

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effectiveness of balance exercise in comparison with aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

#### Protocol summary

##### Study aim

Comparison of EMG-NCV characteristics between the two groups

##### Design

After giving the necessary explanations, written consent is obtained from the mentioned patients, and then they are treated with balance or aerobic exercises in one of the two groups in a simple random manner and in a block method.

##### Settings and conduct

This is randomized clinical trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include diabetics patient between the ages of 30 and 65 who are able to stand and walk independently without any assistive devices, and Electrodiagnostic tests have confirmed the presence of diabetic Neuropathy. Exclusion criteria include people with diabetic foot ulcers, uncontrolled blood sugar, inner ear infection, neurological diseases (other than neuropathy) or other disorders of balance, a history of recurrent ankle sprains in the past year, severe pain It is a disturbance of balance and the presence of any disturbing factor of balance other than diabetic neuropathy.

##### Intervention groups

Diabetic patients are divided into two groups of balance and aerobic exercise. Before the intervention, patients are tested for EMG-NCV and then they are given balance or aerobic exercise 3 days a week for 8 weeks. After 8 week EMG-NCV tests are taken again from patients.

##### Main outcome variables

Comparison of emg-ncv characteristics in diabetic patients into two groups of balance and aerobic exercise

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039324N4**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

##### Registration date

2021-12-01, 1400/09/10

##### Registrant information

##### Name

Sirous Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4382 3476

##### Email address

s.azizi@ajaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-17, 1400/09/26

##### Expected recruitment end date

2022-04-23, 1401/02/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of balance exercise in comparison with

aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

#### Public title

Effectiveness of balance exercise in comparison with aerobic exercise on electro diagnostic parameters in patient with diabetic peripheral neuropathy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Diabetics patient between the ages of 30 and 65 are able to stand and walk independently without any assistive devices, are able to walking independently without any assistive devices, electrodiagnostic tests have confirmed the presence of diabetic neuropathy

##### Exclusion criteria:

Diabetic ulcers in the legs, uncontrolled blood sugar, inner ear infection, neurological diseases (other than neuropathy) or other disorders of balance, history of recurrent ankle sprains in the past year, severe disturbing balance presence Any factor that disturbs the balance other than diabetic neuropathy

#### Age

From **30 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **66**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients are randomly assigned to balance or aerobic exercise in one of two groups using block randomization. To randomly assign two groups with 33 participants in each group (66 patients in total), we use block randomization with different block sizes. The size of the blocks is a multiple of 3 and a divisor of 66 (3,6,9). Initially, the size of the blocks is randomly selected. Then for each block, different permutations are determined for the size of the equal group. Finally, one of the permutations is randomly selected. Random numbers are generated using a computer in an independent statistical unit.

#### 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 mical university for the islamic republic of iran s Army

##### Street address

Imam Reza hospital, Etemad zade street, Fatemi street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718546

#### Approval date

2021-05-15, 1400/02/25

#### Ethics committee reference number

IR.AJAUMS.REC.1400.025

## Health conditions studied

### 1

#### Description of health condition studied

DIABETS

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

emg-ncv

#### Timepoint

Before intervention -8 weeks after intervention

#### Method of measurement

Using a emg-ncv machine

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

ntervention group 1 is treated with aerobic exercise in 24 sessions (3 days a week for 8 weeks).

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Intervention group 2 is treated with

balance exercises in 24 sessions (3 days a week for 8 weeks).

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital in Tehran

**Full name of responsible person**

Fatemeh Vashaei

**Street address**

Imam Reza hospital, Etemad zade street, Fatemi street

**City**

Tehran

**Province**

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**Postal code**

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**Phone**

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**Email**

f\_vashaei@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Fatemeh Vashaei

**Street address**

Imam Reza hospital, Etemad zade street, Fatemi street

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Artesh University of Medical Sciences

**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**

Artesh University of Medical Sciences

**Full name of responsible person**

Fatemeh Vashaei

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

f\_vashaei@yahoo.com

### Contact

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**Email**

## 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**

Undecided - It is not yet known if there will be 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