

# 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 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

##### Phone

+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 for 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

**Street address**

Al-Shifa Clinic near THQ Ahmed Pur East

**City**

Ahmedpur East

**Postal code**

63350

**Phone**

+92 301 8611448

**Email**

Al.shifaclinicape@gmail.com

**Web page address**

<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=ve&opi=89978449&ved=0CAQQn5wMahcKEwi4946tit-KAxUAAAAAHQAAAAQBA>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Riphah International university

**Full name of responsible person**

Dr Binish Afzal

**Street address**

25 Raza Street Rd Gulberg 3 Lahore

**City**

Lahore

**Postal code**

54660

**Phone**

+92 343 4539092

**Email**

binish.afzal@riphah.edu.pk

**Web page address**

<https://riphah.edu.pk/home-lahore/>

**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

**Street address**

25 Raza Saeed Rd block M Gulberg 3 lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54660

**Phone**

+92 347 4716107

**Email**

sana.rcrs@riphah.edu.pk

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Riphah international university

**Full name of responsible person**

Dr Sana Riaz

**Position**

Supervisor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

25 Raza Street Rd Block M Gulberg 3 lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54660

**Phone**

+92 347 4716107

**Email**

sana.rcrs@riphah.edu.pk

## Person responsible for updating data

### Contact

**Name of organization / entity**

Riphah international university

**Full name of responsible person**

Mehjabeen Ali

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

25 Raza St Rd Block M Gulberg 3 lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54660

**Phone**

+92 316 0638841

**Email**

talhaalibaig@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**

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**