

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 absence 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  $\geq 126$  mg/dl, manual muscle test with degree  $\geq 3$  in the ankle muscles, Visual test score of at least 20.40 at dominant eye, Body Mass Index between 25-29.9 kg.m<sup>2</sup> 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

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##### 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  $\geq$  126 mg/dl or 7 mmol/l A1c between 7 to 9 Manual muscle test with degree  $\geq$  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 beginning 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 beginning of the research , After 2 weeks, After intervention (After 10 Sessions ), After 2 weeks follow up

### **Method of measurement**

Functional performance tests ( Functional Reach Test, Time Up and Go Test test )

## 4

### **Description**

Vibratory perception, Skin pressure perception, Achilles tendon reflex

### **Timepoint**

At the beginning 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 beginning 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 beginning of the research, After 2 weeks, After intervention ( After 10 sessions), After 2 weeks follow up

### **Method of measurement**

Michigan questionnaire ( includes two parts of the history and physical assessment )

## 3

### **Description**

Light Touch Sense

### **Timepoint**

At the beginning 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 repetitions. 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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Shariati Hospital, Shomali Kargar Ave,

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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

#### **Street address**

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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**  
Mahdieh Ravand  
**Position**  
Phd Student  
**Latest degree**  
Master  
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Physiotherapy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**