Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
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Pakistan

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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 maximum13 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

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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
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Mayo Hospital Road, Anarkali Bazar
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Sponsors / Funding sources

1

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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
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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