

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of resistance exercises using TheraBand on balance, timed up and go, and fear of fall in diabetic type 2 patients with peripheral neuropathy referring to Iranian diabetes foundation, in the city of Mashhad, 2020

Protocol summary

Study aim

To determine the effect of resistance exercises using TheraBand on balance, timed up and go, and fear of fall in diabetic type 2 patients with peripheral neuropathy referred to the Iranian diabetes foundation in city of Mashhad in 2020

Design

Two arm randomized trial, with parallel groups design on 60 elderly

Settings and conduct

Initial identification of eligible individuals will be done by reviewing their medical records. Then, during home visit, those who fully meet the study criteria will be recognized. After obtaining informed consent, baseline outcome measurements will be done. Then, participants will be randomly allocated to intervention and control groups, according to the list of permuted blocks of random codes. Intervention and control groups will receive resistance exercises using TheraBand, and resistance exercises without TheraBand, respectively for 12 weeks. Scales for measuring balance, timed up and go, and fear of fall will be used at five time points (study onset, weeks 4, 8, 12, and 16) to evaluate the study outcomes.

Participants/Inclusion and exclusion criteria

1. Having type 2 diabetes 2. No restrictions on activities of daily living 3. Gaining balance score less than or equal to 25 on the Fullerton Advanced Balance Scale; and less than 32 on Berg Balance Scale 4. Having peripheral neuropathy with endocrinologist confirmation 5. No diabetic foot ulcer 6. Having physician's permission for doing exercise 7. Having no vision problems 8. Presence of a caregiver during exercises 9. Age between 75-60 years

Intervention groups

Intervention group: performing resistance exercises using TheraBand; Control group: performing resistance

exercises without using TheraBand

Main outcome variables

Balance; timed up and go; and fear of fall

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201022049110N1**

Registration date: **2021-02-27, 1399/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-27, 1399/12/09**

Update count: **0**

Registration date

2021-02-27, 1399/12/09

Registrant information

Name

Saeedeh Baghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3821 5041

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of resistance exercises using TheraBand on balance, timed up and go, and fear of fall in diabetic type 2 patients with peripheral neuropathy referring to Iranian diabetes foundation, in the city of Mashhad, 2020

Public title

Effect of resistance exercise using TheraBand on balance, timed up and go, and fear of fall in elderly diabetic type 2 patients with peripheral neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having diabetes type 2 Having peripheral neuropathy with Endocrinologist diagnosis Have physician's permission for exercise Having caregiver during exercises Gaining balance score less than 25 based on the Fullerton Advanced Balance Scale; and less than 32 based on Berg Balance Scale Age between 60-75 years

Exclusion criteria:

Gaining score less than 12 in scale for measuring activities of daily living Having diabetic foot ulcer with physician's confirmation Having vision problems

AgeFrom **60 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Before identifying the eligible participants, 60 random codes in the form of permuted random blocks with different sizes of 2, 4, and 6 for two equal groups will be generated by the software. Then each participants will be given a unique code on their enrolment, and finally they will be allocated to the intervention and control groups based on their random codes. At online software (<https://www.sealedenvelope.com>) will be used for permuted block randomization.

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 North Khorasan University of Medical Sciences

Street address

Central Building of North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd

City

Bojnurd

Province

North Khorasan

Postal code

7487794149

Approval date

2021-01-06, 1399/10/17

Ethics committee reference number

IR.NKUMS.REC.1399.125

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

Balance impairment due to Diabetic type 2 peripheral neuropathy

ICD-10 code

R26.8

ICD-10 code description

Other abnormalities of gait and mobility

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

Balance score in elderly with diabetic peripheral neuropathy

Timepoint

Study onset, weeks 4, 8, 12, and 16

Method of measurement

Using Fullerton advanced balance scale; and Berg balance scale

2**Description**

Timed up and go in elderly with diabetic peripheral neuropathy

Timepoint

Study onset, weeks 4, 8, 12, and 16

Method of measurement

Implementing timed up and go test

3

Description

Fear of fall in elderly with diabetic peripheral neuropathy

Timepoint

Study onset, weeks 4, 8, 12, and 16

Method of measurement

Use of short form of International Fall Efficacy Scale (IFES)

Secondary outcomes

empty

Intervention groups

1

Description

Participants in intervention group will perform resistance exercises using TheraBand, four days a week, 30 minutes each day, for twelve weeks. In the first six weeks red TheraBand (weak resistance) and in the last six weeks, green TheraBand (medium resistance) will be used. Exercises include hip flexion and extension, hip adduction and abduction, knee flexion and extension, ankle dorsiflexion, and ankle flexion inward and outward. All movements will be performed in standing and sitting positions. Each movement will be in 3 sets with 10 repetitions. Participants will pause for 2 to 3 seconds between repetitions, 1 to 2 minutes between sets and 2 to 3 minutes between different exercises.

Category

Rehabilitation

2

Description

Participants in intervention group will perform resistance exercises without using TheraBand, four days a week, 30 minutes each day, for twelve weeks. Exercises include hip flexion and extension, hip adduction and abduction, knee flexion and extension, ankle dorsiflexion, and ankle flexion inward and outward. All movements will be performed in standing and sitting positions. Each movement will be in 3 sets with 10 repetitions. Participants will pause for 2 to 3 seconds between repetitions, 1 to 2 minutes between sets and 2 to 3 minutes between different exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

International Iranian Diabetes Prevention and Control Foundation

Full name of responsible person

Farhad Rajabpour Sanati

Street address

No. 56, Milad Ave., Sajad Blvd., International Iranian Diabetes Prevention and Control Foundation, Mashhad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Amir Amani

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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

Bojnourd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Saeedeh Baghizadeh

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Mohammad Reza Armat

Position

Academic member - Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available