

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Whole-Body Vibration Therapy in Weight-Bearing and Non-Weight Bearing positions for Upper and Lower Extremities on Balance and Function in Cerebral Palsy children.

Protocol summary

Study aim

This study aims to compare the effects of Whole-Body Vibration therapy in Weight Bearing and Non-Weight Bearing positions for the Upper and Lower extremities in spastic Cerebral Palsy children.

Design

A double-blinded Randomized control trial with 6 groups. A total of 60 children will be recruited from a single center. The sample size was calculated using Gpower version 3.1.9.7. Random Allocation Software Version 1.0 (as per the description of Randomization).

Settings and conduct

It will be carried out at PAF School for Persons with Special Needs (PSNs) PAF Base Nur Khan Rawalpindi, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5-15 years; Both Genders; With Spastic hemiplegic cerebral palsy; Degree of Spasticity Grade 1, and 2 on Modified Ashworth Scale; Level I and II of GMF Classification System; Not taking any medication to manage spasticity; No unhealed fractures; No visual or auditory problem; Not taking botulinum toxin injections; Does not have any sensory and motor loss; Does not have recent surgery (1 year); MMSE score ≥ 18 .

Intervention groups

There will be a total of 6 groups. (WBVT = Whole-body Vibration Therapy) Group Aa = WBVT in Weight Bearing positions for Upper limbs only. Group Ab = WBVT in Weight Bearing position for Lower limbs only. Group Ac = WBVT in Weight Bearing position for both the Upper and Lower limbs simultaneously. Group Ba = WBVT in Non-Weight Bearing position for Upper limbs only. Group Bb = WBVT in Non-Weight Bearing position for Lower limbs only. Group Bc = WBVT in Non-Weight Bearing position for both the Upper and Lower limbs simultaneously.

Main outcome variables

Joint Range of Motion; Hand Grip Strength; Balance

Quantification using MFT 2.0 Disc; Cervical Joint Position Sense Error Test; Timed Up and Go Test; Jebsen Taylor Hand Function Test; Modified Ashworth Scale; Pediatric Balance Scale.

General information

Reason for update

Two words in the title were missing.

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N27**

Registration date: **2023-05-29, 1402/03/08**

Registration timing: **prospective**

Last update: **2023-06-02, 1402/03/12**

Update count: **1**

Registration date

2023-05-29, 1402/03/08

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

hadianrs@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-01, 1402/03/11

Expected recruitment end date

2023-10-15, 1402/07/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Whole-Body Vibration Therapy in Weight-Bearing and Non-Weight Bearing positions for Upper and Lower Extremities on Balance and Function in Cerebral Palsy children.

Public title

Effect of whole-body vibration in children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 5-15 years. Both Genders (Boys and Girls) With a diagnosis of spastic cerebral palsy. Degree of Spasticity Grade 1, 1+ and 2 according to Modified Ashworth Scale. Mild Severity of cerebral palsy Level I and II of Gross Motor Function Classification System

Exclusion criteria:

Children with fixed musculoskeletal deformities With a history of recent surgery (less than 1 year) Unhealed fractures Any case of epilepsy or visual or auditory problems Under treatment with botulinum toxin Non-Spastic cerebral palsy (Ataxic, Dyskinetic etc.) Children having Sensory loss in upper and lower extremity.

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Before the process of randomization, we will screen all the participants and assign them a unique number from 1 to 60. Then the process of randomization will be carried out using Random Allocation software version 1.0 (developed by the Department of Anaesthesia, Isfahan University of Medical Sciences, Isfahan, Iran). It is a randomization software for parallel group trials. It requires the total sample size and the total number of groups. We will add a total sample size of 60 participants and 6 groups into the software with only one block. The software generates an output file that can be opened with internet explorer. The output file contains a list of number along with assigned groups. In our case, the groups will be Aa, Ab, Ac, Ba, Bb, and Bc with 10 participants in each group. Then this sequence will be

used for participant allocation in the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The care provider will be blinded to the groups of the study (i.e. Treatment and Control Group). While the outcome assessors will be blinded to the treatment protocols and study hypothesis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences (TUMS)

Street address

School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.TUMS.FNM.REC.1402.024

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

Cerebral Palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

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

Modified Ashworth Scale

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

2

Description

Timed up and go test

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

One Chair, Measurement Tape and Stop Watch

3

Description

Pediatric Balance Scale

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

Pediatric Balance Scale Questionnaire

4

Description

MFT balance score

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

MFT Balance Disc 2.0

5

Description

Jebsen-Taylor Hand Function Test

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

Writing a short sentence (24 letters, 3rd grade reading difficulty)Turning over a 3x5-inch card,Picking up small common objects (coins, paper clips and metal bottle caps) and transferring them into a container,Simulated feeding (by collecting beans with a spoon and transferring them into a container),Stacking checkers,Picking up and transferring large light objects (empty cans)Picking up and transferring large heavy objects (cans with weight of 0.453 kg). The subtests are scored by recording the number of seconds required to complete each test.

6

Description

Hand Grip Strength

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing

position.

Method of measurement

Hand Held Digital Dynamometer

7

Description

Joint Range of motion

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

Universal Goniometer

8

Description

Cervical Joint Position Sense Error Test

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

Laser Tracker System

9

Description

Center of Pressure of Both Feet

Timepoint

Before and After the intervention for Upper Limb and lower limb in weight bearing and non weight bearing position.

Method of measurement

BWT-61 CL Digital Gyroscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1. The Whole-body vibration therapy in weight-bearing (WBV-WB) lower extremity group will receive the WBV training for 20 min a day, 3 days a week for a 4-week period. The children assigned to the WBV-WB group will be instructed to maintain a standing posture on a vibration platform. Children will stand barefooted with feet parallel and knees straight or in slight flexion (30°). The feet will be placed in an equal distance from the center line of the device when standing. During the 20 min of therapy, every 3 minute of vibration training and 2 minutes of rest will be repeated 4 times. The frequency of the WBV stimulation will be (12–18 Hz) and will achieved gradually increasing 1 Hz per 2 seconds, till the desired frequency is achieved.

Category

Rehabilitation

2

Description

Intervention group: 2. The Whole-body vibration therapy in weight-bearing (WBV-WB) upper extremity group will receive the same protocol like Lower Extremity, but in a kneeling quadruped position with the hands-on the platform.

Category

Rehabilitation

3

Description

Intervention group: 3. The Whole-body vibration therapy in weight-bearing (WBV-WB) combine upper and lower extremity group will receive same protocol like (Upper and Lower Extremity Protocol Mentioned above) in standing on one whole-body vibrator while leaning on the other whole-body vibrator with hands. A total of 2 Whole body vibration units will be used simultaneously.

Category

Rehabilitation

4

Description

Intervention group: 4. The Whole-body vibration therapy in non weight-bearing (WBV-NWB) lower extremity group will receive the WBV training for 20 min a day, 3 days a week for a 4-week period. The children assigned to the WBV-NWB group will be instructed to maintain seated posture on a chair. Children will place their feet on the whole-body vibrator. During the 20 min of therapy, every 3 minute of vibration training and 2 minutes of rest will be repeated 4 times. The frequency of the WBV stimulation will be (12–18 Hz) and will achieved gradually increasing 1 Hz per 2 seconds, till the desired frequency is achieved.

Category

Rehabilitation

5

Description

Intervention group: 5. The Whole-body vibration therapy in non weight-bearing (NWBV-WB) upper extremity group will receive the same protocol like Lower Extremity, but in seated position with the hands-on on the platform.

Category

Rehabilitation

6

Description

Intervention group: 6. The Whole-body vibration therapy in non weight-bearing (NWBV-WB) combine upper and lower extremity group will receive same protocol like (Upper and Lower Extremity Protocol Mentioned above) in seated position. One platform will be under the feet and the other will be under the hands. A total of 2 Whole body vibration units will be used simultaneously.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

PAF School for Persons with Special Needs (PSNs) PAF
Base Nur Khan

Full name of responsible person

Samina Ali

Street address

Rawal Road

City

Rawalpindi

Postal code

46000

Phone

+92 334 5882886

Email

saminaali2517@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer e Millat University

Full name of responsible person

Dr. Abdul Ghafoor Sajjad

Street address

Park Road

City

Islamabad

Postal code

46000

Phone

+92 333 5468034

Email

abdulghafoor.dpt@stmu.edu.pk

Web page address

<https://stmu.edu.pk/>

Grant name

Faculty Development Fund

Grant code / Reference number

HR # 534-2021

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

Yes

Title of funding source

Shifa Tameer e Millat University

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad-Reza Hadian Rasanani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Pich e Shemiran, Enghelab
Street Tehran Tehran Iran,

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 8891 3469

Fax

Email

hadianrasan@gmail.com

Web page address

Phone

+98 21 7753 6134

Fax

+98 21 7753 4133

Email

hadianrs@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Syed Ali Hussain

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

23

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 331 5191713

Email

shahjee102001@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Hadian

Position

Professor, Faculty of Rehabilitation, TUMS

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation faculty, pich e shemiran, enghlab street

City

Tehran

Province

Tehran

Postal code

1148965141

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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