

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 peripheral neuropathy, group A receive Whole-body vibration and group B receive 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 between 45 to 60, both male and female participants, presence of sensorimotor 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 receives Whole-body vibration technique by standing on a vibratory platform to get vibrational stimulation. Group B receives PNF(proprioceptive neuromuscular facilitation) techniques where the participants' limbs are moved through diagonal patterns to achieve the desired goal. 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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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 from 4 to 6 weeks Non-pregnant adults

Exclusion criteria:

Patients with cardiac condition 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 receive Whole-body vibration therapy and Group B will receive PNF techniques with conventional treatment. All participants will receive interventions for 35-40 minutes 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 be analysed by using SPSS (statistical package for social sciences) 23 version.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study employs 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 functions 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**

Research 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 which the nerves in the peripheries get damaged and produce symptoms like pain, numbness, tingling and burning sensations. The prevalence 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

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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

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Position

Supervisor

Latest degree

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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 available to the researchers and analysts for legitimate research purposes

Under which criteria data/document could be used

The deidentified IPD set can be used for research purposes, academic purpose (e.g. thesis, assignments), 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