

Clinical Trial Protocol

Iranian Registry of Clinical Trials

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Effects of Whole Body Vibration on balance of diabetic type2 patients' neuropathy.

Protocol summary

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Summary

Aim: Effects of WBV on diabetic type 2 patients with neuropathy. Design and intervention: Twenty diabetic type 2 patients with neuropathy will be divided to control and intervention groups in this study. Intervention group will receive WBV for 6 weeks twice a week. Inclusion criteria: BMI between 25 and 35- age between 50 and 70; mild (7-12) to moderate (13-29) neuropathy according to MDNI. Exclusion criteria: visual disturbances; epilepsy; umbilical or abdominal herniation; kidney or bladder stone; and severe cardio pulmonary disease. After treatment course balance and strength factors will be compared between study groups.

Recruitment status

Recruitment complete

Funding source

Rehabilitation Faculty- Diabetes and Metabolic disorders Research Centre

Expected recruitment start date

2011-04-30, 1390/02/10

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

WBV= whole body vibration

IRCT registration information

IRCT registration number: **IRCT201106156806N1**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Amin Kordi Yoosefinejad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7762 9011

Email address

Scientific title

Effects of Whole Body Vibration on balance of diabetic type2 patients' neuropathy.

Public title

Effect of Exercise Therapy on Diabetes type2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being a case for diabetes type 2; Body Mass Index between 25 to 35 and mild to moderate neuropathic involvement according to MNSI Exclusion criteria: Visual disturbances; Epilepsy; Umbilical, abdominal or disc herniation; acute infection; fracture or sprain for recent 6 weeks; migraine; kidney or bladder stone; severe cardio vascular disease; regular exercise; severe osteoporosis and dDrugs affecting balance

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 20

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Rehabilitation Faculty Ethics Committee

Street address
Piche shemiran

City
Tehran

Postal code

Approval date
2011-02-07, 1389/11/18

Ethics committee reference number
260/621

Health conditions studied

1

Description of health condition studied
Diabetic Mellitus type 2 with Peripheral neuropathy

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Balance- Specific and General muscle strength

Timepoint
6 weeks

Method of measurement
Force Plate- Dynamometer- Chest Back Leg Apparatus

Secondary outcomes

1

Description
Blood profiles including FBS, HbA1C, TG, Cholesterol

Timepoint
6 weeks

Method of measurement
Blood Routine Tests: Blood sample(5 cc) from antebachial vein before breakfast

Intervention groups

1

Description
Control group: patients do not receive any treatment during this 6 weeks.

Category
N/A

2

Description
Intervention Group: patients receive WBV for 6 weeks

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation Faculty of TUMS- Diabetes and Metabolic disorders research centre

Full name of responsible person
Dr Mohajeri Tehrani

Street address
Shariaati hospital- Metabolic and Endocrine diseases centre

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rehabilitation Faculty of TUMS- Diabetes and Metabolism disorders Centre

Full name of responsible person
Amin Kordi Yoosefinejad

Street address
Rehabilitation Faculty of Teran University of Medical Sciences

City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rehabilitation Faculty of TUMS- Diabetes and Metabolism disorders Centre

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Rehabilitation Faculty

Full name of responsible person

Amin Kordi Yoosefinejad

Position

PhD student of Physical Therapy

Other areas of specialty/work**Street address**

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Rehabilitation Faculty of Tehran University of Medical Sciences

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty