

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Immediate effect of vibrating sandal in swing phase of gait on postural indices and lower limb muscles activity in patients with moderate diabetic neuropathy compared with age-matched controls

#### Protocol summary

##### Study aim

Immediate effect of vibrating sandal on people with diabetic peripheral neuropathy

##### Design

Before-after clinical trial including normal control and intervention group (No randomisation). 10 normal control, 15 Diabetic

##### Settings and conduct

Biomechanical and gait laboratory of Tarbiat Modares University

##### Participants/Inclusion and exclusion criteria

elderly patients aged between 50-75 diagnosed with moderate diabetic peripheral neuropathy. no insulin treatment. no history of cardiovascular or lung disease, neurological disease, rheumatoid arthritis, severe osteoarthritis problem. Michigan neuropathy screening instrument (MNSI) score between 13-29. right dominant side. no severe retinopathy. lower limb muscles score based on manual muscle testing must be 4 (hip, knee and ankle muscles). normal range of motion in joints. HbA1c score between 6.5 - 9. no diabetic foot ulcer. no history of falling accidentally. no partnership in any kind of WBV training and exercise therapy course over last year. no interest to continue in this study.

##### Intervention groups

intervention group are elderly patients aged 50 to 75 diagnosed with moderate diabetic peripheral neuropathy who suffer from peripheral nervous system disorder which lead to balance deficiency and muscle disorder. in order to evaluate the effect of vibration on foot sole through wearing vibrating sandal and 10 minuets walking and at the end measuring the dynamic balance factors and muscles function. control group is healthy and the same age people with intervention group.

##### Main outcome variables

Sit to stand and Turn dynamic balance tests of Mars software: Center of pressure sway; cop sway velocity;

cop sway path, Reaction time; Movement velocity; Median frequency; Weight transfer ; Turn time; Turn sway Lower limb muscles function and activation: Mean actual error; SD of absolute error; maximum voluntary isometric contraction; Root mean square

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181108041593N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Niloofar Eslami ghelichi

##### Name of organization / entity

The University of Tarbiat Modares

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7670 1860

##### Email address

n.eslami@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-07, 1398/07/15

##### Expected recruitment end date

2020-02-04, 1398/11/15

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Immediate effect of vibrating sandal in swing phase of gait on postural indices and lower limb muscles activity in patients with moderate diabetic neuropathy compared with age-matched controls

**Public title**  
Effect of Vibration on dynamic balance

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Non insulin diabetic patients Diabetic patients with BMI between 25 and 30 Diabetic patients who diagnosed with diabetes between 8 to 12 years Neuropathic diabetic patients with Michigan score between 13 and 29 Diabetic patients with 75-200 mg fast blood sugar in test's day Diabetic patients who get at least 4 minus score in manual muscle test Diabetic patients with normal range of motion in hip, knee and ankle joints Diabetic patients with less than 9 and more than 5/6 Hba1c Diabetic patients with less than 140/90 and more than 100/70 blood pressure and less than 100 heart beat before starting tests Diabetic patients with right dominant side Diabetic patients with normal skin temperature in plantar surface, 30.6±2.6  
**Exclusion criteria:**  
 Special drug usage that interfere patient's balance Rhetinopathy and severe visual dysfunction Routine smoking and alcohol consumption History of unexpected falling Diabetic foot ulcer WBW trainings during recent one year Pes planus, Knee varus and valgus, severe kyphosis Postural hypotension Participating in regular physical, balance or resistance exercise program Pain, inflammation and swelling or severe arthrosis in lower limb joints Pain in mild and moderate osteoarthritic joints during previous one month Patient willingness to quit the research Orthopedic, nourologic diseases like stroke, parkinson, cerebral paralysis, poliomyelitis, rheumatoid arthritis, prosthesis, uncontrolled hypertension, severe cardiovascular disease such as severe coronary ischemia, acute cardiac disease and caridac arrhythmia

**Age**  
From **50 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: **25**

**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

Ethics committee of Tarbiat Modares University of Medical Sciences

##### Street address

No. 7, Nasr, Jalal AleAhmad Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

14115111

#### Approval date

2019-03-03, 1397/12/12

#### Ethics committee reference number

IR.MODARES.REC.1397.265

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committe on medical researches of Tarbiat Modares university

##### Street address

Jalal, Ale-Ahmad, Nasr

##### City

Tehran

##### Province

Tehran

##### Postal code

14111-115

#### Approval date

2019-03-02, 1397/12/11

#### Ethics committee reference number

IR..MODARES.REC.1397.265

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic peripheral neuropathy

#### ICD-10 code

E11.40

## ICD-10 code description

Type 2 diabetes mellitus with diabetic neuropathy,

## Primary outcomes

### 1

#### Description

Sit to stand and Turn dynamic balance tests of Mars software.

#### Timepoint

Immediately before and Immediately after functional task

#### Method of measurement

Dynamic balance tests by Kistler Mars Software

### 2

#### Description

Lower limb muscles function and activation

#### Timepoint

Immediately Before and Immediately after functional test

#### Method of measurement

Electromyography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Moderate diabetic neuropathy patients will use vibrating sandal in swing phase of walking.

#### Category

Diagnosis

### 2

#### Description

Control group: Matched normal subjects who same as diabetic group tested by vibration sandal.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tarbiat Modares University

##### Full name of responsible person

Roya ravanbod

##### Street address

No. 7, Nasr, Jalal AleAhmad Ave

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#### Phone

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royaravanbod@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The university of Tarbiat Modares

##### Full name of responsible person

Yaghoub Fathollahi

##### Street address

Jalal al ahmad street, nasr bridge, Tarbiat modares University, physiotherapy faculty, room No 225

##### City

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##### Fax

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##### Email

fatollahi@modares.ac.ir

##### Web page address

<https://www.modares.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Tarbiat modares University

#### 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

The University of Tarbiat Modares

##### Full name of responsible person

Niloofar Eslami ghelichi

##### Position

Student  
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Physiotherapy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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

Yes - There is 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

All the data will be shared after getting subject's identity indiscernible

### When the data will become available and for how long

six months after results publishing

### To whom data/document is available

people with activity in academic and scientific environment

### Under which criteria data/document could be used

Data would be useful and effective for diabetic neuropathy patients in order to increase the somatosensory feedback. Therefore, vibrating sandal could positive influence their functional dynamic daily living tasks.

### From where data/document is obtainable

Doctor Roya Ravanbod. email: rravanbod@hotmail.com  
tel: 02182884510

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

After the permission of vice chancellor of research of Tarbiat Modares university, the data could be available. This procedure might take about two months.

### Comments