Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of whole body vibration on ankle joint proprioception and balance in diabetic neuropathy patients

Protocol summary

Study aim

The aim of this study is investigating the effect of whole body vibration on ankle joint proprioception and balance in diabetic neuropathy patients.

Design

The clinical trial is included a control group and a sample size of 26 persons that are assigned to either intervention or control group with regard to random number table.

Settings and conduct

This study will be carried out at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. The intervention group is progressively undergoing WBV twice a week for 6 weeks.Both in the intervention group and in the control group static and dynamic balance and ankle proprioception are measured by Biodex System at the beginning of the study and after the first session and after 6 weeks of intervention and one month after the end of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having diabetes that lasts at least 5 years from their diabetes. Age 40 to 65 years؛ Exclusion criteria: Having a diabetic wound in the foot Internal ear disorder Neurology and rheumatology diseases Severe osteoarthritis in the lower limb joints

Intervention groups

Intervention group (whole body vibration): undergo whole body vibration progressively 2 times a week for 6 weeks. Control group: They are matched with the intervention group regarding to age, duration of diabetes and severity of neuropathy and do not receive any intervention.

Main outcome variables

Static stability index؛ dynamic stability index؛ functional balance؛ ankle reconstruction error from a reference angle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045369N1**
Registration date: **2019-12-09, 1398/09/18**
Registration timing: **prospective**

Last update: **2019-12-09, 1398/09/18**
Update count: **0**

Registration date

2019-12-09, 1398/09/18

Registrant information

Name

Hamed Manafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3444 6616

Email address

hamedmanafi3654@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of whole body vibration on ankle joint proprioception and balance in diabetic neuropathy patients

Public title
whole body vibration and diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having diabetes that lasts at least 5 years. Age 40 to 65 years BMI 22-30 kg / m2 Earning the score above 2 on the basis of questionnaire on diabetic neuropathy test scale of the University of Göringen in Netherlands that means existence of diabetic neuropathy.
Exclusion criteria:
Having a diabetic wound in the foot Internal ear disorder History of ankle dislocation and charcot joint Neurology and rheumatology diseases Severe osteoarthritis in the lower limb joints Visual disorders Vertigo Participation in balance, resistance or endurance exercise programs in the last year
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **26**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization is applied by using the random number table. Individuals with diabetic neuropathy are voluntarily recruited to the study and after completing the consent form are included in the study by matching with inclusion and exclusion criteria.Then each participant is devoted a number and the numbers are given to an assignment expert. The expert uses random number table to put individuals into two groups, intervention (whole body vibration) or control group.
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 Semnan University of Medical Sciences
Street address
Ethics committee of Semnan University of Medical Sciences, Basij Blvd
City
Semnan
Province
Semnan
Postal code
3519899951
Approval date
2019-11-19, 1398/08/28
Ethics committee reference number
IR.SEMUMS.REC.1398.206

Health conditions studied

1

Description of health condition studied
Diabetic Neuropathy
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Static stability index in anteroposterior, mediolateral and overal axes
Timepoint
At the beginning of the study, after the first session, after 6 weeks of intervention and one month after the end of intervention in both groups.
Method of measurement
Based on Biodex Balance System (millimeter)

2

Description
Dynamic stability index in anteroposterior, mediolateral and overal axes
Timepoint
At the beginning of the study, after the first session, after 6 weeks of intervention and one month after the end of intervention in both groups.
Method of measurement
Based on Biodex Balance System(milimeter)

3

Description
Functional balance
Timepoint

At the beginning of the study, after the first session, after 6 weeks of intervention and one month after the end of intervention in both groups.

Method of measurement

Berg Balance score

4

Description

Ankle reconstruction error from a reference angle (proprioception)

Timepoint

At the beginning of the study, after the first session, after 6 weeks of intervention and one month after the end of intervention in both groups.

Method of measurement

Based on Biodex System (degree)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive whole body vibration (WBV) progressivly 2 times a week for 6 weeks.In the first week, WBV with 30 Hz frequency, 2mm amplitude is applied five times for 30 seconds , with 1 minute rest between periods. During the following week, the frequency and amplitude are kept the same, but the WBV change to five times for 45 seconds, with 1 minute rest between periods. During the last week, the patient undergoes WBV five times for 1 minute, with 1 minute rest between periods.

Category

Rehabilitation

2

Description

Control group: They do not receive any intervention. In this group, all subjects will be evaluated for static and dynamic balance and proprioception before beginning the study, after the first session, after 6 weeks of intervention and one month after the end of intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Atefe Aminian Far

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Sq

City

Semnan

Province

Semnan

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3513138111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Fax

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Atefe Aminian Far

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Sq

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Atefe Aminian Far

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hamed Manafi

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

It will only be available to researchers working in academic institutions.

Under which criteria data/document could be used

If there are any relevant studies

From where data/document is obtainable

Atefe Aminian Far. Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Sq Tel: 0098 23 33654180 Postal code: 3513138111

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

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Comments