

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Combined Resistance Training With or Without Aerobic Training on Sensation, Balance and Proprioception among Diabetic Polyneuropathy Patients

Protocol summary

Study aim

Comparative effects of resistance training with or without aerobic training on sensation, balance, and proprioception in individuals with diabetic polyneuropathy

Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

Settings and conduct

Mayo Hospital, Services Hospital, Jamil Health Care Centre, and Physiofam clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria were as follows: Diabetic peripheral neuropathy was assessed using the Michigan Neuropathy Screening Instruments, the age range was 45-65 years, and Participants were capable of performing both resistance and aerobic exercises. Eligible subjects went under a physical examination and medical screening to exclude individuals with a History of amputation or sole injury and severe retinopathy. Undergoing dialysis or having neuropathy, Upper body neuropathy or arthritis that could hinder exercise participation, failure to attend exercise for more than 3 sessions, and subjects with musculoskeletal, neuromuscular, nervous, and peripheral vascular disorders such as myasthenia gravis, Parkinsonism, Alzheimer's, multiple sclerosis, and benign paroxysmal positional vertigo.

Intervention groups

The control group received a protocol of Resistance Training only, and the Experimental group received a protocol of Resistance Training combined with Aerobic Training

Main outcome variables

Sensation, Balance and Proprioception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230725058920N1**

Registration date: **2025-04-26, 1404/02/06**

Registration timing: **retrospective**

Last update: **2025-04-26, 1404/02/06**

Update count: **0**

Registration date

2025-04-26, 1404/02/06

Registrant information

Name

Aiza Yousaf

Name of organization / entity

University of South Asia

Country

Pakistan

Phone

+92 322 8018986

Email address

aiza.yousaf@usa.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-10, 1402/11/21

Expected recruitment end date

2024-07-10, 1403/04/20

Actual recruitment start date

2024-02-10, 1402/11/21

Actual recruitment end date

2024-07-10, 1403/04/20

Trial completion date

2024-08-15, 1403/05/25

Scientific title

Effects of Combined Resistance Training With or Without Aerobic Training on Sensation, Balance and Proprioception among Diabetic Polyneuropathy Patients

Public title

Resistance Training With or Without Aerobic Training in Diabetic Polyneuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic peripheral neuropathy assessed using the Michigan Neuropathy Screening Instrument 10-Point Test. (In part A, a maximum 13 points out of 15, and in part B, 8 points out of 10). Capable of performing both resistance and aerobic exercises

Exclusion criteria:

History of amputation or sole injury and severe retinopathy Undergoing dialysis or having neuropathy subjects with musculoskeletal, neuromuscular, nervous, and peripheral vascular disorders such as myasthenia gravis, Parkinsonism, Alzheimer's, multiple sclerosis, and benign paroxysmal positional vertigo (BPPV)

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were selected randomly using the lottery method. Each eligible participant was assigned a unique number. These numbers were written on identical slips of paper, folded to conceal them, and placed in a container. After thorough mixing, slips were drawn one by one. The first drawn slip was assigned to Group A, the second to Group B, the third to Group A, and so on alternately, until all participants were allocated. This method ensured random and unbiased allocation to the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both patients and the outcome assessor were blinded, by preventing participants and evaluators from knowing the treatment allocation, ensuring objective assessment of outcomes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board

Street address

47, Tufail Road, Cantt Lahore

City

Lahore

Postal code

54000

Approval date

2024-01-05, 1402/10/15

Ethics committee reference number

IRB-USA-FAHS/148/2024

Health conditions studied

1

Description of health condition studied

Diabetic Polyneuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description

Sensation

Timepoint

Pre & Post

Method of measurement

Michigan Neuropathy Screening Instrument

2

Description

Balance

Timepoint

Pre & Post

Method of measurement

Berg Balance Scale

3

Description

Proprioception

Timepoint

Pre & Post

Method of measurement

JPS

Secondary outcomes

1

Description

HbA1C

Timepoint

Pre - Post

Method of measurement

Lab Test

2

Description

Heart rate reserve

Timepoint

Pre - Post

Method of measurement

Pulse oximeter

3

Description

Oxygen Saturation

Timepoint

Pre post

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group: combined training (Aerobic & Resistance Training)

Category

Treatment - Other

2

Description

Control group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

MAYO Hospital Lahore

Full name of responsible person

Dr. Faizan

Street address

Mayo Hospital Road, Anarkali Bazar

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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

University of South Asia

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**

University of South Asia

Full name of responsible person

Aiza Yousaf

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

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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

Ethical concerns

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

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

Title and more details about the data/document

Effects of Combined Resistance Training With or Without Aerobic Training on Sensation, Balance and Proprioception among Diabetic Polyneuropathy Patients

When the data will become available and for how long

1-Year

To whom data/document is available

Professionals

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

Email ID

What processes are involved for a request to access data/document

Contact through Email

Comments