Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of strength and muscular endurance resistance training in patients with diabetic neuropathy

Protocol summary

Study aim
Comparing the effects of strength-oriented and endurance-oriented resistance training on clinical outcomes in patients with diabetic neuropathy

Design
A randomized clinical trial with two parallel groups. A total of 34 participants will be randomly allocated to either the strength resistance training group or the muscular endurance resistance training group using Research Randomizer software.

Settings and conduct
This trial compares strength- and endurance-oriented resistance training in patients with diabetic neuropathy at the Sports Medicine Clinic, Loghman Hakim Hospital, during 2026–2027. Participants and trainers cannot be blinded due to the intervention; outcome assessors and the statistician will be blinded to allocation, and groups will be coded for analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of diabetes with diabetic neuropathy, medical eligibility for resistance training, and provision of informed consent. Exclusion criteria: Presence of autonomic neuropathy; Presence of non diabetic neuropathy; Current tobacco use; Diagnosis of rheumatoid arthritis; History of surgery within the past month

Intervention groups
Intervention Group 1 (Resistance Strength Training): Twice-weekly training for 8 weeks, starting at 50% of one-repetition maximum (1RM), with 8–12 repetitions per set, progressively increasing to 90% of 1RM according to individual tolerance.Intervention Group 2 (Resistance Endurance Training): Twice-weekly training for 8 weeks, starting at 30% of 1RM, with 12–20 repetitions per set, progressively increasing to 40% of 1RM according to individual tolerance.

Main outcome variables
One-Repetition Maximum (1RM); Michigan score (MNSI)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20261011071374N1**
Registration date: **2026-10-30, 1405/08/08**
Registration timing: **prospective**

Last update: **2026-10-30, 1405/08/08**
Update count: **0**

Registration date
2026-10-30, 1405/08/08

Registrant information
Name
Pardis sadeqi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-11-16, 1405/08/25
Expected recruitment end date
2027-01-13, 1405/10/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the effects of strength and muscular endurance resistance training in patients with diabetic neuropathy

Public title

The effects of resistance training on diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of diabetic neuropathy Age between 18 and 75 years Written informed consent to participate in the study Fasting blood glucose (FBS) greater than 120 and less than 250 mg/dL Blood pressure between 60/70 and 140/90 mmHg HbA1c level between 6.5% and 8.5%

Exclusion criteria:

Presence of autonomic neuropathy Presence of non diabetic neuropathy Current tobacco use Diagnosis of rheumatoid arthritis History of surgery within the past month Presence of significant motor impairment or edema in the lower extremities History of limb amputation Presence of an active foot ulcer Presence of significant limitations in joint range of motion History of orthopedic surgery or presence of significant musculoskeletal disorders that interfere with the proper performance of the exercise protocol Presence of hemiparesis, tremor, or other movement disorders that interfere with the performance of exercises or study assessments Presence of vestibular disorders that affect balance and motor function Presence of significant central nervous system dysfunction Presence of significant peripheral nervous system or vascular disorders that may affect study outcomes or the safety of exercise performance Presence of cardiac disease that medically contraindicates or renders resistance training unsafe Presence of deep vein thrombosis Use of medications specifically prescribed for the treatment of diabetic neuropathy, except vitamin B1,thiamine; and other supplements permitted under the study protocol Presence of underlying metabolic abnormalities that may affect study outcomes, including anemia, magnesium deficiency, or vitamin B12 deficiency

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized clinical trial with two parallel groups: A resistance strength training group and a resistance muscular endurance training group, with 17 participants allocated to each group. The unit of randomization is the individual participant, and allocation will be performed using block randomization. The random allocation sequence will be generated using the online tool Research Randomizer and will be designed to ensure that, at the end of the allocation process, 17 participants are assigned to each group. No stratified randomization will be used.The generation of the random allocation sequence and the preparation of allocation envelopes will be carried out by an individual associated with the research who is independent of the informed consent process, data collection, and implementation of the exercise intervention. To conceal allocation, the group assignments will be placed in opaque, externally non-transparent, sealed envelopes bearing consecutive numbers. After eligibility criteria have been verified and written informed consent has been obtained from each participant, the envelope corresponding to that participant will be opened according to the sequential numbering, and the allocated group will be revealed. Thus, the person responsible for participant recruitment and enrollment will not know the group assignment before the allocation takes place, preventing the next assignment from being predicted. After the group assignment has been revealed, the corresponding intervention will be implemented.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran

Street address

Ayatollah Taleghani Hospital, Shahid Arabi Street, Yaman Street, Velenjak, Tehran, Iran.

City

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Province

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Postal code

1985711151

Approval date

2026-10-11, 1405/07/19

Ethics committee reference number

IR.SBMU.MSP.REC.1405.485

Health conditions studied

1

Description of health condition studied
Type one Diabetic neuropathy
ICD-10 code
E10.42
ICD-10 code description
Type 1 diabetes mellitus with diabetic polyneuropathy

2

Description of health condition studied
Type two Diabetic neuropathy
ICD-10 code
E11.42
ICD-10 code description
Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description
Change in the Michigan Neuropathy Screening Instrument (MNSI) score
Timepoint
At baseline (before the intervention) and at the end of week 8 (after completion of the intervention).
Method of measurement
The Michigan Neuropathy Screening Instrument, including the symptom questionnaire and physical examination, together with the monofilament test to assess protective sensation, the tuning fork test to assess vibration sensation, and clinical examination of the limbs.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Strength Resistance Training; Participants will perform supervised strength resistance training twice a week for 8 weeks. Exercise intensity will start at 50% of the one-repetition maximum (1RM) and will be gradually increased according to each participant's individual ability, physical condition, and progress, potentially reaching up to 90% of 1RM. Reaching the target intensity will not be mandatory for all participants. Exercise intensity will be adjusted individually, and participants' training performance and progression will be monitored throughout the intervention.
Category
Rehabilitation

2

Description
Intervention group 2: Muscular Endurance Resistance Training; Participants will perform supervised muscular endurance resistance training twice a week for 8 weeks. Exercise intensity will start at 30% of the one-repetition maximum (1RM) and will be gradually increased according to each participant's individual ability, physical condition, and progress, potentially reaching up to 40% of 1RM. Reaching the target intensity will not be mandatory for all participants. Exercise intensity will be adjusted individually, and participants' training performance and progression will be monitored throughout the intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Pardis Sadeqi
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Loghman Hakim Hospital, Kamali Street, South Kargar Street, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Research Deputy Office, 3rd Floor, Shahid Beheshti University of Medical Sciences, Near Taleghani Hospital, Arabi Street, Velenjak, Tehran
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Pardis Sadeqi
Position
Resident
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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
All data are available for sharing.
When the data will become available and for how long
Access will be provided after publication of the results.
To whom data/document is available
Researchers at academic and scientific institutions
Under which criteria data/document could be used

For use in university research projects.

From where data/document is obtainable

University Research Vice-Chancellery

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

Visit the university's research website and submit an access request.

Comments