

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of two type of therapeutic exercise Frenkel vs. Swiss ball on the clinical balance indices in patients with diabetes type 2 associated with neuropathy

Protocol summary

Summary

This study was planned to evaluate compare between two therapeutic exercise on the clinical balance indices in patients with diabetes type 2 associated with neuropathy. It is a double blinded clinical trial study. 60 diabetic neuropathy type 2 with the age of 40-65 that had 18-30 body mass index should have the score of more than two in Michigan neuropathy test, classified into three groups (each group contain 20 patient) with accident blocking method. Exclusion criteria: lower extremity complication such as fracture and dislocation at least during 6 months ago and cardio-vascular problems. One group do Frenkel exercise and another group ball training exercise and there was a control group besides. During of each sessions is 55 min daily 5 times a week in 3 weeks. The clinical balance indices are measured before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307142391N13**

Registration date: **2014-05-08, 1393/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-08, 1393/02/18

Registrant information

Name

Zahra Rojhani Shirazi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Shiraz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two type of therapeutic exercise Frenkel vs. Swiss ball on the clinical balance indices in patients with diabetes type 2 associated with neuropathy

Public title

The effect of therapeutic exercise in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetic neuropathy type 2 referred from physician ; between 40-65 years old ; with 18-30 body mass index should have the score of more than two in Michigan neuropathy test. Exclusion criteria: lower extremity complications such as fracture and dislocation

at least during six months ago ; any history of surgical operations in muscles,bones and joints of lower extremity ; pain in ankle and knee joint during test ; musculo-skeletal disorders such as rheumatoid and myopathy ; middle ear and vestibular impairments in the patient self report ; knee joint flexion contracture ; using supportive equipments in gait ; stop intervention more than two days any way ; cardiovascular problems and hypertension.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science

Street address

Shiraz faculty Rehabilitatin,Abyverdy Street,Chamrac
Boulevard

City

Shiraz

Postal code

Approval date

2014-04-14, 1393/01/25

Ethics committee reference number

93/17350

Health conditions studied

1

Description of health condition studied

Diabete type2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Balance

Timepoint

Before intervention,one day after intervantion

Method of measurement

Berg Balance Scale Test,Star excursion Test,time of leg stance

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1,Swiss ball training: balance training in sitting position: 1- holding balance position on ball 2- holding balance position on ball with active movements of one sided upper extremity 3- holding balance position on ball with active movements of two sided upper extremity 4- holding balance position on ball with trunk movements (bending forward and rotation) 5- holding balance position on ball with heel raising 6- holding balance position on ball with toes raising 7- holding balance position on ball with raising heel and toes simultaneous 8- resistance against perturbation 9- weight shifting on ball ball training in standing position: 1- picking up and down the ball with two upper extremity in a straight line 2- picking up and down the ball with two upper extremity in an oblique line 3- moving the ball forward and backward with left and right lower extremity 4- moving the ball in lateral sides with left and right lower extremity 5- throwing ball toward the wall with hand 6- throwing ball toward the wall with foot

Category

Other

2

Description

control group: clinical balance indices is measured without intervention

Category

N/A

3

Description

intervention group 2,Frenkel exercise: in supine position: 1- patient bends one leg at the hip and knee, as heel along the bed,Repeats with the other leg 2- Bends one leg at the hip and knee and Then straights his hip and knee to return to the starting position. Repeats with the

other leg 3- Bends one leg with the heel raises from the bed. Repeats with the other leg 4- Bends one leg and place it at the at any point of command. Repeats with the other leg 5- Bends one leg and places that heel on the opposite knee Then slides her heel down the shin to the ankle and back up to his knee and Returns to the starting position.repeats with the other leg 6- Bends both legs and then keeps his ankles together Straighten both legs to return to starting position 7- Bend one leg in a bicycling motion in sitting position: 1- raises the heel Then progress to alternately lifts the entire foot and placing the foot on the floor upon a traced foot print 2- Alternately glides the foot over the marked cross forward, backward and lateral side 3- at first rises from the chair, at second bends trunk forward then rises the trunk and Reverses the procedure to sit down in standing position: 1- shifts the weight to the left foot and places the right foot 12 inches to the right and Repeats exercise with the left side 2- Walks forward between two parallel line 14 inches apart placing 3- Walks forward placing each foot on a footprint traced on the floor(Foot prints is parallel and 2 inches from a center line) 4- Turns to the right and places at the right toe and rotates the right and places right foot on the floor then rotates the right, repeats to the left 5- Walks up and down the stairs and Places the right foot on one step and brings the left up beside it.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Rehabilitation Sciences,Physiotherapy Clinic
Full name of responsible person
Zahra Rojhani Shirazi
Street address
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Shiraz University of Medical Sciences
Full name of responsible person
Seid Basir Hashemi
Street address
Shiraz,Zand Street,Shiraz University of Medical Sciences,University of Central Building
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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 of Shiraz 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

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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