

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 intervene 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 $24 \leq$ 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

rasool.bagheri@gmail.com

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 $24 \leq$ 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 Comittee 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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Next to Sepah Bank., 17 shahrivar Blvd., Semnan town

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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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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

Rasool Bagheri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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