

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### An investigation of rhythm and body percussion effects on motor and social skills of 8-12 years old children with intellectual disability

#### Protocol summary

Change in motor skills (gross, fine, Upper limb coordination skills); Change in social skills.

#### Study aim

An investigation of rhythm and body percussion effects on motor and social skills of 8-12 years old children with intellectual disability

#### Design

A randomized clinical trial with a control group, parallel group

#### Settings and conduct

Two schools will be selected non randomly and then the Bruininks-Oseretsky test will be taken from the 60 students who have inclusion criteria and a letter of consent. The tests will be conducted by a blinded/trained evaluator and the Matson Evaluation of Social Skills with Youngsters-II will be completed by the teachers. The students will be randomly assigned to experimental and control groups. The control group will not receive any intervention. The experimental group will receive body percussion exercises for 3 mounts in a group format.

#### Participants/Inclusion and exclusion criteria

- Detection of mild intellectual disability by the measurement of Khorasan Razavi Exceptional Education department
- Being in the age group of 8-12 years
- No neurological disorders
- No psychiatric disorders such as ADHD and Autism
- No orthopedic disorders that cause problems on baby's movements.
- No vision and hearing impairment that disrupts understanding of orders.

#### Intervention groups

The experimental group will receive rhythmic body percussion exercises in a group format. The exercises include: clapping, hitting hands on the chest, hitting hands on the leg, hitting feet on the floor and hitting hand of the opponent. The exercises are researcher made, from simple to complex and based on team experience and resources review. They will be selected under the guidance of rhythmic instrument experts. The exercises will take place 3 months, 24 sessions and 2 days per week for 30 minutes per session. The control group will not receive any body percussion exercises.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190518043624N1**

Registration date: **2019-08-01, 1398/05/10**

Registration timing: **retrospective**

Last update: **2019-08-01, 1398/05/10**

Update count: **0**

##### Registration date

2019-08-01, 1398/05/10

##### Registrant information

##### Name

Salehe Lotfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7124

##### Email address

lotfi.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2019-02-20, 1397/12/01

**Trial completion date**

2019-05-22, 1398/03/01

**Scientific title**

An investigation of rhythm and body percussion effects on motor and social skills of 8-12 years old children with intellectual disability

**Public title**

The effect of rhythm and body percussion on motor and social skills of children with intellectual disability

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Detection of mild intellectual disability by the measurement of Khorasan Razavi Exceptional Education department Being in the age group of 8-12 years

**Exclusion criteria:**

Neurological disorders such as cerebral palsy, epilepsy and seizure (based on medical records or doctor's diagnosis) Psychiatric disorders such as ADHD and Autism Orthopedic disorders that cause problems on baby's movements. Vision and hearing impairment that disrupts understanding of orders.

**Age**

From **8 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **57**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At first, two schools will be selected non randomly, and 60 students will be chosen based on inclusion criteria and after taking satisfaction they will be assigned into the two groups of experimental and control by using simple randomization methods. Card or envelopes shuffling will be used for simple randomization.

**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**

Iran University of Medical Sciences

**Street address**

Crossroads of Shahid Hemmat and Shahid Chamran Expressways, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-03-06, 1397/12/15

**Ethics committee reference number**

IR.IUMS.REC.1397.1132

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

Mild mental retardation

**ICD-10 code**

F70

**ICD-10 code description**

Mild mental retardation

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

Change in motor skills (gross, fine and Upper limb coordination motor skills)

**Timepoint**

At the beginning of the study and 1 week after the end of the intervention

**Method of measurement**

1-The Bruininks-Oseretsky test of motor proficiency

**2****Description**

Change in social skills

**Timepoint**

At the beginning of the study and after the end of the intervention

**Method of measurement**

The Matson Evaluation of Social Skills with Youngsters-II (MESSY-II )

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

The experimental group will receive body percussion exercises in a group format. The percussion exercises include: clapping, hitting hands on the chest, hitting hands on the leg, hitting feet on the floor and hitting hand of the opponent. The exercises are researcher made type, from simple to complex and based on team experience and resources review. These exercises will be selected under the guidance of rhythmic instrument experts. The exercises will take place 3 months, 24 sessions and 2 days per week with the time of 30 minutes per session. At first, the exercises will be done individually in order to the candidate learn rhythmic percussion and then the number of participants in the group will be increased gradually.

### Category

Other

## 2

### Description

Control group: will receive school routine instruction without any body percussion exercises

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Department of exceptional Education Khorasan Razavi

#### Full name of responsible person

Mahin Tavakoli

#### Street address

Akhound Khorasani 20, Akhound Khorasani Ave, Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9133714165

#### Phone

+98 51 3225 4060

#### Email

salehe.lotfi@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Vice-chancellor for Research

#### Street address

Crossroads of Shahid Hemmat and Shahid Chamran Expressways, Tehran

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Tehran

#### Province

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1449614535

#### Phone

+98 21 7774 5945

#### Email

salehe.lotfi@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Iran 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

Iran University of Medical Sciences

#### Full name of responsible person

Salehe lotfi

#### Position

Master student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Occupational Therapy

#### Street address

Nezam Alley, Shah Nazari Ave., Mohseni Square, Tehran

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#### Province

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1545913487

#### Phone

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#### Email

salehe.lotfi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Salehe Lotfi  
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Master student  
**Latest degree**  
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**Other areas of specialty/work**  
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salehe.lotfi@gmail.com

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Salehe Lotfi  
**Position**  
Master student  
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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

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

### Data Dictionary

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

### Title and more details about the data/document

The data that related to primary outcome are available.

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

Starting 6 months after publication

### To whom data/document is available

This is only available for people working in academic institutions or people working in rehabilitation clinics.

### Under which criteria data/document could be used

No analyzes are allowed

### From where data/document is obtainable

salehe.lotfi@gmail.com

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

Email: salehe.lotfi@gmail.com I'm responding as soon as possible

### Comments