

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of the Training Program on Balance, Motor Function, Proprioceptive Sense and Walking speed of Patients with Diabetic Neuropathy

Protocol summary

Summary

(1) Objective: Determining the effect of the training program on balance, motor function, proprioceptive sense and speed walking of patients with diabetic neuropathy (2) Design: Parallel clinical trial (3) Setting and conduct: Selecting 44 patients with diabetic neuropathy referring to diabetes clinic of 5 Azar tertiary hospital affiliated to Golestan university of medical sciences and assigning them to two groups of intervention and control by simple random allocation. (4) Participants including major eligibility criteria: Inclusion Criteria: diabetes for at least 5 years; diagnosis of diabetic peripheral neuropathy with score greater than 2 by Michigan neuropathy screening instrument (MNSI); visual acuity of 20/ 40 by Snellen chart; normal range of motion of the hip, knee and ankle joint; ability to stand and walk; independently and without assistive devices; filling the informed consent form. Exclusion Criteria: foot ulceration and lower limb deformity; history of surgery or chronic pain in the lower extremity or low back; history of hypotension, myocardial infarction and stroke; other peripheral neurologic and musculoskeletal disorders; using drugs effective on balance during the examination to test. (5) Intervention: Before intervention, walking and stretching to warm up the body. The, functional balance training program three times a week in 75 minutes for 8 weeks by expert in exercise science. Functional balance training program include balancing on one leg, exercises on the wobble board, ankle simple exercises (dorsiflexion and plantar flexion), static stretching of hamstring and rotated 30 degrees in a standing position and cool down at the end of the training program. (6) Main outcome measures (variable): balance, motor function, proprioceptive sense, and speed walking, before and 48 hours after end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022231875N3**
Registration date: **2017-04-03, 1396/01/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

Name

Maryam Zahedi

Name of organization / entity

Golestan university of Medical Sciences, Gorgan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 911 177 8055

Email address

dr.zahedi-m@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences, Gorgan, Iran.

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Training Program on Balance, Motor Function, Proprioceptive Sense and Walking speed of Patients with Diabetic Neuropathy

Public title

Effect of the Training Program on Balance, Function, Sense and Walking speed of Patients with Diabetic Neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes for at least 5 years; Diagnosis of Diabetic Peripheral Neuropathy with Score Greater than 2 by Michigan Neuropathy Screening Instrument (MNSI); Visual Acuity of 20/ 40 by Snellen Chart; Normal Range of Motion of the Hip, Knee and Ankle Joint; Ability to Stand and Walk; Independently and without Assistive Devices; Filling the Informed Consent Form. Exclusion criteria: Foot Ulceration and Lower Limb Deformity; History of Surgery or Chronic Pain in the Lower Extremity or Low Back; History of Hypotension, Myocardial Infarction and Stroke; Other Peripheral Neurologic and Musculoskeletal Disorders; Using Drugs Effective on Balance during the Examination to Test.

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Golestan University of Medical Sciences

Street address

Postal code: 4934174515, beginning of the Shastkola road, Falsafi educational campus, Gorgan, Golestan province, Iran.

City

Postal code: 4934174515, beginning of the Shastkola road, Falsafi educational campus, Gorgan, Golest

Postal code**Approval date**

2016-12-18, 1395/09/28

Ethics committee reference number

IR.GOUMS.REC.1395.213

Health conditions studied**1****Description of health condition studied**

Diabetic Neuropathy

ICD-10 code

E14

ICD-10 code description

مبتلا به عوارض نورولوژیکی

Primary outcomes**1****Description**

balance, motor function, proprioceptive sense and speed walking

Timepoint

before and 48 hours after end of the study

Method of measurement

Measurement of balance by Berg Balance Scale; Timed Up and Go test (TUG) for assessment of motor function; Using tuning fork for assessment of proprioceptive sense; and 25-Foot Walk Test (T25FW) for measurement of speed walking

Secondary outcomes

empty

Intervention groups**1****Description**

Before intervention, walking and stretching to warm up the body. The, functional balance training program three times a week in 75 minutes for 8 weeks by expert in exercise science. Functional balance training program include balancing on one leg, exercises on the wobble board, ankle simple exercises (dorsiflexion and plantar flexion), static stretching of hamstring and rotated 30 degrees in a standing position and cool down at the end of the training program.

Category

Rehabilitation

2

Description

Control group: there is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of 5 Azar tertiary hospital affiliated to Golestan university of medical sciences

Full name of responsible person

Dr. Maryam Zahedi

Street address

5th Azar street, 5 Azar tertiary hospital, Gorgan, Golestan province, Iran.

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Taziki

Street address

Postal code: 4934174515, beginning of the Shastkola road, Falsafi educational campus, Gorgan, Golestan province, Iran.

City

Gorgan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Golestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr. Maryam Zahedi

Position

Internal medicine specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Maryam Zahedi

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty