

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

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
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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

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Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty