

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

#### 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

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#### Full name of responsible person

Dr. Maryam Zahedi

#### Position

Internal medicine specialist

#### Other areas of specialty/work

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## Person responsible for updating data

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#### 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*