Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
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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, nourologic diseases like stroke, parkinson, cerebral paralysis, poliomyelis, rheumatoid arthritis, prostheis, 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

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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

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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
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Sponsors / Funding sources

1

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Web page address
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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
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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