

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effect of resistance training on balance, postural control, risk of fall, reaction time and walking signs of neuropathy in type 2 diabetic patients with peripheral neuropathy - randomized controlled clinical trial

Protocol summary

Study aim

To investigate the effect of resistance training on postural control and clinical symptoms of diabetic neuropathy

Design

A randomized clinical trial with control group and parallel design, with no blinding and a sample size of 60

Settings and conduct

Three months supervised resistance training with the intensity of 50% to 60% of one repetition maximum with the frequency of 3 sessions per week will be conducted at the laboratory of sport physiology of Shahrood university of technology. Resistance training will include 10 exercises of 4 upper body , 4 lower body and 2 core exercises. The measurements will be performed at baseline and 48 hours following the last exercise session in a fasting state. It is impossible to blind the participants and instructor to group allocation but laboratory specialists assessing the variables and data analyst will be blinded to the group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 30-70 years, Diagnosis of Type 2 diabetes for more than 5 years, HbA1c over 6.6%, Sedentary life-style, No restriction for exercise

Intervention groups

Resistance training group: participants will undergo resistance training over 3 months with the frequency of 3 days a week at the intensity of 50 to 70% of one repetition maximum. Control group: they will be required to maintain daily physical activity

Main outcome variables

Balance, walking, postural control, risk of falling, reaction time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170120032066N2**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **prospective**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Farhad Gholami

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of resistance training on balance, postural control, risk of fall, reaction time and walking signs of neuropathy in type 2 diabetic patients with peripheral neuropathy - randomized controlled clinical trial

Public title
Effect of resistance training on postural control parameters and clinical symptoms in diabetic peripheral neuropathy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age ranges from 30 to 70 years
Diagnosis of type 2 diabetes for more than 5 years
HbA1c over 6.6%
Sedentary life-style
No restriction for exercise
Exclusion criteria:

Age
From **30 years** old to **70 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
Participants will be enrolled by one of the research colleagues. An independent evaluator, blinded to group allocation will provide a random allocation sequence using computer software of SAS prior to the initiation of the study that will 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 enrolled participants completed all baseline assessments. It is impossible to blind the participants and instructor to group allocation but laboratory specialists assessing the variables and data analyst will be blinded to the group allocation.

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 Shahroud University of Medical Sciences
Street address
7-Tir Square., Tehran St.
City
Shahrud
Province
Semnan
Postal code
3614773947
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.SHMU.REC.1397.086

Health conditions studied

1
Description of health condition studied
Peripheral Neuropathy Type 2 Diabetes
ICD-10 code
E11.42
ICD-10 code description
Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1
Description
Balance index
Timepoint
Before and after the intervention.
Method of measurement
Balance will be measured using Tendon test.

2
Description
Risk of falling
Timepoint
Before and after the intervention.
Method of measurement
Risk of falling will be assessed with the international questionnaire of falling efficiency

3
Description
Posture control
Timepoint
Before and after the intervention.
Method of measurement
Posture control will be assessed using foot scanner.

4
Description

Reaction time
Timepoint
Before and after the intervention.
Method of measurement
Reaction time will be assessed with reaction analyzer

5

Description
Score of neuropathy symptoms
Timepoint
Before and after the intervention.
Method of measurement
Neuropathy score will be assessed using Michigan diabetic neuropathy score.

Secondary outcomes

1

Description
Fasting blood glucose
Timepoint
Before and after the intervention
Method of measurement
Blood glucose level will be measured using Pars-azmoon kit with calorimetric method.

Intervention groups

1

Description
Intervention group: Resistance exercise 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 Shahrood
Full name of responsible person
Farhad Gholami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrood University of Technology
Full name of responsible person
Ali Dastfan
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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
Shahrood 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
Shahrood 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

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable