

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### EFFECTS OF PLANTER VIBRATION ON BALANCE AND POSTURAL INSTABILITY IN CHRONIC STROKE PATIENTS

#### Protocol summary

##### Study aim

To determine the effect of Planter Vibration on balance and postural instability in chronic stroke patients.

##### Design

Single Blind, randomized controlled clinical trial

##### Settings and conduct

This randomized clinical trial will be conducted in Department of Physical Therapy and Rehabilitation, Pakistan Railway Hospital, Rawalpindi.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of the participants between 40 to 70 years. Participants who have stroke  $\geq$  6 months ago. Participants who are medically stable. Able to walk without use of walking aids Able to understand verbal commands. Rankin Modified Scale 4 score Exclusion criteria Participation in other treatment protocols for balance Presence of other neurological or musculoskeletal conditions affecting balance History of fracture or lower-limb surgery within the 12 months Patients having vestibular, visual or auditory disorders Abnormal synergies, fixed ankle contractures Uncontrolled diabetes or hypertension Use of medication that may affect balance Unwillingness for participation in the study

##### Intervention groups

Control Group: Will receive Strengthening Exercises, Stretching Exercises, Gait Training and Balancing Exercises. Treatment group: Will receive routine physiotherapy treatment plus receive planter vibration for 5 minutes with frequency of 20-40Hz on alternative days 3 times per week for 6 weeks. A planter vibratory device (OTO electro reflexologist ER 839S) will be used to give vibration, during the intervention subjects will be positioned in sitting position, ask to sit on chair with leg flexed and put the most affect foot on vibratory device.

##### Main outcome variables

The primary outcomes of the study of the study will be berg balance scale Secondary outcome measures of the study will be stroke quality of life scale and modified

postural assessment scale for stroke patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210830052336N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

##### Registration date

2021-09-06, 1400/06/15

##### Registrant information

##### Name

Yaser Majeed

##### Name of organization / entity

Riphah International University, Islamabad, Pakistan

##### Country

Pakistan

##### Phone

+92 51 5578434

##### Email address

yasirmajeed216@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-02, 1400/03/12

##### Expected recruitment end date

2021-09-20, 1400/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

EFFECTS OF PLANTER VIBRATION ON BALANCE AND POSTURAL INSTABILITY IN CHRONIC STROKE PATIENTS

## Public title

Single Blind, randomized controlled clinical trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of the participants between 40 to 70 years  
Participants who have their first ever stroke  $\geq$  6 months ago  
Participants who are medically stable  
Able to walk without use of walking aids  
Rankin Modified Scale 4 score  
Able to understand verbal commands.

### Exclusion criteria:

Participation in other treatment protocols for balance  
Presence of other neurological or musculoskeletal conditions affecting balance  
History of fracture or lower-limb surgery within the 12 months  
Patients having vestibular, visual or auditory disorders  
Abnormal synergies, fixed ankle contractures  
Uncontrolled diabetes or hypertension  
Use of medication that may affect balance  
Unwillingness for participation in the study

## Age

From **40 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The subjects will be randomly divided into 2 groups (control group A and experimental group B) by coin toss method using convenient sampling technique and informed consent will be taken from each patient who willing to participate in the study.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

participant will be blinded

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research ethical Committee, Riphah College of Rehabilitation Sciences Islamabad

##### Street address

Riphah International University Islamabad City Campus 7th Avenue, Sector G-7/4, Islamabad

##### City

Islamabad

##### Postal code

47311

#### Approval date

2021-05-11, 1400/02/21

#### Ethics committee reference number

RIPHAH/RCRS/REC/letter-00392

## Health conditions studied

### 1

#### Description of health condition studied

Patients suffering from Stroke who feel difficulty in performing activities of daily living.

#### ICD-10 code

G46.4

#### ICD-10 code description

Cerebellar stroke syndrome

## Primary outcomes

### 1

#### Description

Berg Balance Scale

#### Timepoint

Before intervention and after six weeks of 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.

## Secondary outcomes

### 1

#### Description

The Modified of the Postural Assessment Scale for Stroke Patients (PASS)

#### Timepoint

Before intervention and weeks after intervention.

#### Method of measurement

It consists of a 4-point scale where the items are scored from 0 to 3, and the total scoring ranges from 0 to 36

## 2

### **Description**

Stroke Specific Quality of Life Scale (SS-QOL)

### **Timepoint**

Before intervention and weeks after intervention

### **Method of measurement**

The Stroke Specific Quality of Life scale (SS-QOL) is a patient-centered outcome measure intended to provide an assessment of health-related quality of life (HRQOL) specific to patients with stroke. Scoring: each item shall be scored with the following key Total help - Couldn't do it at all - Strongly agree (1), A lot of help - A lot of trouble - Moderately agree (2), Some help - Some trouble - Neither agree nor disagree (3), A little help - A little trouble - Moderately disagree (4) No help needed - No trouble at all - Strongly disagree (5)

## **Intervention groups**

### 1

#### **Description**

Control group:

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group:

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Pakistan Railway Hospital ,Rawalpindi, Pakistan.

##### **Full name of responsible person**

Mirza Obaid Baig

##### **Street address**

Railway Carriage Factory Rd, Railway Scheme 7

##### **City**

Rawalpindi

##### **Postal code**

46000

##### **Phone**

+92 51 4509595

##### **Email**

yasirmajeed216@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Riphah international university

##### **Full name of responsible person**

Yaser Majeed

##### **Street address**

Railway Carriage Factory Rd, Railway Scheme 7

##### **City**

Islamabad

##### **Postal code**

46000

##### **Phone**

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##### **Email**

yasirmajeed216@gmail.com

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Riphah international university

##### **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**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Riphah International University

##### **Full name of responsible person**

Yaser Majeed

##### **Position**

Lecturer

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Rehabilitation management

##### **Street address**

Railway Carriage Factory Rd, Railway Scheme 7

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

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## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

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Lecturer

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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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

IPD collected for the primary outcome measure only

**When the data will become available and for how long**

After the publication of the study.

**To whom data/document is available**

academic institutions and researchers

**Under which criteria data/document could be used**

On informed request from the investigators

**From where data/document is obtainable**

by email

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

on email request, data will be provided .

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Riphah international university

**Full name of responsible person**

Yaser Majeed

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

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**Province**