

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

AgeFrom **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

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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 From-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

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37147-76593

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+98 25 3783 4064

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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

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37147-76593

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Email

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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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