Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Vida Farhan
Name of organization / entity
Kharazmi University
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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 exept 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 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
City
qom
Province
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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 streeet
City
Qom
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Ghoum
Postal code
37147-76593
Phone
+98 25 3293 9111
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