Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

EFFECTS OF PLANTER VIBRATION ON BALANCE AND POSTURAL INSTABLITY 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 ≥ 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 INSTABLITY 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 ≥ 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
+92 51 4509595
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
Islamabad
Province
Punjab
Postal code
46000
Phone
+92 51 4509595
Email
yasirmajeed216@gmail.com

Person responsible for scientific 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
Islamabad
Province
Punjab
Postal code
46000
Phone
+92 51 4509595
Email
yasirmajeed216@gmail.com

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
Railway Carriage Factory Rd, Railway Scheme 7
City
Islamabad
Province
Punjab
Postal code
46000
Phone
+92 51 4509595
Email
yasirmajeed216@gmail.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
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