Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 europathy with 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
Tehran
Province
Tehran
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
Tehran
Province
Tehran
Postal code
1616913111
Phone
+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
Physiotherapy

Street address
Damavand Ave., Imam Hossein Square

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 21 7756 1721

Email
e.sohrabzadeh88@gmail.com

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