Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Whole Body Vibration on Functional Performance and Balance of Chronic Stroke Patients

Protocol summary

Study aim
To determine the effect of Whole Body Vibration on functional performance and balance in chronic stroke patients.

Design
Single Blind, randomized controlled clinical trial

Settings and conduct
This randomized clinical trial was performed in the Department of Physical Therapy Lahore General Hospital Lahore. Outcome Assessor has been blinded and he was not aware of the allocated group of the participants.

Participants/Inclusion and exclusion criteria
Participants of both of the genders aging from 40 to 75 years having a single stroke more than six months ago.

Intervention groups
Routine Physiotherapy Group received Strengthening Exercises, Stretching Exercises, Gait Training and Balancing Exercises. WBV Group received routine physiotherapy treatment plus WBV session for 2 weeks. During the intervention, subjects were positioned on the platform in a standing position and both knees extended[0 degrees as the anatomic position] to keep an upright position with even weight distribution on both feet. The time course included 5 bouts of 2 minutes of vibration with a 1-minute rest interval between every two steps making the total time duration of 15 minutes with a frequency of 20-30Hz and a vibration amplitude of 3-6mm for 6 days per week for 2 weeks. The vertical type of vibratory stimulus was used.

Main outcome variables
The primary outcomes of the study were the improvement in Stair Negotiation Time and Obstacle Clearance measurements. [Obstacle height that patient can clear without tripping] Secondary outcome measures were the improvement in Self-Selected Walking Speed, Balance Score according to BBS, Muscle Tone according to Modified Ashworth Scale Score, Timed Up and Go Test Score and Timed 10-Meter Walk Test Score.

General information

Reason for update

Acronym
WBVT

IRCT registration information
IRCT registration number: **IRCT20190328043131N1**
Registration date: **2019-08-03, 1398/05/12**
Registration timing: **retrospective**

Last update: **2019-08-03, 1398/05/12**
Update count: **0**

Registration date
2019-08-03, 1398/05/12

Registrant information

Name
Ijaz Ahmed

Name of organization / entity
The University of Lahore

Country
Pakistan

Phone
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Email address
burq802@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-01, 1396/08/10

Expected recruitment end date
2019-04-30, 1398/02/10

Actual recruitment start date
2017-11-01, 1396/08/10

Actual recruitment end date
2019-04-01, 1398/01/12

Trial completion date
2019-04-13, 1398/01/24

Scientific title
Effect of Whole Body Vibration on Functional Performance and Balance of Chronic Stroke Patients

Public title
Effect of Whole Body Vibration in Treatment of Stroke Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Gender of participants should be male or female. Age of the participants should lie between 40 to 75 years. Participants should have their first ever stroke more than 6 months ago. Participants should be medically stable. Participants should have the ability to stand independently with or without aids for at least 20 minutes. Participants should be able to perform the experimental treatment independently.

Exclusion criteria:
Participants having acute thrombotic diseases, severe cardiovascular diseases or a pacemaker. Participants having an acute hernia or diabetes. Participants having brain tumors, Parkinson's disease, multiple sclerosis, epilepsy, peripheral neuropathy or migraine. Participants having rheumatoid arthritis, arthrosis, osteoarthritis, diskopathy or spondylosis.

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants were divided into two groups by random computer number generator method using the sequence generated list and the allocation was kept concealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor was a third person in our study who remained blind about the allocation of the groups. The participants who met the inclusion criteria were sent to the outcome assessor who took the initial assessment. Participants received treatment and post-interventional assessment was again carried out by the outcome assessor. The outcome assessor was aware of the patient id only while the participants, principle investigator, care providers, data collectors, and the data safety and monitoring board were aware of the allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional Review Board, University of Lahore

Street address
Raiwind Road, Sultan Town,

City
Lahore

Postal code
53720

Approval date
2017-06-13, 1396/03/23

Ethics committee reference number
IRB-UOL-FAHS/00259A

Health conditions studied

1

Description of health condition studied
Patients suffering from Stroke who feel difficulty in performing activities of daily living, especially walking and obstacle clearance capacity due to spasticity in muscle groups of lower extremities.

ICD-10 code
G81.9

ICD-10 code description
Hemiplegia, unspecified

Primary outcomes

1

Description
Stair Negotiation time

Timepoint
Before Intervention and 2 weeks after intervention

Method of measurement
Stairs Negotiation Time will be measured using a stopwatch as it is time taken to climb up and down three standard stair steps.

2

Description
Obstacle Clearance measurements [Obstacle height that patient can clear without tripping]

Timepoint
Before Intervention and 2 weeks after intervention

Method of measurement
Obstacle Clearance will be measured using 8 obstacles of different height and depth.

Secondary outcomes

1

Description
Berg Balance Scale
Timepoint
Before intervention and 2 weeks after intervention.
Method of measurement
Berg Balance Scale constitutes 14 different activities. Each item is scored along a 5-point scale, ranging from 0 to 4, each grade with well-established criteria. Zero indicates the lowest level of function and 4 the highest level of function. The total score ranges from 0 to 56.

2

Description
Modified Ashworth Scale
Timepoint
Before intervention and 2 weeks after intervention.
Method of measurement
The Modified Ashworth scale measures resistance during passive soft-tissue stretching by scoring according to change in muscle tone ranging from 0 to 4. 0 for no increase in muscle tone, 1 for slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension, 1+ for slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the range of motion, 2 for more marked increase in muscle tone through most of the range of motion, but affected part(s) easily moved, 3 for considerable increase in muscle tone, passive movement difficult and 4 for affected part(s) rigid in flexion or extension.

3

Description
Timed Up and Go Test
Timepoint
Before intervention and 2 weeks after intervention.
Method of measurement
The patient starts in a seated position. The patient stands up upon therapist’s command, walks 3 meters, turns around, walks back to the chair and sits down. The time stops when the patient is seated. The subject is allowed to use an assistive device.

4

Description
10-Meter Walk Test
Timepoint
Before intervention and 2 weeks after intervention.
Method of measurement
Individual walks 10 meters without assistance and the time is measured for the intermediate 6 meters to allow for acceleration and deceleration. Start timing when the toes of the leading foot crosses the 2-meter mark and stop timing when the toes of the leading foot crosses the 8-meter mark. Assistive devices can be used but should be kept consistent. It is performed at preferred walking speed and the fastest speed possible. Collect three trials and calculate the average of the three trials.

Intervention groups

1

Description
Intervention group: WBV Group received routine physiotherapy treatment plus WBV session for 2 weeks. During the intervention, subjects were positioned on the platform in a standing position with both knees extended[0 degree as the anatomic position] to keep an upright position with even weight distribution on both feet. The time course included 5 bouts of 2 minutes of vibration with a 1-minute rest interval between every two steps making the total time duration of 15 minutes with a frequency of 20-30 Hz and a vibration amplitude of 3-6 mm for 6 days per week for 2 weeks. The vertical type of vibratory stimulus was used. In front of the subject was a wall bar that could be grabbed if he/she had to fall.
Category
Rehabilitation

2

Description
Control group: Routine Physiotherapy Group received Strengthening Exercises, Stretching Exercises, Gait Training and Balancing Exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Lahore General Hospital
Full name of responsible person
Dr. Umoal Bunin
Street address
Ferozpur Road, Near، Ismail Nagar
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Postal code
54000
Phone
+92 42 99264092
Email
lahoreghospital@gmail.com
Web page address
https://lgh.punjab.gov.pk/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Lahore
Full name of responsible person
Dr. M. H. Qazi
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1-km Defense Road, Near Bhuptian Chowk
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53720
Phone
+92 42 35322501
Email
info@uol.edu.pk
Grant name
N/A
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Lahore
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
University of Lahore
Full name of responsible person
Syed Ijaz Ahmed Burq
Position
Physiotherapist
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Effect Of Whole Body Vibration on Functional Performance and Balance of Chronic Stroke Patients

When the data will become available and for how long

Data will be available when my Ph.D. study will complete.

To whom data/document is available

For academic institutions only.

Under which criteria data/document could be used

People who will request for data.

From where data/document is obtainable

Through Email which is as follows: burq802@yahoo.com

What processes are involved for a request to access data/document

Send a request through email to assess data which would be provided within a month.

Comments