

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Effects of 12 Weeks Aerobic, Strength and Concurrent Training on Heart Rate Variability (HRV) and some Specification of Heart Structural in Type-2 Diabetic Neuropathy Men

#### Protocol summary

##### Summary

Objective: The aim of this study was to examine the effects of 12 weeks Aerobic, Strength and Concurrent Training on Heart Rate Variability (HRV) and some specification of heart structural in Type-2 Diabetic Neuropathy Men. Design: 60 male diabetic Neuropathy patients divided randomized into four groups: control (n=15), aerobic training (n=15), Strength training (n=15) and Concurrent training (n=15). Participants including major eligibility criteria: age 30-70 year; diabetic duration > 3 year; HbA1c  $\geq$  6.5; FBS  $\geq$  126 mg/dL; GTT  $\geq$  200 mg/dL; lack of regular physical activity, Lack of medical Prohibition from physical activity. Participants' exclusion major eligibility criteria: Cardiovascular disease; Cancer; Suspected Heart Disease; BMI > 40 kg; Absence from the exercise. The experimental group participated 3 sessions per week for 12 weeks based on the training schedule with defined intensity and duration (according to the standard protocol). Control group received no intervention. At the end of the third month, NCV and HRV tests, structural and functional characteristics of the heart, hematology, biochemistry, VO2MAX and body composition conducted again. The participants will not be trained for a month (Detraining) and for assessment the effect of detraining, the aforementioned tests will be taken again. Exercise training are an independent variables and heart rate variability, structural and functional characteristics are dependent variables.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042227529N1**

Registration date: **2017-05-01, 1396/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-05-01, 1396/02/11

##### Registrant information

###### Name

Elaheh Piralaity

###### Name of organization / entity

University of Tabriz

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3331 1696

###### Email address

epiralaity@tabrizu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2016-04-08, 1395/01/20

##### Expected recruitment end date

2016-10-21, 1395/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of 12 Weeks Aerobic, Strength and Concurrent Training on Heart Rate Variability (HRV) and some Specification of Heart Structural in Type-2 Diabetic Neuropathy Men

##### Public title

Effects of Exercise on Heart Rate Variability and  
Specification of Heart Structural in Diabetic Neuropathy  
Men

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Age 30-70 Year; diabetic duration > 3  
year; suffering from peripheral neuropathy; HbA1c  $\geq$  6.5;  
FBS  $\geq$  126 mg/dL; GTT  $\geq$  200 mg/dL; lack of regular  
physical activity, Lack of medical Prohibition from  
physical activity Exclusion criteria: Cardiovascular  
disease; Cancer; Suspected Heart Disease; BMI > 40  
kg/m<sup>2</sup>; Absence from the exercise

**Age**

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

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**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**

Vice chancellor for research, Tabriz University of  
Medical Sciences

**Street address**

Central Building- Number 2, Tabriz University of  
Medical Sciences, Golgasht St

**City**

Tabriz

**Postal code**

+98

**Approval date**

2016-10-10, 1395/07/19

**Ethics committee reference number**

IR.TBZMED.REC.1395.754

**Health conditions studied**

**1**

**Description of health condition studied**

Type-2 Diabetic Neuropathy

**ICD-10 code**

G63.2\*

**ICD-10 code description**

Diabetic polyneuropathy

**Primary outcomes**

**1**

**Description**

HRV

**Timepoint**

Pre test; mid test 1; mid test 2; post test

**Method of measurement**

Holter Monitoring VX3+

**2**

**Description**

Specification of Heart Structural and Functional

**Timepoint**

pre test; post test

**Method of measurement**

Echocardiography

**3**

**Description**

Hematology

**Timepoint**

pre test; post test

**Method of measurement**

Cell Counter

**4**

**Description**

Fbs, GTT

**Timepoint**

pre test; post test

**Method of measurement**

spectrophotometry

**5**

**Description**

Cholesterol; Triglycerides; HDL; LDL

**Timepoint**

pre test; post test

**Method of measurement**

spectrophotometry

**6**

**Description**

Insulin

**Timepoint**

pre test; post test

**Method of measurement**

Indirect immunofluorescence (IFA)

## 7

### **Description**

Body Composition

### **Timepoint**

Pre test; mid test 1; mid test 2; post test

### **Method of measurement**

Body Composition Monitor

## 8

### **Description**

Gas Analysis

### **Timepoint**

pre test; post test

### **Method of measurement**

Cortex Gas Analyser

## 9

### **Description**

Anthropomorphic Indices

### **Timepoint**

Pre test; mid test 1; mid test 2, post test

### **Method of measurement**

Tape Measure

## 10

### **Description**

Neuropathy

### **Timepoint**

pre test; post test

### **Method of measurement**

NCV test

## 11

### **Description**

HbA1c

### **Timepoint**

pre test, post test

### **Method of measurement**

Bionate Affinity Assay

## **Secondary outcomes**

## 1

### **Description**

Quality of Life

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

WHO quality of life-BREF 26 questionnaire; SF-36 questionnaire

## 2

### **Description**

Insulin Resistance

### **Timepoint**

pre test; post test

### **Method of measurement**

HOMA-IR

## 3

### **Description**

Depression

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

Beck's Depression Inventory

## 4

### **Description**

Medicinal Plants

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

Interview and Questionnaire

## 5

### **Description**

Family History of Diabetes

### **Timepoint**

In the past and during the research

### **Method of measurement**

Interview and Questionnaire

## 6

### **Description**

Self Efficacy

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

Sherer Self Efficacy Scale

## 7

### **Description**

Psychological Well-being

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

Ryff's Psychological Well-being Scales

## 8

### **Description**

Sleep Quality and Quantity

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

### **Method of measurement**

Sleep quality assessment(PSQI) and Sleep Duration

## 9

### **Description**

Spiritual Health

### **Timepoint**

Pre test; mid test 1; mid test 2; post test; detraining

#### Method of measurement

Ellison & Palutzian Spiritual Health

### Intervention groups

#### 1

##### Description

The experimental groups participated 3 sessions per week for 12 weeks based on the training schedule with defined severity and duration (according to the standard protocol). Control group received no intervention.

##### Category

Prevention

#### 2

##### Description

Control group received no intervention.

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

SINA Hospital

###### Full name of responsible person

Mr Hashemi

###### Street address

SINA Hospital, Azadi Blvd

###### City

Tabriz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice chancellor for research, University of Tabriz

###### Full name of responsible person

Eskandar Fathiazar

###### Street address

Floor 2, Central Bldg, Jame Jam St, 29 Blvd, University of Tabriz

###### City

Tabriz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research, University of Tabriz

##### Proportion provided by this source

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

#### 2

##### Sponsor

###### Name of organization / entity

Vice chancellor for research, University of Mohaghegh Ardabili

###### Full name of responsible person

Mohamad Narimani

###### Street address

University of Mohaghegh Ardabili, Central Bldg, Daneshgah St

###### City

Ardabil

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research, University of Mohaghegh Ardabili

##### Proportion provided by this source

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

### Person responsible for general inquiries

##### Contact

###### Name of organization / entity

University of Mohaghegh Ardabili, University of Tabriz

###### Full name of responsible person

Elaheh Piralaui

###### Position

Ph.D Student

###### Other areas of specialty/work

###### Street address

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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahar Branch, Islamic Azad University

**Full name of responsible person**

Mahboub Sheikhalizadeh