

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

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+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

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46000

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+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

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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

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

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Person responsible for scientific inquiries

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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**

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Full name of responsible person

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