Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the conjunct effects of Electrical Stimulation and Whole-Body Vibration Therapy with Transcranial Direct Current Stimulation and Whole-body Vibration Therapy on Balance and Function in Spastic Cerebral Palsy Children.

Protocol summary

Study aim

To compare the conjunct effects of Electrical Stimulation and Whole-body Vibration Therapy with Transcranial Direct Current Stimulation and whole-body vibration therapy on balance and function in children with spastic cerebral palsy

Design

A double-blinded Randomized control trial with 3 groups. A total of 42 children will be recruited from a single center. The sample size was calculated using Gpower version 3.1.9.7. RandomAllocation Software Version 1.0 (as per the description of Randomization).

Settings and conduct

It will be carried out at Dimension inxtitute of Special education and sehat medical complex lahore Pakistan

Participants/Inclusion and exclusion criteria

Inclusion Crtieria Age of 5- 15 years. Both Genders (Boys and Girls). Children diagnosed with Spastic Hemiplegic cerebral palsy. Degree of Spasticity Grade 1, 1+, and 2 according to Modified Ashworth Scale Level I and level II of Gross Motor Function Classification System. Manual Ability Classification System level I to IV. Eclusion criteria The child or the guardian is not interested to carry out the study. Failing to complete the study.

Intervention groups

There will be 3 main groups: Group A Whole Body Vibration only Group B Whole Body Vibration only and electrical stimulation Group C Whole Body Vibration and Transcranial Direct Current stimulation

Main outcome variables

Joint Range of motion, Hand Grip Strength, Isometric Muscle strength test by (digital force gauge)SF-500, Centre of Gravity, and Balance test scores through Nintendo Wii-Fit, Gait parameters (walking speed, cadence(stride length and step length) using cinematography (Kinovea version 0.9.5), Timed up and go test, Manual dexterity (9 hole-peg test), Modified Ashworth Scale, Berg Balance scale and GMFM-88(Standing and sitting component)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N29**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-15, 1402/03/25**
Update count: **0**

Registration date

2023-06-15, 1402/03/25

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

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

Comparison of the conjunct effects of Electrical Stimulation and Whole-Body Vibration Therapy with Transcranial Direct Current Stimulation and Whole-body Vibration Therapy on Balance and Function in Spastic Cerebral Palsy Children.

Public title

Effects of Electrical stimulation and Whole Body vibration therapy with transcranial direct current stimulation on spactic cerebral palsy children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 5- 15 years. Both Genders (Boys and Girls). Children diagnosed with Spastic Hemiplegic cerebral palsy. Degree of Spasticity Grade 1, 1+, and 2 according to Modified Ashworth Scale in the following muscles (hip flexors, hip adductors, hamstrings and ankle plantar flexors). Level I(Can walk indoors and outdoors and climb stairs without using hands for support, and II (ability to walk indoors and outdoors and climb stairs with a railing) of Gross Motor Function Classification System. Manual Ability Classification System level I to IV. No history of epilepsy. No unhealed fractures. No visual impairments and auditory impairments. Not taking botulinum toxin injections. Does not have any sensory and motor loss. Does not have cardiopulmonary problems. Does not have recent surgery (less than 1 year). Children who would not experience joint contractures Children with no Muscle or tendon inflammation Children with no Leg length discrepancy

Exclusion criteria:

The child or the guardian is not interested to carry out the study. Failing to complete the study.

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: **42**

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 42. 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 42 participants and 3 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 A, B, C with 14 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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Province

Tehran

Postal code

1417614411

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.TUMS.FNM.REC.1402.041

Health conditions studied

1

Description of health condition studied

Cerbral Palsy

ICD-10 code

Cerebral P

ICD-10 code description

G80

Primary outcomes

1

Description
Range of Motion
Timepoint
Before and After the intervention for Upper and lower extremity joints
Method of measurement
Universal Goniometer

2

Description
Hand Grip Strength
Timepoint
Before and After the intervention for Upper Limb
Method of measurement
Hand Held Digital Dynamometer

3

Description
Isometric Muscle strength test
Timepoint
Before and After the intervention for lower extremity muscles
Method of measurement
digital force gauge SF-500

4

Description
Centre of Gravity, and Balance test scores
Timepoint
Before and After the intervention for lower extremity
Method of measurement
Nintendo Wii-Fit, Balance board

5

Description
Gait parameters (walking speed, cadence(stride length and step length) using cinematography
Timepoint
Before and after the intervention for the lower extremity
Method of measurement
Kinovea software version 0.9.5

6

Description
Timed up and go test
Timepoint
Before and After the intervention
Method of measurement
One Chair, Measurement Tape and Stop Watch

7

Description
Manual dexterity
Timepoint
before and after the intervention for the upper extremity
Method of measurement
9 hole and peg board

8

Description
Modified Ashworth Scale
Timepoint
before and after intervention for upper and lower extremity
Method of measurement
Modified Ashworth Scale Questionnaire

9

Description
berg balance scale
Timepoint
before and after the intervention for spastic Cerebral palsy children
Method of measurement
Berg Balance scale questioner

10

Description
Gross motor function
Timepoint
before and after the intervention for spastic crebral palsy children
Method of measurement
GMFM-88 scale (Standing and sitting component)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 WBV training for 20 min a day,4 days a week for 4 weeks. The children will be instructed to maintain a standing posture on the vibration platform. Children will stand barefooted with feet parallel and in slight flexion (30°). The feet will be placed at an equal distance from the center line of the device when standing. During the 20 min of therapy, every 3 minutes 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 achieve gradually increase by 1 Hz per 2 seconds, till the desired frequency is achieved.
Category
Rehabilitation

2

Description
Intervention group 2 WBV training for 20 min a day,4

days a week for 4 weeks. The children will be instructed to maintain a standing posture on the vibration platform. Children will stand barefooted with feet parallel and in slight flexion (30°). The feet will be placed at an equal distance from the center line of the device when standing. During the 20 min of therapy, every 3 minutes 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 achieve gradually increase by 1 Hz per 2 seconds, till the desired frequency is achieved. Functional Electrical stimulation with Rectangular biphasic pulses with a pulse width of 250 µs, the stimulus intensity 70 mA, and a frequency ranged from 40 Hz,4 days a week for 4 weeks will be administered on motor points of the spastic muscles mainly for the lower extremity (quadriceps and gastrocnemius and soleus).

Category

Rehabilitation

3

Description

Intervention group 3 Transcranial Direct Current Stimulation (tDCS) will be given with 2mA intensity for 20 min a day,4 days sessions a week for 4 weeks. 5*7 cm square electrodes will be placed as Anodal tDCS, will be placed over the primary motor cortex and cathodal tDCS will be placed over the contralateral supraorbital region. It will receive the WBV training for 20 min a day,4 days a week for 4 weeks. The children will be instructed to maintain a standing posture on the vibration platform. Children will stand barefooted with feet parallel and in slight flexion (30°). The feet will be placed at an equal distance from the center line of the device when standing. During the 20 min of therapy, every 3 minutes 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 achieve gradually increase by 1 Hz per 2 seconds, till the desired frequency is achieved.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dimensions institute of Special education and psychological services

Full name of responsible person

Dr Samia Sarmad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Tehran University of Medical Sciences , Qods Corner Keshavarz Blvd

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

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

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Email
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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