

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Email address

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 resistance training on performance, balance and pain in patients with diabetic peripheral neuropathy: A randomized controlled clinical trial

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

diagnosed T2DM for at least 5 years 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 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 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

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: routine 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

City

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Province

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Postal code

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Phone

+98 912 640 8725

Email

az.shirin@mail.sbu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azin Shirin

Full name of responsible person

Azin Shirin

Street address

Pasdaran, meydan khash,

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1983969411

Phone

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Email

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

Health Promotion

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Aghdasieh, Golzar street, Neda alley, Royan diabetes clinic

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Tehran

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Email

azamkouhkan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azin Shirin

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Pasdaran, 10th Baharestan, No 2, floor 1

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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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 neuropathy, 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