# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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**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**
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**Province**
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**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**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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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**

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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