

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of whole body vibration on muscle mass, biomechanical parameters and metabolic factors in diabetic patients with sarcopenia

Protocol summary

Study aim

Investigating the effect of whole body vibration on muscle mass, muscle strength, biomechanical parameters of gait and balance, glucose metabolism factors and inflammatory factors in people with diabetic sarcopenia

Design

People with diabetic sarcopenia are randomly (with block randomization method) divided into intervention group (with whole body vibration) and control group (without vibration). The clinical trial has a randomized control group with a sample size of 60. There is no trial phase.

Settings and conduct

This study would be conducted at the Movement Disorders Research Center of Tarbiat Modares University and the Endocrine Center of Tehran University of Medical Sciences. The subjects under study are patients with diabetic sarcopenia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic patients who have been diagnosed for at least 6 months and are diagnosed with sarcopenia according to the diagnostic parameters; age between 60 to 80 years old; Exclusion criteria: History of acute ischemia in the past 6 months; GFR score above 30; neuropathy score above 13; suffering from thyroid problems.

Intervention groups

The intervention group will receive 12 weeks of whole body vibration. The control group will receive any intervention during 12 weeks.

Main outcome variables

Ground Reaction Force parameters, body sway parameters, quality of life questioner , body mass parameters

General information

Reason for update

Update study information

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049511N6**

Registration date: **2024-01-16, 1402/10/26**

Registration timing: **prospective**

Last update: **2025-05-02, 1404/02/12**

Update count: **1**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

Sahar Boozari

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 5053

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of whole body vibration on muscle mass, biomechanical parameters and metabolic factors in diabetic patients with sarcopenia

Public title

The effect of whole body vibration on patients with diabetic sarcopenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 6 months history of diabetes
Diagnosis of sarcopenia in people with diabetes
Score less than 13 on Michigan Neuropathy Screening Instrument

Exclusion criteria:

Having thyroid disorders
GFR score above 30
History of acute ischemia such as infarction in less than 3 months
History of falling in the past year
Taking drugs and supplements that have known effects on the neuromuscular system (such as corticosteroids)

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done by block randomization method. Participants will be randomly assigned into intervention or control groups. The size of blocks will be 4. Also, the blocks will be randomly placed in the envelopes. For random assignment, code 1 denotes the intervention group and code 0 denotes the control group in the envelopes. Subjects will choose an envelope and then, based on the chosen code, they are assigned to one of the groups.

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**

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2023-11-26, 1402/09/05

Ethics committee reference number

IR.MODARES.REC.1402.123

Health conditions studied**1****Description of health condition studied**

Sarcopenia

ICD-10 code

M62.84

ICD-10 code description

Sarcopenia

2**Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Ground Reaction Force Parameters

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Force plate device

2**Description**

Quality of Life Index

Timepoint

Before and after 12 weeks of interventions

Method of measurement

SarQoL questionnaire

3**Description**

Parameters of the body sway

Timepoint

قبل و بعد از 12 هفته مداخله

Method of measurement

Force plate

4

Description

body mass parameters

Timepoint

قبل و بعد از 12 هفته مداخله

Method of measurement

DXA

Secondary outcomes

1

Description

Muscle strength

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Dynamometer

2

Description

lipid profile

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Blood test

3

Description

fasting blood sugar(FBS)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Blood test

4

Description

glycated hemoglobin (A1C)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Blood test

5

Description

inflammation factors

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: The intervention consists of 12 weeks of whole body vibration for individuals with diabetic sarcopenia. In the first session, after registering the basic information and getting familiar with how to perform the tests, the subjects will perform biomechanical and blood tests and then the variables will be recorded. In the next sessions, people should perform 3 times a week for 12 weeks, 5 to 12 vibration sets each with 60 seconds of vibration and 30 seconds of rest. After the end of 12 weeks, the final assessment session will be done in the laboratory like the first session. If subjects complete 80% of the sessions, which includes at least 30 treatment sessions, they will be included in the statistical analysis.

Category

Treatment - Other

2

Description

Control group: This group will not receive any vibration and the subjects will be evaluated before and after 12 weeks. In the first session, after registering the basic information and getting familiar with how to perform the tests, the subject will perform biomechanical and blood tests and then the variables will be recorded. After the end of 12 weeks, the final assessment session will be done in the laboratory like the first session.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Treatment Center for Movement Disorders of Tarbiat Modares University

Full name of responsible person

Sahar Boozari

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2

Recruitment center

Name of recruitment center

Research Institute of Endocrinology and Metabolism,
Tehran University of Medical Sciences

Full name of responsible person

Gita Shafiee

Street address

Research Institute of Endocrinology and Metabolism,
Tehran University of Medical Sciences ,Next to Dr.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tarbiat Modares

Full name of responsible person

Amir Abdollahzadeh

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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

University of Tarbiat Modares

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Research Institute of Endocrinology and Metabolism,
Tehran Faculty of Medical Sciences

Full name of responsible person

Azadeh Shahbazi

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Email

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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

Research Institute of Endocrinology and Metabolism,
Tehran Faculty of Medical Sciences

Proportion provided by this source

50

Public or private sector

Private

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

Motahare Ababaf Behbahani

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Sahar Boozari

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

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Position

Assistant Professor

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Other areas of specialty/work

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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

Information about the main outcome can be shared when
the subjects be made unidentifiable.

When the data will become available and for how long

The access phase starts six months after the results
publication

To whom data/document is available

Researchers in academic and research organizations will
have access to the data.

Under which criteria data/document could be used

To do scientific research

From where data/document is obtainable

Sahar Boozari, Address: Tarbiat Modares University; Jalal
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What processes are involved for a request to access data/document

After sending the project plan and a complete evaluation
of the persons and organizations involved in the project,
the data will be sent following the approval.

Comments