

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Tehran

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

Street address

Damavand Ave., Imam Hossein Square

City

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Postal code

1616913111

Phone

+98 21 7756 1721

Email

e.sohrabzadeh88@gmail.com

Person responsible for scientific 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

Street address

Damavand Avenue., Imam Hossein Square

City

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+98 21 7756 1721

Email

e.sohrabzadeh88@gmail.com

Person responsible for updating data

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

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Street address

Damavand Ave., Imam Hossein Square

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+98 21 7756 1721

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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