

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of stretching exercises with whole body vibration on range of motion of lower extremity in spastic cerebral palsy children 4 to14 years

#### Protocol summary

##### Summary

Objectives: whole body vibration is a new treatment in children with cerebral palsy that impact on spasticity and range of motion is still investigating. This project aim is examine the effectiveness of stretching exercises with vibration training on active and passive range of motion in the lower extremity joints in children with cerebral palsy. Design: This study is a randomized trial stage two or three. Participants: 12 children with spastic cerebral palsy 4 to 14 years. Intervention: The intervention will be done in the spring and summer 95. In the control group 6 children with cerebral palsy will receive stretching exercises three times a week for 6 weeks. In the intervention group in additional stretching exercise they will receive whole body vibration 9 minutes three times a week for 6 week. Before the intervention and after 6 weeks of treatment, primary and secondary assessment, including: the severity of spasticity, fine motor skills and gross motor skills and manual 6-minute walk test and active and passive lower extremity range of motion will be done. The main outcome variables: flexion and abduction of the hip, knee flexion, dorsiflexion and Plantar flexion in ankle, spasticity and 6-minute walking test

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040521686N2**

Registration date: **2016-06-11, 1395/03/22**

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

Last update:

Update count: **0**

##### Registration date

2016-06-11, 1395/03/22

#### Registrant information

##### Name

Zahra Ahmadizadeh

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4180

##### Email address

ahmadizadeh.z@semums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Semnan University of Medical Sciences

#### Expected recruitment start date

2016-04-20, 1395/02/01

#### Expected recruitment end date

2017-02-19, 1395/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effectiveness of stretching exercises with whole body vibration on range of motion of lower extremity in spastic cerebral palsy children 4 to14 years

#### Public title

Effectiveness of stretching exercises with whole body vibration on range of motion of lower extremity in spastic cerebral palsy children 4 to14 years

#### Purpose

Other

#### Inclusion/Exclusion criteria

Inclusion criteria: The medical diagnosis of cerebral palsy children; Having aged 4 to 14 years; The ability to walk without falling for 6 minutes with or without assistive device; The ability to execute commands 5. Being in the GMFCS 3, 2 and 1. Exclusion criteria being: Any severe or progressive disease with cerebral palsy; children with fixed musculoskeletal deformity in the lower extremity; lower extremity surgery in the last 6 months; children with untreated fractures and uncontrolled seizure; treatment by a botulinum toxin injection in the last three months; the limitations in range of motion in the knee more than 10 degrees

#### **Age**

From **4 years** old to **14 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **12**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **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**

Semnan University of Medical Sciences Ethics Committee

###### **Street address**

No.47, Semnan university of medical sciences, Basij Blvd, Semnan, Iran

###### **City**

Semnan

###### **Postal code**

##### **Approval date**

2016-05-08, 1395/02/19

##### **Ethics committee reference number**

ir.semums.rec.1395.6

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Children with cerebral palsy

##### **ICD-10 code**

G80.0, G80

##### **ICD-10 code description**

G80.0 Spastic quadriplegic cerebral palsy Spastic tetraplegic cerebral palsy G80.1 Spastic diplegic cerebral palsy Congenital spastic paralysis (cerebral) Spastic cerebral palsy . G80.2 Spastic hemiplegic cerebral palsy

### **Primary outcomes**

#### **1**

##### **Description**

Active and Passive range of motion

##### **Timepoint**

6 weeks

##### **Method of measurement**

Goniometer by degree

### **Secondary outcomes**

#### **1**

##### **Description**

Spasticity

##### **Timepoint**

6 Weeks

##### **Method of measurement**

Modified ashworth scale

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: stretching exercise for hamstring, iliopsoas, cuff and adductor muscles along with whole body vibration for three sets of three-minute with break every three minutes three times a week for 6 weeks

##### **Category**

Other

#### **2**

##### **Description**

Control group: stretching exercise for hamstring, iliopsoas, cuff and adductor muscles along with standing on off whole body vibration for three sets of three-minute with break every three minutes three times a week for 6 weeks

##### **Category**

Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

**Name of recruitment center**

Neruromuscular rehabilitation research center

**Full name of responsible person**

Zahra Ahmadizadeh

**Street address**

No.24, Neuromuscular Rehabilitation Research Center, Ghods Blvd, Mashahir square, Semnan, Iran

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Zahra Ahmadizadeh

**Position**

Master of sciences

**Other areas of specialty/work****Street address**

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Semnan University of Medical Sciences

**Full name of responsible person**

Dr Ali Rashidipour

**Street address**

No.47, Semnan university of medical sciences, Basij Blvd, Semnan, Iran

**City**

Semnan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Semnan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Zahra Ahmadizadeh

**Position**

Master of sciences / Faculty member

**Other areas of specialty/work****Street address**

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**Postal code****Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*