Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Street address
5th Azar street, 5 Azar tertiary hospital, Gorgan, Iran.
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
dr.zahedi-m@goums.ac.ir
Web page address

Person responsible for scientific 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
Street address
5th Azar street, 5 Azar tertiary hospital, Gorgan, Iran.
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
dr.zahedi-m@goums.ac.ir
Web page address

Person responsible for updating data

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
Street address
5th Azar street, 5 Azar tertiary hospital, Gorgan, Iran.
City
Gorgan
Postal code
Phone
+98 17 3235 4936
Fax
Email
dr.zahedi-m@goums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty