Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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; T 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 uncontroled 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
Actice 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, Iliopesoas, 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, Iliopesoas, 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
City
Semnan

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
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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
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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