Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Ahvaz Jundishapur university of Medical Sciences
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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
Goleastan 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
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Position
PhD of Physiotherapy
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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