Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effects of Whole-body vibration and PNF techniques on pain,sensorimotor function and balance in diabetic peripheral neuropathy

Protocol summary

Study aim

The aim of the study is to compare the effects of Whole-body vibration and PNF(proprioceptive neuromuscular facilitation) techniques on pain, sensorimotor functions and balance in diabetic peripheral neuropathy

Design

Two arm parallel group randomised trial with single blinded trial with 36 participants with diabetic pheripheral neuropathy,group A recieve Whole-body vibration and grouo B recieve PNF(proprioceptive neuromuscular facilitation) technique after pre and post outcome assessment , enrolled between july 2024 to december 2024.

Settings and conduct

This study was conducted at Al-Shifa clinic Ahmed pur east from july 2024 to December 2024'.

Participants/Inclusion and exclusion criteria

Inclusion criteria: HbA1c level should be >154ml/dL, Age beteeen 45 to 60, both male and femle participants, presence of sensorimoter dysfunction like pain and numbness,persisted pain for 4-6 weeks,Exclusion criteria: diabetic ulcers, high surgical risks,participants with cardiac conditions, neuropathic symptoms other than included in the study.

Intervention groups

Group A recieves Whole-body vibration technique by standing on a vibratory platform to get vibrational stimulation. Group B recieves PNF(proprioceptive neuromuscular facilitation) techniques where the participants' limbs are moved through diagonal patterns to achieve the desired gaol. this intervention is designed for three times a week for eight weeks

Main outcome variables

primary outcome variable: pain intensity measure with Numeric pain rating scale, secondary outcome variable: sensorimotor functions measured using the Leeds Assessment of neuropathic Symptoms and Signs (LANSS) scale balance measured with Berg Balance scale (BBS)

General information

Reason for update

Acronym

PNF(proprioceptive neuromuscular facilitation)

IRCT registration information

IRCT registration number: **IRCT20250103064262N1**
Registration date: **2025-01-30, 1403/11/11**
Registration timing: **retrospective**

Last update: **2025-01-30, 1403/11/11**
Update count: **0**

Registration date

2025-01-30, 1403/11/11

Registrant information

Name

Mehjabeen Ali

Name of organization / entity

Riphah international university

Country

Pakistan

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+92 300 0720887

Email address

talhaalibaig786@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-01, 1403/04/11

Expected recruitment end date

2024-12-01, 1403/09/11

Actual recruitment start date

2024-07-01, 1403/04/11

Actual recruitment end date

2024-11-15, 1403/08/25

Trial completion date

2024-11-24, 1403/09/04

Scientific title
Comparative effects of Whole-body vibration and PNF techniques on pain,sensorimotor function and balance in diabetic peripheral neuropathy

Public title
Comparison of effects of whole body vibration and PNF techniques on pain, sensorimotor function and balance in diabetic peripheral neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
HbA1c level should be >154ml/dL Both genders Age between 45 to 60 years Presence of sensorimotor dysfunction including pain and numbness <45 score of berg balance score Patient should be able to comprehend and fulfill the command Pain persisting fom 4 to 6 weeks Non-pregnant adults

Exclusion criteria:
Patients with cardiac conditon Depression that needs treatment High surgical risks Diabetic ulcers Neuropathic pain other than included in the study

Age
From **45 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **44**
More than 1 sample in each individual
Number of samples in each individual: **22**
Hba1c is required
Actual sample size reached: **36**
More than 1 sample in each individual
Actual sample size in each individual: **18**
HbA1c test is required before further assessment

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be a randomized clinical trial. A total of 36 patients will be recruited according to the inclusion and exclusion criteria according to convenience sampling into two intervention groups. Patients will be divided into Group A(n=18) and Group B(n=18). Group A will recieve Whole-body vibration therapy and Group B will recieve PNF techniques with conventional treatment. All participants will receive interventions for 35-40 mintues per session, three times a week for eight weeks. For pre and post evaluation of all participants Berg Balance Scale, LANSS scale and Numeric pain rating scale will be used. Data will analysed by using SPSS (statistical package for social sciences) 23 version.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study employes a single-blinded design, where participants are unaware of their treatment allocation. Participants are randomly assigned to either the Whole-body vibration group or the proprioceptive neuromuscular facilitation PNF technique group. The researcher knows which treatment each participant receives but will use standardized tools to assess outcomes and minimize bias. This design helps ensure the study results are reliable and accurate.

Placebo
Not used

Assignment
Parallel

Other design features
Neuropathic pain, sensorimotor functions, balance , diabetic neuropathy

Secondary Ids

1

Registry name
Comparative effects of Whole-body vibration and PNF techniques on pain,sensorimotor fucntions and balance in diabetic peripheral neuropathy

Secondary trial Id
81143

Registration date
2025-01-05, 1403/10/16

Ethics committees

1

Ethics committee

Name of ethics committee
Reseach Ethics Committee (REC)

Street address
25 Raza Saeed RD, bhabra Block M Gulberg 3, Lahore

City
Lahore

Postal code
54660

Approval date
2024-04-24, 1403/02/05

Ethics committee reference number
REC/RCR&AHS/24/0224

Health conditions studied

1

Description of health condition studied
Diabetes Mellitus is a serious health disease that causes a person's blood sugar level to be high. It happens when your body cannot make enough insulin or does not respond to the insulin in the body. The most common and serious complication of diabetes mellitus is diabetic peripheral neuropathy in whic the nerves in the peripheries get damaged and produce symptoms like pain, numbness, tingling and burning sensations.The prevalance of diabetic neuropathy is between 6% to 51% in older adults depending on age, duration and sugar

level control.

ICD-10 code
E08.42

ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic polyneuropathy

Primary outcomes

1

Description
Pain reduction

Timepoint
Before intervention and 2,4 and 8th week and after intervention

Method of measurement
Numeric pain rating scale

Secondary outcomes

1

Description
Balance improvement

Timepoint
2, 4 and 6 week

Method of measurement
Berg balance score

Intervention groups

1

Description
Intervention group: the intervention group is divided into two groups. Group A will receive whole-body vibration technique in which we will use a whole-body vibration machine. the participants will stand on the vibrating platform to receive vibrational stimulation

Category
Rehabilitation

2

Description
Intervention group: the Group B will receive PNF technique in which Diagonal patterns will be used where the therapist will move the participants' limbs through diagonal patterns helping to improve proprioception and neuromuscular control

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Shifa clinic Ahmed pur east

Full name of responsible person
Dr Muhammad Abbas

Street address
Al-Shifa Clinic near THQ Ahmed Pur East

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Ahmedpur East

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https://www.google.com/url?sa=i&url=https%3A%2F%2Fphonenumber.pk%2Fal-shifa-clinic-ahmedpur-east-contact%2F&psig=AOvVaw3PDKG4oHZQ0ThP8VWqSdEu&ust=1736183670685000&source=images&cd=vfe&opi=89978449&ved=0CAQQn5wMahcKEwi4946tit-KAxUAAAAAHQAAAAAQBA

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Riphah International university

Full name of responsible person
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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
Dr Sana Riaz

Position
Professor

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Position
Supervisor

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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
Comparative effects of whole-body vibration and PNF techniques on pain,sensorimotor function and balance in diabetic peripheral neuropathy

When the data will become available and for how long
The data will become available from May 2025 to May 2026

To whom data/document is available
The data will be availabe to the researchers and analysts for legitimate research purposes

Under which criteria data/document could be used
The deidentifed IPD set can be used for research purposes, academic purpose(e.g thesis, assigments),presentation at scientific conferences

From where data/document is obtainable
talhaalibaig786@gmail.com

What processes are involved for a request to access data/document
Contact the authorised person

Comments