did not have orthopedic, cognitive, and musculoskeletal disorders. Subjects do not have absolute deafness

#### Age

From **5 years** old to **8 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **24**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Individuals are randomly assigned randomly into a group or two groups using the random numbers table and they receive the intervention of the same 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

Ethics committee of Guilan University of Medical Sciences

##### 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.1397.479

## Health conditions studied

### 1

#### Description of health condition studied

hearing loss individual

#### ICD-10 code

H91

#### ICD-10 code description

Other and unspecified hearing loss

## Primary outcomes

### 1

#### Description

balance

#### Timepoint

measurement of balance tests before and after 6of 6 week intervention

#### Method of measurement

functional test of balance

### 2

#### Description

the timed up and go

#### Timepoint

subtest of bruninks oseretsky test

#### Method of measurement

the duration of this test

## Secondary outcomes

### 1

#### Description

Balance"

#### Timepoint

Tests for relevant tests after 6 weeks"

#### Method of measurement

Bronkins - oseretsky test"

### 2

#### Description

Motor function

#### Timepoint

Tests for relevant tests after 6 weeks"

#### Method of measurement

Bronkins - oseretsky test"

## Intervention groups

### 1

#### Description

Intervention group: The intervention group carries out a training session on Vestibular stimulation for 6 weeks, every 3 sessions per week.

#### Category

Rehabilitation

### 2

#### Description

Control group: There is no intervention.

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Preschool and Deaf Language School, Ghotbzadeh

**Full name of responsible person**

Pourfathi Hadith

**Street address**

Preschool school and schoolGotb zadeh elementary,Imam's sister's stepmother, Motehari street

**City**

Rasht

**Province**

Guilan

**Postal code**

4173653137

**Phone**

+98 13 3335 8501

**Email**

mghotbzadeh1@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 Road, Khalij fars 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**

Mousavi zadeh Vahideh sadat

**Position**

Msc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sport injory and corrective exercise

**Street address**

Faculty of physical education and sport sience, 5th Kilometer Gazvin-tehran Road, Rasht

**City**

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**Province**

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**Postal code**

4199613776

**Phone**

+98 13 3375 3395

**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Mousavizadeh Vahidehsadat

**Position**

Msc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Province**

Guilan

**Postal code**

4199613776

**Phone**

+98 13 3375 3395

**Email**

v.s.mousavizadeh@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 variable data measured after unidentifiable  
individuals can be shared

**When the data will become available and for how long**

Starting in january 2020

**To whom data/document is available**

Only for researchers 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**