

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

s.baghizadeh@nkums.ac.ir

##### 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 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

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9186694748

##### **Phone**

+98 51 3765 0400

##### **Fax**

##### **Email**

s.baghizadeh@nkums.ac.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Bojnourd University of Medical Sciences

##### **Full name of responsible person**

Dr. Amir Amani

##### **Street address**

Central Building of North Khorasan University of Medical Science, DolatBlvd

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##### **Province**

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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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Bojnurd School of Nursing and Midwifery, Shahriar St.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Armat

**Position**

Academic member - Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Saeedeh Baghizadeh

**Position**

Graduate student

**Latest degree**

Bachelor

**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