Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Name of organization / entity

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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
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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

Modified Ashworth Scale Questionnaire

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 3×5-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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shifa Tameer e Millat University

Full name of responsible person
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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

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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