

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The immediate effectiveness of a single session of Whole-Body Vibration in improving the balance in patients with Type 2 diabetic neuropathy

#### Protocol summary

##### Study aim

Determination of the Effect of Whole-Body Vibration in improving the balance in patients with Type 2 diabetic neuropathy

##### Design

A randomized, blinded, sham controlled clinical trial design of 32 patients, enrolled between January 2019 and August 2019

##### Settings and conduct

Whole body therapeutic vibration ,including non-invasive methods, is the improvement of Stability Indexes without Side Effects. This research aimed to determined effect of Whole body vibration therapy on Stability Indexes of People with Peripheral Diabetic Neuropathy in the School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences. in this study at first visit lower extremity neuropathy in 32 diabetic patients was meseared by clinical examination and Michigan questionnaire then demographic form and conscious consent form completed by the patients. After that their Stability Indexes was measured with Biodex Machine by researcher. In the next stage Whole body vibration is performed for 30 seconds and 6 times with one minute rest every time, and Stability Indexes are re-evaluated

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 40-75 years old with type 2 diabetes and europathy Diagnosis of Type 2 Diabetes, Taking medicine in the form of pills, Michigan test score, between 13-29, HbA1C <8.5%, BMI ranges from 25-35 exclusion criteria: En Infectious diabetic wounds, Neurological diseases and rheumatoid arthritis, balance and vestibular system, visual disturbances, Scarring in the areas of the foot and fingers, Severe pain in the lower extremities during the study, History of trauma, injury and surgery in the waist, Knee or hip prosthesis, Epilepsy and cognitive problems, The presence of psychotic diseases and depression, Active implants

##### Intervention groups

Vibration therapy

##### Main outcome variables

Functional Balance Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180302038912N1**

Registration date: **2019-07-09, 1398/04/18**

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

Last update: **2019-07-09, 1398/04/18**

Update count: **0**

##### Registration date

2019-07-09, 1398/04/18

##### Registrant information

##### Name

Elnaz Sohrabzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6612 4365

##### Email address

e.sohrabzadeh88@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-20, 1397/10/30

##### Expected recruitment end date

2019-08-21, 1398/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The immediate effectiveness of a single session of Whole-Body Vibration in improving the balance in patients with Type 2 diabetic neuropathy

**Public title**  
Effect of Whole-Body Vibration in balance

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 patients aged 40-75 years old with type 2 diabetes and neuropathy with the ability to walk independently at least 10 meters without assistance  
 Diagnosis of Type 2 Diabetes Taking medicine in the form of pills, Based on clinical guidelines  
 Michigan test score, between 13-29 (grade of diabetic neuropathy: moderate)  
 HbA1C <8.5% (controlled blood sugar in the last three months)  
 BMI ranges from 25-35  
**Exclusion criteria:**  
 Infectious diabetic wounds  
 Neurological diseases (other than diabetic neuropathy) and rheumatoid arthritis, balance and vestibular system, visual disturbances  
 Scarring in the areas of the foot and fingers  
 Severe pain in the lower extremities during the study  
 History of trauma, injury and surgery in the waist  
 Knee or hip prosthesis  
 Epilepsy and cognitive problems  
 The presence of psychotic diseases and depression  
 Active implants

**Age**  
From **40 years** old to **75 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **32**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization will be done using www.randomization.com to assign equal participants in each group (1:1 allocation). An independent researcher will make random allocation cards using computer-generated random numbers. he will keep the original random allocation sequences until analysis time. Another independent researcher will measure the patients outcome and she will not know the allocation.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Participants were blind about the grouping and assignments. Also group assignment listed were only accessed by study staff following completion of baseline assessments. Statistical analysts were also blind to the groups.

**Placebo**  
Used

**Assignment**  
Other

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Arabi Ave., Yaman Ave., Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

#### Approval date

2018-04-09, 1397/01/20

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1396.1399

## Health conditions studied

### 1

#### Description of health condition studied

diabetic neuropathy

#### ICD-10 code

E14

#### ICD-10 code description

With neurological complication

## Primary outcomes

### 1

#### Description

balance

#### Timepoint

Immediately before and after intervention

#### Method of measurement

Biodex machine

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Vibration therapy

**Category**

Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Physiotherapy Clinic of School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sci

**Full name of responsible person**

Elnaz Sohrabzadeh

**Street address**

Damavand Ave., Imam Hossein Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1616913111

**Phone**

+98 21 7756 1721

**Email**

e.sohrabzadeh88@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Rezaei Tavirani

**Street address**

Shahid Arabi Ave., Yaman Ave., Shahid Chamran Highway

**City**

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**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 23871

**Email**

e.sohrabzadeh88@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elnaz Sohrabzadeh

**Position**

MSc Physiotherapy

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Contact**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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**

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