Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 envelops of "(Planter vibrator)" and 26 envelops 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
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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
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Position
Assosiate Professor
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Person responsible for updating data

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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