

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 minutes 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

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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, nurologic 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 arhythmia

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 committee on medical researches of Tarbiat Modares university

Street address

Jalal, Ale-Ahmad, Nasr

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of Tarbiat Modares

Full name of responsible person

Yaghoub Fathollahi

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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

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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