

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of circuit resistance training on arterial stiffness in type 2 diabetic men with peripheral neuropathy

Protocol summary

Study aim

To investigate the effect of circular resistance training on arterial stiffness in type 2 diabetic men with peripheral neuropathy

Design

A clinical trial with control group, parallel design, double blind and randomized design. sample size is 30.

Settings and conduct

Three months supervised circuit resistance training with the intensity with the frequency of 3 sessions per week will be conducted at the laboratory of sport physiology of Shahrood university of technology. The samples size in this study will be 30. The measurements will be performed at baseline and 48 hours following the last exercise session in a fasting state. In this study the instructor and the participants will not be blinded to the group allocation but laboratory specialists and data analyst will be blinded to the group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of type 2 diabetes for more than 5 years; diagnose of peripheral neuropathy by a neurologist; hemoglobin A1c over 6.6%; no restriction for exercise; sedentary life-style. Non-inclusion criteria: regular exercise training; orthopedic problems; heart surgery.

Intervention groups

Resistance training group: after 2 weeks of familiarization, participants will perform circuit resistance training over 3 months with the frequency of 3 days a week. Control group: they will be required to maintain daily physical activity.

Main outcome variables

Ankle-brachial index; Toe-brachial Index; Cardio-ankle vascular stiffness index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170120032066N4**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **retrospective**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

Registration date

2019-12-17, 1398/09/26

Registrant information

Name

Farhad Gholami

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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+98 41332395900

Email address

gholami-fa@shahroodut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-20, 1398/08/29

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of circuit resistance training on arterial stiffness in type 2 diabetic men with peripheral neuropathy

Public title

Circuit resistance training and arterial stiffness in neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type 2 diabetes for more than 5 years
diagnose of peripheral neuropathy by a neurologist
HbA1c over 6.6% No restriction for exercise Sedentary life-style

Exclusion criteria:

regular exercise training Orthopedic problems Heart Surgery

Age

From **30 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be enrolled by one of the research colleagues. A person, blinded to group allocation will provide a random allocation sequence using computer software of SAS prior to the initiation of the study to be used to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 4, 6) will be applied to ensure an equal number of participants in each group. Group allocation will be concealed in sequentially numbered, opaque, sealed envelopes, and corresponding envelopes will be opened after the enrolled participants are analyzed. In this study the instructor and participants will not be blinded to the group allocation but laboratory specialists and data analyst will be blinded to the group allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study the instructor and participants will not be blinded to the group allocation but laboratory specialists and data analyst will be blinded to the group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud university of medical sciences

Street address

7-Tir Square., Tehran St.

City

Shahroud

Province

Semnan

Postal code

3614773947

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.SHMU.REC.1398.087

Health conditions studied

1

Description of health condition studied

Peripheral Neuropathy of Type 2 Diabetes

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description

Ankle-brachial index

Timepoint

Before and after the intervention

Method of measurement

Arterial stiffness analyzer

2

Description

Toe-brachial Index

Timepoint

Before and after the intervention

Method of measurement

Arterial stiffness analyzer

3

Description

Cardio-ankle vascular stiffness index

Timepoint

Before and after the intervention

Method of measurement

Arterial stiffness analyzer

4

Description

Score of neuropathy symptoms

Timepoint

Before and after the intervention

Method of measurement

Michigan diabetic neuropathy score

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before and after the intervention

Method of measurement

Blood pressure monitor

2

Description

Diastolic blood pressure

Timepoint

Before and after the intervention

Method of measurement

Blood pressure monitor

3

Description

Fasting blood glucose

Timepoint

Before and after the intervention

Method of measurement

Calorimetric method

Intervention groups

1

Description

Intervention group: Circuit resistance training over 3 months with the frequency of 3 sessions per week and 36 sessions in total, with the intensity of 50-70% of one repetition maximum .

Category

Rehabilitation

2

Description

Control group: no further activity other than daily physical activity.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasargad Clinic of Shahroud

Full name of responsible person

Farhad Gholami

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7-Tir Square., Tehran St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Technology

Full name of responsible person

Ali Dastfan

Street address

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Shahroud

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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

Shahroud University of Technology

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

Shahroud University of Technology

Full name of responsible person

Farhad Gholami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Technology

Full name of responsible person

Farhad Gholami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise physiology

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Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Technology

Full name of responsible person

Farhad Gholami

Position

Assistant professor

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

Yes - There is 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

Title and more details about the data/document

No decision has been made.

When the data will become available and for how long

No decision has been made.

To whom data/document is available

No decision has been made.

Under which criteria data/document could be used

No decision has been made.

From where data/document is obtainable

No decision has been made.

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

No decision has been made.

Comments