

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Protocol summary

Summary

Peripheral neuropathy is a common complaint of diabetes. Peripheral neural damage in turn will cause balance impairments in diabetic patients. Diabetic neuropathy plays a significant role in falling among elderly patients, people with peripheral neuropathy caused by diabetes often experience balance disorder. Postural sway in these patients is increased, especially with the eyes closed. Peripheral neuropathy caused by diabetes causes significantly impaired sensation in the feet, reducing patients' ability to control their balance properly during daily activities. Poor balance can be due to proprioception impairment. Balance problems are also caused by movement-strategy impairment, biomechanical structural disorders, and disorientation. 34 patient with moderate to severe neuropathy (toronto scale>8) that confirmed with electrodiagnosis are divided accidentally into two group. All patient are examined for balance index with biodex balance system and berg balance scale questionnaire and then received physical therapy with IR and TENS for 30 minute 3 time in week. Intervention consists of 20 minute balance training with biodex balance system in ten sessions for 20 minute every session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211214641N6**
Registration date: **2012-12-05, 1391/09/15**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-05, 1391/09/15

Registrant information

Name

Bina Eftekharsadat

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 3193

Email address

binasadat@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

physical medicine and rehabilitation research center

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Public title

Effect of ten sessions balance training on balance in diabetic neuropathy patient.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 50 to70; confirmed diabetes type 2; moderate or severe diabetic neuropathy in toronto scale; peripheral neuropathy which confirmed with electrodiagnostic tests; the ability to stand

independently, BMI less than 30. Exclusion criteria: diabetic ulcer; infection or partial amputation in feet; inability to stand independently; other diseases affecting balance; neurologic or orthopedic problem affecting balance; History of repeated ankle sprains in the year prior to the study; severe pain influencing balance; visual problems inability to see the stabilometer cursor; severe pain interfere with balance.

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Tabriz university of medical sciences

Street address

Golgasht Avenue

City

Tabriz

Postal code**Approval date**

2012-10-29, 1391/08/08

Ethics committee reference number

91140

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

Endocrine, nutritional and metabolic diseases

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

change in balance index with biodex balance system

Timepoint

before and after training

Method of measurement

Balance idex with biodex system

Secondary outcomes**1****Description**

functional balance

Timepoint

befor and after training

Method of measurement

Berg balance scale

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

control :physical therapy(IR and TENS)

Category

Rehabilitation

2**Description**

intervention: 10 session balance training with biodex balance system with physical therapy(IR and TENS)

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Mis Poorahmadian

Street address

Physical medicine and rehabilitation research center, Emam Reza hospital

City

Tabriz

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Physical medicine and rehabilitation research center

Full name of responsible person

Dr. Seyed Kazem Shakouri

Street address

Emam Reza Hospital, Golgasht avenue

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Physical medicine and rehabilitation research center

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**

Tabriz university of medical sciences

Full name of responsible person

Dr. Bina Eftekharsadat

Position

Associated professor-Physiatrist

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Tabriz University of Medical Sciences

Full name of responsible person

Roghaye Azizi

Position

Physical medicine and rehabilitation resident

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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*