Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of functional balance, dynamic balance, and neuropathic changes in patients with Type 2 diabetes following ankle proprioceptive training

Protocol summary

Study aim

Evaluation of functional balance, dynamic balance, and neuropathic changes in patients with Type 2 diabetes following ankle proprioceptive training

Design

Semi experimental study, 24 patients with type 2 diabetes and moderate neuropathy with abscence of control group, not randomized and convenience with blinded outcome assessor

Settings and conduct

This study evaluates the functional balance, dynamic balance, and neuropathic changes in type 2 diabetic patients with neuropathy following ankle proprioceptive training. At first Patients refer to the endocrinology clinic and then qualified patients will perform balance and neuropathy tests in Shahid Beheshti Rehabilitation Faculty Laboratory and clinic at different Sessions. The exercises will perform on balance boards in different modes for 10 sessions. The study is single blinded by individual assignment as an outcome assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria : patients aged 40-65 years old with at least five years history of type 2 diabetes and neuropathy, Fasting Blood Sugar ≥126 mg/dl, manual muscle test with degree ≥ 3 in the ankle muscles, Visual test score of at least 20.40 at dominant eye, Body Mass Index between 25-29.9 kg.m2 with vibration perception disorder. Exclusion criteria : patients with foot ulcer, non-diabetic neuropathy, orthopedic, neurologic and amputation problems.

Intervention groups

The exercises will perform on Wobble and Rocker boards in both plantar and dorsi, right and left directions for 10 sessions. Each exercise conducts for five times and each time takes 15s to perform with a 45s rest between the repetitions. Walking and training programs is also planned to monitor blood glucose.

Main outcome variables

Anterior Posterior, Medial Lateral and Overall stability index, Functional Reach Test, Time Up and Go Test, Vibration perception, Skin sensation perception

General information

Reason for update

The study is over. it is also necessary to make some minor changes, for example in the title.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039250N1**
Registration date: **2018-11-08, 1397/08/17**
Registration timing: **prospective**

Last update: **2021-10-23, 1400/08/01**
Update count: **1**

Registration date

2018-11-08, 1397/08/17

Registrant information

Name
Mahdieh Ravand
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 29901
Email address
ravand@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-17, 1397/08/26

Expected recruitment end date

2019-03-17, 1397/12/26

Actual recruitment start date

2018-12-12, 1397/09/21

Actual recruitment end date

2019-09-16, 1398/06/25

Trial completion date

2019-09-16, 1398/06/25

Scientific title

Evaluation of functional balance, dynamic balance, and neuropathic changes in patients with Type 2 diabetes following ankle proprioceptive training

Public title

Evaluation of balance and neuropathic changes in type 2 diabetic patients.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 40 to 65 years old with type 2 diabetes and neuropathy Patients with ability to walk at least 10 meters without assistance Fasting Blood Sugar≥126 mg/dl or 7 mmol/l A1c between 7 to 9 Manual muscle test with degree ≥ 3 in plantars, dorsi flexors, evertors, and invertors Minimum Visual test scale should be 20/40 at dominant eye Vibratory perception test with diapason (difference in absence vibratory perception between assessors and patients > 10 seconds) Skin pressure perception test with monofilament Body Mass Index between 25- 29.9 The absence of diabetic ulcers in either foot or ankle during the study The absence of severe pain in the lower extremities during the study The patients should not be involved in regular physical training during the previous 3 months

Exclusion criteria:

Lower extremity fracture Lower extremity dislocation Surgery or Lower extremity amputation Cardiac autonomic neuropathy (drop in systolic blood pressure of 20 mmHg or diastolic blood pressure of 10mmHg within three minutes after changing the body position from supine to standing.) Non-diabetic neuropathies Vestibular system disease Internal ear infections Other neurological pathologies Sever vascular disease (palpation of the posterior of tibial artery and dorsalis pedis)

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding outcome assessor by employing a person other than the researcher in order to reduce the bias in the study

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Shahid Beheshti University Of Medical Science

Street address

Physiotherapy group, Rehabilitation Science School Of Shahid Beheshti Medical University., Damavnd Ave

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.589

Health conditions studied

1

Description of health condition studied

Involvement of distal regions of limbs in type 2 diabetic patients with peripheral neuropathy

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

Blood sugar

Timepoint

At the begining of the research

Method of measurement

Glucometer

2

Description
Stability Index " Anterior Posterior(AP), Medial Lateral (ML) and Overall "
Timepoint
At the begining of the research , After 2 weeks, After intervention (After 10 Sessions), After 2 weeks follow up
Method of measurement
Biodex Balance System

3

Description
Physical performance
Timepoint
At the begining of the research , After 2 weeks, After intervention (After 10 Sessions), After 2 weeks follow up
Method of measurement
Functinal performance tests (Functional Reach Test, Time Up and Go Test test)

4

Description
Vibratory perception, Skin pressure perception, Achilles tendon reflex
Timepoint
At the begining of the research , After 2 weeks, After intervention (After 10 Sessions), After 2 weeks follow up
Method of measurement
128 Hz diapason, Monofilament, Hammer Reflex

Secondary outcomes

1

Description
Neuropathy assessment
Timepoint
At the begining of the research, After 2 weeks, After intervention (After 10 sessions), After 2 weeks follow up
Method of measurement
Valk questionnaire (10 questions)

2

Description
Neuropathy assessment
Timepoint
At the begining of the research, After 2 weeks, After intervention (After 10 sessions), After 2 weeks follow up
Method of measurement
Michigan questionnaire (includs two parts of the history and physical assessment)

3

Description
Light Touch Sense
Timepoint
At the begining of the research, After 2 weeks, After intervention (After 10 sessions), After 2 weeks follow up
Method of measurement
Brushing

Intervention groups

1

Description
Ankle proprioception exercise composed of training on the rocker and wobble boards and on both feet. Rocker board exercise will perform in both plantar & dorsi, right & left directions. Each exercise will perform five times, each time takes 15s and there is 45s rest between the repititions. Progress training are including eyes open and head forward, eyes closed and head forward, eyes open and head back, eyes closed and head back, decreasing the visual and vestibular inputs, the amount of external support and rest interval and increasing the exercise duration gradually during sessions. Also they have walking program twice a week for 30 minutes and have general instructions for blood glucose control
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Institute of Shariati Hospital
Full name of responsible person
Mohammad Reza Mohajeri Tehrani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Akbarzade baghban
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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
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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
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
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

No - There is not a plan to make this available

Title and more details about the data/document

All collected data can be shared after deidentification of the patients

When the data will become available and for how long

All the data can be available 3 months after publication

To whom data/document is available

All of the academic researchers and clinicians

Under which criteria data/document could be used

Research & therapeutic use is permitted

From where data/document is obtainable

Contact with corresponding

What processes are involved for a request to access data/document

Accurate features of applicant

Comments