

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Combined Training on Range of Activity and the Amount of Lower Limb Muscles Co-Contraction in Elderly Women with Diabetic and Diabetic Neuropathy During Gait

#### Protocol summary

##### Study aim

The purpose of this study was to determine the effect of combined training on the range of activity and contraction of the lower extremity muscles of elderly women with diabetes and diabetic neuropathy in walking motion and a number of functional factors.

##### Design

The present study is an applied clinical trial and semi-experimental method. The research design includes pre-test and post-test with the control group. Sampling method is available. The sample size includes 15 elderly women with diabetes, 15 elderly women with diabetic peripheral neuropathy and 15 healthy individuals.

##### Settings and conduct

This study will be carried out in cooperation with the Spring Medical Center and the Sporting Board of Special Patients and the Transplant of Qom members.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include no history of foot ulcer, signs of infection, neurological disorders (other than diabetic neuropathy), lower extremity surgery or cardiovascular disease, blood sugar control and blood pressure control, score over 4 in the Michigan questionnaire, showing Neuropathy was assessed by testing the speed of conduction of the sural and peroneal sensory and motor nerves. Exit criteria included foot ulcer, retinopathy, nephropathy, high blood pressure or low blood pressure, and patients' unwillingness to continue to participate regularly in the program.

##### Intervention groups

The intervention was based on 8 weeks of combined exercises in elderly women with diabetes and peripheral diabetic neuropathy. These exercises include 4 exercises of strength, balance, flexibility and walking pattern. During the exercise, the control group will continue to live normally.

##### Main outcome variables

Range of Activity: Co-Contraction: Balance: Falling: Strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180703040327N1**

Registration date: **2018-07-26, 1397/05/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-26, 1397/05/04**

Update count: **0**

##### Registration date

2018-07-26, 1397/05/04

##### Registrant information

##### Name

Vida Farhan

##### Name of organization / entity

Kharazmi University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3337 3333

##### Email address

std\_farhan@khu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-08-01, 1397/05/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Combined Training on Range of Activity and the Amount of Lower Limb Muscles Co-Contraction in Elderly Women with Diabetic and Diabetic Neuropathy During Gait

**Public title**

The Effect of Exercise on Muscle Electromyography in Diabetic Patients

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Involved to type 2 diabetes Involved to diabetic peripheral neuropathy Not having a foot ulcer Have a controlled sugar

**Exclusion criteria:**

The presence of diabetic foot ulcers The use of drugs and supplements with known effects on the central nervous system, the environment and muscles presence of a neurological disease except neuropathy

**Age**

From **60 years** old to **70 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shahid Beheshti University Research Ethics Committees

**Street address**

Amin Boulevard, Department of Sports and Youth of

Qom

**City**

QOM

**Province**

Ghoum

**Postal code**

3713994399

**Approval date**

2018-07-01, 1397/04/10

**Ethics committee reference number**

IR.SBU.ICBS.97/1011

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

diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

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

Range of Activity

**Timepoint**

pre-test and post-test

**Method of measurement**

Electromyography

**2****Description**

Co-contraction

**Timepoint**

pre-test and post-test

**Method of measurement**

Electromyography

**3****Description**

Balance

**Timepoint**

pre-test and post-test

**Method of measurement**

Berg

**4****Description**

Falling

**Timepoint**

pre-test and post-test

**Method of measurement**

Fear of Falling Tests

## 5

### **Description**

Strength

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Dynamometer

## **Secondary outcomes**

## 1

### **Description**

Muscle Indurance

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Dynamometer

## 2

### **Description**

Quality of Life

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Short Form-36 items

## 3

### **Description**

proprioceptive

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Goniometer

## 4

### **Description**

Range of Motion

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Goniometer

## 5

### **Description**

Depression

### **Timepoint**

pre-test and post-test

### **Method of measurement**

questionnaires of depression (Beck)

## 6

### **Description**

stride and steplength

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Electromyography

## 7

### **Description**

duration of single and double supports

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Electromyography

## 8

### **Description**

velocity

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Electromyography

## 9

### **Description**

Mental Health

### **Timepoint**

pre-test and post-test

### **Method of measurement**

Mental Health Standard Questionnaire

## **Intervention groups**

## 1

### **Description**

Intervention group 1: People with type 2 diabetes will do involved with combined exercise for 8weeks, 3 sessions per week, and 1 hour per session

### **Category**

Prevention

## 2

### **Description**

Intervention group 2: People with diabetic peripheral neuropathy will do involved with combined exercise for 8weeks, 3 sessions per week, and 1 hour per session

### **Category**

Prevention

## 3

### **Description**

Control group: Control group will not participate in any exercise program.

### **Category**

N/A

## **Recruitment centers**

## 1

### **Recruitment center**

**Name of recruitment center**

bahar Specialist Clinic

**Full name of responsible person**

hamid reza rahbari

**Street address**

Somayeh street, next to the Keshavarzi Bank

**City**

qom

**Province**

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**Postal code**

37147-76593

**Phone**

+98 25 3783 4064

**Email**

sphe1504@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Department of Sports and Youth of Qom Province

**Full name of responsible person**

hossein doali

**Street address**

Department of Sports and Youth, Bolvar Amin street

**City**

Qom

**Province**

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**Postal code**

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**Phone**

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hdoali@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

The research project of the Department of Sports and Youth

**Proportion provided by this source**

15

**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**

Other

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

The University of Kharazmi

**Full name of responsible person**

vida farhan

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Physical Education

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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farhan.vida@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data on observed changes in the combined training effect on muscle activity in the intervention group will generally be reported.

**When the data will become available and for how long**

Get started since 2021

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

The mention of the results of this research is only possible by mentioning its source.

**From where data/document is obtainable**

Faculty of Physical Education and Sport Sciences, Kharazmi University, Karaj, Iran.

**What processes are involved for a request to access data/document**

By submitting a written request to the library librarian and obtaining consent, it is accessible.

**Comments**