

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effects of the Weight Bearing Exercise for a Better Balance program on static, dynamic and functional balance in people with diabetic neuropathy.

Protocol summary

Summary

The aim of this randomized control trial study is to determine the effects of the exercise program of Weight-bearing Exercise for Better Balance on static, dynamic and functional balance in people with diabetic polyneuropathy. Inclusion criteria are the diagnosis of diabetic polyneuropathy and the ability to perform the tests and exercises; exclusion criteria are the presence of any orthopaedic, neurological and cardiopulmonary problems which may interfere with exercise and test performance. 30 People diagnosed with diabetic polyneuropathy will be randomly assigned to intervention and control group. Participants in intervention group will perform the Weight-bearing Exercise for Better Balance program, containing 11 strengthening, balance, coordination and aerobic exercises. Participants in the control group will perform a battery of balance-strengthening exercises. All participants will perform the exercise programs for 8 weeks and will undergo balance assessment twice: once 24 hours before the beginning of the exercises and another time 24-48 hours after the last session of the exercise interventions. The primary outcome measures are displacement and velocity of postural sway, stability index and functional balance score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091619188N1**

Registration date: **2016-04-05, 1395/01/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-05, 1395/01/17

Registrant information

Name

Tabassom Ghanavati

Name of organization / entity

Ahvaz Jundishapur university of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3332 0800

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-09-12, 1394/06/21

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of the Weight Bearing Exercise for a Better Balance program on static, dynamic and functional balance in people with diabetic neuropathy.

Public title

The effect of an exercise program on balance in people with diabetic neuropathy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes mellitus diagnosed by physician; DPN diagnosis via clinical and laboratory assessments; Ability to participate in tests and exercises; Ability to perform aerobic activities for at least 30 mins without assistance Exclusion: Foot ulcer; Orthopedic or surgical impairments interfering with walking; Neurological consequences except diabetic polyneuropathy interfering with walking; Peripheral vascular disease; CNS involvement signs (dementia, Parkinson Disease, or Multiple Sclerosis); Musculoskeletal deformities at Lower Limb; Uncontrolled cardiopulmonary disease; History of dizziness, unstable angina, uncontrolled BP, tachycardia or resting arrhythmia; People who participated in balance training exercise, three months before starting study; Corrected visual acuity less than 20/70; MMSE score less than 24

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan BLVD. Ahvaz Jundishapur University of Medical Sciences Campus

City

Ahvaz

Postal code

Approval date

2015-10-16, 1394/07/24

Ethics committee reference number

IR.AJUMS.REC.1394.400

Health conditions studied

1

Description of health condition studied

Diabetic Polyneuropathy

ICD-10 code

G63.2*

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes

1

Description

Sway Area

Timepoint

8 weeks

Method of measurement

force plate & instrumental wobble board

2

Description

Mean velocity of center of pressure

Timepoint

8 weeks

Method of measurement

force plate & instrumental wobble board

3

Description

Standard deviation of center of pressure velocity (Anteroposterior)

Timepoint

8 weeks

Method of measurement

force plate & instrumental wobble board

4

Description

Standard deviation of center of pressure velocity (Mediolateral)

Timepoint

8 weeks

Method of measurement

force plate & instrumental wobble board

5

Description

Functional balance score

Timepoint

8 weeks

Method of measurement

Berg balance scale

Secondary outcomes

1

Description

Depression

Timepoint

8 weeks

Method of measurement

GDS15 questionnaire

2

Description

Functional mobility

Timepoint

8 weeks

Method of measurement

Timed up and go test

Intervention groups

1

Description

Intervention Group: WEBB Exercise: 1.High stepping on the spot 2. Standing with a decreased base 3. Graded reaching in standing 4. Stepping in different directions 5. Walking practice 6. Sit-to-stand 7. Heel raises 8. Lateral step-up 9. Forward step-up 10. Half- squats sliding down a wall 11. Bike, treadmill walk, overground walk or sit-to-stand

Category

Rehabilitation

2

Description

Control Group: Balance-resisted exercise: 1. single leg standing 2. standing on toes and heels 3. tandem standing 4. Quadriceps strengthening 5. Lunge exercise

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ghanavati Tabassom

Street address

Golestan BLVD- Ahvaz University of Medical Sciences
Campus- Rehabilitation Sciences Faculty-
Musculoskeletal Rehabilitation Research Center

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

Full name of responsible person

Nader Saki

Street address

Golestan BLVD. Ahvaz University of Medical Sciences
Campus. The deputy of research development

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur University of Medical Sciences, Ahvaz,
Iran

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

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences, Ah

Full name of responsible person

Ghanavati Tabassom

Position

PhD of Physiotherapy

Other areas of specialty/work

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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