Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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. Shariati Hospital, Jalal Al ahmad Highw
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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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  Endocrinology and Metabolism Research Institute, Next to Shariati Hospital, Jalal Al Ahmad Highway
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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**

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Person responsible for scientific inquiries

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Assistant Professor
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Person responsible for updating data

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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, Adress: Tarbiat Modares University; Jalal Al Ahmad Highway; Email: s.boozari@modares.ac.ir; Phone number: 00982182885053
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