Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The immediate and delayed effects of whole body vibration on the static balance during cognitive tasks in patients with chronic ankle sprain

Protocol summary

Study aim
To evaluate the effect of 1 and 12 sessions of vibration training on the displacement of the center of pressure in people with chronic ankle sprain while maintaining a standing balance that is simultaneously conducting a cognitive activity.

Design
A controlled clinical trial in the thirty two patients and healthy

Settings and conduct
This study will be carried out at the Neuromuscular Rehabilitation Center of Semnan University of Medical Sciences. In the intervention group, the static balance will be evaluated in the standing position on the affected ankle on the force plate. Then, an experienced physiotherapist will intervened patients for 12 sessions, 2 sessions per week for 6 weeks, via the whole body vibration. Training in each session consists of 3 series of 4-trials for 45-second with 45-second of rest between each trials. After the intervention in the first session and session 12, the balance will be evaluated. Healthy matched group according to the BMI and sex will be evaluated for the static balance.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. People with chronic ankle sprain who have had a history of at least 1 sprain over the past 2 years. 2. Having giving way for at least 2 times in the history of chronic ankle sprain 3-score 24 ≤ based on the Cumberland Ankle Instability Tool. Exclusion criteria: 1. Neuromuscular disorders, ear and balance disorder, Addiction and consumption of psychoactive drugs 2. History of surgery and fractures of the lower limb and cardiovascular diseases

Intervention groups
The patients with chronic ankle sprain is placed in the intervention group and will be subjected to whole vibration for 12 sessions. The control group, which will only evaluate the parameters of the displacement of the center of pressure.

Main outcome variables
The parameters of the center of pressure in standing position on the affected foot

General information

Reason for update

Acronym
WBV

IRCT registration information
IRCT registration number: **IRCT20160808029264N3**
Registration date: **2019-02-28, 1397/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-28, 1397/12/09**
Update count: **0**

Registration date
2019-02-28, 1397/12/09

Registrant information

Name
Rasool Bagheri
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
1919-04-22, 1298/02/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The immediate and delayed effects of whole body vibration on the static balance during cognitive tasks in patients with chronic ankle sprain

Public title
The effect of whole body vibration on ankle sprain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. People with chronic ankle sprain who have had a history of at least 1 degree of torsion over the past 2 years. 2. Having at least 2 times the empty leg in the history of chronic ankle sprain 3-score of 24≤ based on the Cumberland Ankle Instability Tool
Exclusion criteria:
Memory impairment and neurological defects such as dementia, Parkinson's disease, brain trauma, encephalitis, dizziness and anemia, diabetes and ear disorder and addiction History of surgery and fractures of the lower limb History of cardiovascular disease History of any disturbance affecting the balance system use of psychoactive drugs
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Comitee of Semnan University of Medical Sciences
Street address
Basij Blvd.,Semnan., Semnan Province
City
Semnan
Province
Semnan
Postal code
99951-35198
Approval date
2019-02-20, 1397/12/01
Ethics committee reference number
IR.SEMUMS.REC.1397.267

Health conditions studied

1

Description of health condition studied
Chronic ankle sprain
ICD-10 code
S93.4
ICD-10 code description
Sprain of ankle

Primary outcomes

1

Description
Center of pressure displacement on the force plate in both patients and healthy groups
Timepoint
Before, immediately after sessions 1 and 12 and 1 times in healthy group
Method of measurement
Force plate

Secondary outcomes

1

Description
pain
Timepoint
Before and immediately after the 1th and 12th sessions
Method of measurement
A 100-mm numerical pain questionnaire

Intervention groups

1

Description
Intervention group: Whole body vibration for 12 sessions and 2 sessions per week for 6 weeks. 3sets of 4 repetition with 45 second hold and 45 second rest between trials will performed.
Category
Rehabilitation

2

Description
Control group: There will be no intervention in the healthy control group.In this group, everyone will be assessed once for the static balance.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn-e-Sina Rehabilitation Clinic
Full name of responsible person
Rasool Bagheri
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Sponsors / Funding sources

1

Sponsor
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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
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Position
Assisstant professor
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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
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