

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Planter Vibrator versus Transcutaneous Electric Nerve Stimulation (TENS) on Balance Dysfunction in Patient with Stroke

Protocol summary

Study aim

To compare the effect of planter vibrator versus Transcutaneous Electrical Nerve Stimulation on life independence.

Design

Two arms Parallel group randomized trial

Settings and conduct

The study setting was the District medical and Rehabilitation complex charsadda and Shifa Rehab and Research Center Peshawar. It was the single-blinded and Only the researcher doing the study knows which treatment or intervention the participant is receiving.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diagnosed stroke; Stroke patients having issues of balance dysfunction who stands for at least 20 seconds independently; Patient score minimum from 2 on Ashworth scale. Exclusion criteria: Patient under the influence of any sedatives; Any other pathological conditions; Malignancy; Multiple sclerosis; Vestibular dysfunction; Suffering from severe visual problem

Intervention groups

Intervention group received plantar vibration for 10 min 3 sessions per week for 4 weeks along with the conventional therapy. In the Planter vibration protocol, the patient was either in a standing or sitting position with 90 degrees flexed knee and support with belts and a frame to avoid the risk of fall. The Control group received the same conventional physical therapy was given as for treatment group. Patients were also received electrical stimulation via TENS. TENS sessions were applied to the tibial nerve branch of the sciatic nerve of the affected limb on the plantar surface of the foot each one was lasting for 10 minutes with 110 Hz frequency 3 times a day. The patient has received 3 sessions per week for 4 weeks.

Main outcome variables

Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210615051585N4**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **retrospective**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Saima Gul

Name of organization / entity

Shifa Tameer - e - Millat University

Country

Pakistan

Phone

+92 51 8441751

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-10, 1400/01/21

Expected recruitment end date

2021-07-29, 1400/05/07

Actual recruitment start date

2021-04-11, 1400/01/22

Actual recruitment end date

2021-08-02, 1400/05/11

Trial completion date

2021-09-02, 1400/06/11

Scientific title

Effects of Planter Vibrator versus Transcutaneous Electric Nerve Stimulation (TENS) on Balance Dysfunction in Patient with Stroke

Public title

Effects of Balance Training in Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diagnosed stroke Stroke Patients having issues of balance dysfunction who Stands for at least 20 seconds independently Patient score minimum from 2 on Ashworth scale.

Exclusion criteria:

Patient under the influence of any sedatives Any other pathological conditions Malignancy Multiple sclerosis Vestibular dysfunction Suffering from severe visual problem

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **52**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment was used for treatment using a sealed envelope. For that, 52 sheets of aluminum paper are properly cut. This paper should be double the size of the paper. 26 Sheets of Carbon paper cut into appropriate size according to the paper used. A standard-sized square paper was taken in which group "(Planter vibrator)" was marked. In this way, 26 papers were prepared marked with "(Planter vibrator)" and 26 square-shaped papers marked with "(TENS)". The sheet of paper on which either (Planter vibrator) or (TENS) was marked was folded to fit the envelope. A sheet of Carbon paper was placed on the top of the folded paper (marked either (Planter vibrator) or (TENS)) facing the envelope. Then the sheet of Aluminum foil was wrapped on the carbon paper (with folded paper inside). All the above prepared were placed in the envelope (which was completely opaque), the envelope was then sealed. In this way 26 envelopes of "(Planter vibrator)" and 26 envelopes of "(TENS)" were prepared with a total number of 52 envelopes. These 52 envelopes were then thoroughly shuffled like a deck of cards. The envelopes were then marked with numbers 1-52. Each participant picked the envelope in order from 1-52 and was given an intervention (Planter vibrator or TENS) accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the researcher doing the study knows which treatment or intervention the participant is receiving. It makes results less likely to be biased. For that, they received an additional device that is not connected and they feel they are receiving treatment apart from their actual treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board and Ethics Committee (IRB and EC) Shifa International Hospital.

Street address

Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University

City

Islamabad

Postal code

25000

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IRB#096-21

Health conditions studied**1****Description of health condition studied**

stroke patients with balance dysfunction

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Balance

Timepoint

At Baseline and after intervention

Method of measurement

Berg balance scale

Secondary outcomes

1

Description

Functional Independence

Timepoint

4th Week

Method of measurement

Functional Independent Measure

Intervention groups

1

Description

Planter Vibrator Group: Treatment for 10min 3 sessions per week for 4 weeks along with the conventional therapy was used to avoid spasticity and increase muscular strength. In Planter vibration protocol, patient was either in a standing or sitting position with 90 degrees flexed knee and support with belts and frame to avoid the risk of fall.

Category

Rehabilitation

2

Description

Transcutaneous Electric Nerve Stimulation Group: The same conventional physical therapy was given as for planter vibrator group. Patients was also received electrical stimulation via TENS. TENS sessions were applied to the tibial nerve branch of the sciatic nerve of the affected limb on the plantar surface of the foot each one was lasting for 10 minutes with 110Hz frequency 3 times in a day. Patient were received 3 sessions per week for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The OPD patients of District medical and Rehabilitation complex charsadda and Shifa Rehabilitation

Full name of responsible person

Muhammad Suleman Sikandar

Street address

Debgaree garden near Khyber medical center peshawar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer e Millat University

Full name of responsible person

Dr. Saima Gul

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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

Shifa Tameer e Millat 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shifa Tameer e Millat University

Full name of responsible person

Dr. Saima Gul

Position

Assosiate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to Ethical Considerations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available