Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of sensory motor training effect with or without resistancetraining on performance, balance and pain in patients with diabeticperipheral neuropathy: A randomized controlled clinical trial

Protocol summary

Study aim
Comparison of sensory motor training effect with or without resistance training on performance, balance and pain in patients with diabetic peripheral neuropathy

Design
Randomized controlled trial method: Balanced, Block Randomization in three equal groups Determining and comparing the effect of 8 weeks of sensorimotor exercises with or without resistance exercises on static and dynamic balance, Function and pain in patients with peripheral diabetic neuropathy

Settings and conduct
The exercise was conducted thrice a week (alternate days with gap not exceeding more than 48 hours) for eight weeks (total 24 sessions). Each session comprised 10 minutes of warm-up, followed by 50- 60 minutes of exercise, followed by 5-10 minutes of cool down.

Participants/Inclusion and exclusion criteria
• Male and female subjects aged between 40 and 65 years; • diagnosed T2DM for at least 5years; • BMI was between 20 and 29.9 kg/m2; • Subjects had scored more than 2/13 points in the Michigan neuropathy screening instrument) questionnaire • A score greater than 1/10 of the MNSI physical examination score, including vibration perception impairment • Score 4 to 6 in VAS DPN patients who do not eligible or give consent Absence in more than 3 meetings without any episode of plantar ulceration; no partial or total amputation; and ability to walk independently in the laboratory. Patients were excluded from the study if they had any other neurological impairment; any major vascular complication; severe retinopathy; severe nephropathy; severe musculoskeletal impairment to lower limb; cardiovascular complication; and been receiving any supervised physical intervention

Intervention groups
1.Sensory-motor exercises 2.Sensory-motor exercises + resistance training

Main outcome variables
Static and Dynamic Balance Function Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250212064710N1**
Registration date: **2025-03-12, 1403/12/22**
Registration timing: **retrospective**

Last update: **2025-03-12, 1403/12/22**
Update count: **0**

Registration date
2025-03-12, 1403/12/22

Registrant information

Name
Azin Shirin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 640 8725

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az.shirin@mail.sbu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-08, 1403/11/20

Expected recruitment end date
2025-02-20, 1403/12/02

Actual recruitment start date
2025-02-08, 1403/11/20

Actual recruitment end date
2025-02-20, 1403/12/02
Trial completion date
2025-05-22, 1404/03/01

Scientific title
Comparison of sensory motor training effect with or without resistancetraining on performance, balance and pain in patients with diabeticperipheral neuropathy: A randomized controlled clinical trial

Public title
Comparison of sensory motor training effect with or without resistancetraining on performance, balance and pain in patients with diabeticperipheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
diagnosed T2DM for at least 5years BMI was between 20 and 29.9 kg/m2 Subjects had scored more than 2/13 points in the Michigan neuropathyscreening instrument) questionnaire A score greater than 1/10 of the MNSI physical examination score, including vibrationperception impairment Score 4 to 6 in VAS Male and female subjects aged between 40 and 65 years
Exclusion criteria:
DPN patients who do not eligible or give consent Absence in more than 3 meetings without any episode of plantar ulceration; no partial or total amputation; and ability to walk independently in thelaboratory. Patients were excluded from the study if they had any other neurological impairment; any major vascular complication; severe retinopathy; severe nephropathy; severe musculoskeletal impairment tolower limb; cardiovascular complication; and been receiving any supervised physical intervention
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **45**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
We performed randomization using the block randomization method to allocate participants into three groups. A predetermined block size was used to ensure an equal distribution of participants across groups. The randomization sequence was generated using a computer-based random number generator, and allocation was concealed to prevent selection bias. Participants were then assigned to their respective groups based on the generated sequence, ensuring that the allocation process was truly random and balanced.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, we applied single-blind blinding, meaning that participants were unaware of their group assignments. Additionally, the investigator responsible for administering interventions and the data analysts were blinded to the group allocations to minimize potential bias in outcome assessment and data interpretation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Royan institute
Street address
Aghdasieh street
City
Tehran
Province
Tehran
Postal code
1693913741
Approval date
2024-11-24, 1403/09/04
Ethics committee reference number
IR.ACECR.ROYAN.REC.1403.059

Health conditions studied

1

Description of health condition studied
Diabetes neuropathy
ICD-10 code
E13.40
ICD-10 code description
Other specified diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Static balance
Timepoint
8 weeks
Method of measurement

Single leg stance

2

Description
Dynamic balance
Timepoint
8 weeks
Method of measurement
FRT

3

Description
Pain
Timepoint
8 weeks
Method of measurement
VAS

4

Description
Function
Timepoint
8 weeks
Method of measurement
TUG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: sensory motor exercises
Category
Treatment - Devices

2

Description
Intervention group: Sensory-motor exercises + resistance training
Category
Treatment - Other

3

Description
Control group: routin lifestyle
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan diabetes clinic
Full name of responsible person
Azin Shirin
Street address
Aghdasieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Phone
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az.shirin@mail.sbu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Azin Shirin
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Royan diabetes clinics
Full name of responsible person

Dr Azam kouhkan
Position
Consultant
Latest degree
Medical doctor
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)
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
The document contains research data related to title including anonymized individual participant data (IPD) and supporting materials. The data primarily focuses on Diabetics neurapathy, collected through Randomized controlled trials
When the data will become available and for how long
The data will be available starting from date mentioned prior and will remain accessible for six months after publication of results
To whom data/document is available
The data will be accessible to researchers affiliated with academic institutions and professionals in related industries, provided they submit a formal request.
Under which criteria data/document could be used
Access will be granted based on ethical approval and alignment with the research objectives. Applicants must submit a research proposal detailing how the data will be used.
From where data/document is obtainable
The data can be obtained from Shahid beheshti university by submitting a request through email mentioned in the file.
What processes are involved for a request to access data/document
Just email to: az.shirin@mail.sbu.ac.ir
Comments