

# 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 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

##### Street address

Next to Sepah Bank., 17 shahrivar Blvd., Semnan town

##### City

Semnan

##### Province

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##### Postal code

3513135111

##### Phone

+98 23 3336 4180

##### Email

rasool.bagheri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Rasool Bagheri

##### Street address

Basij Blvd., Semnan., Semnan Province

##### City

Semnan

##### Province

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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 scientific inquiries

### Contact

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#### Position

Assistant professor

#### Latest degree

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Km 5 Damghan Road., Semnan University of Medical Sciences., School of Rehabilitation., Semnan town

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## Person responsible for updating data

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Semnan University of Medical Sciences

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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