

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

+92 42 99268801

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

City

Lahore

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

Street address
1-km Defense Road, Near Bhuptian Chowk

City
Lahore

Postal code
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

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
Defense Road, Near Bhuptian Chowk,

City
Lahore

Province
Punjab

Postal code
53720

Phone
+92 42 35322501

Email
burq802@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Lahore

Full name of responsible person
Syed Ijaz Ahmed Burq

Position
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Postal code
53720

Phone
+92 42 35322501

Email
burq802@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Lahore

Full name of responsible person
Syed Ijaz Ahmed Burq

Position
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burq802@yahoo.com

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