Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 4.Having physician's permission for doing exercise 6.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)

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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
Age
From **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 perform 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 perform 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
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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 updating data

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Other areas of specialty/work
Nursery

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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