

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the effect of vibratory and non-vibratory orthosis on sensorimotor function in people with chronic ankle instability

#### Protocol summary

##### Study aim

Comparison of the effect of two types of vibrating and non-vibrating ankle orthosis on sensory-motor function in people with chronic ankle sprain after a 4 weeks of using the orthosis

##### Design

A clinical trial with a control group, with parallel groups, randomized, on 57 patients. Randomization will be used by 2, 4, and 6 blocks.

##### Settings and conduct

Muscle reaction time, posture control, and proprioception will be evaluated before the intervention and 4 weeks after receiving the ankle support. Measuring tools include surface electromyography, force plate, and biodex isokinetic. The place of the tests is the Sport Sciences Research Institute of Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: history of at least 1 ankle sprain; the primary sprain must have occurred at least 12 months prior to study participation; the sprain was accompanied by inflammatory symptoms (pain, swelling, etc.); sprain that leads to at least 1 day away from daily activities; the last injury must have occurred more than 3 months before participating in the study; feeling of emptying and ankle instability; at least 2 episodes of giving way in the 6 months prior to study participation; a score of less than 24 on the Cumberland Instability Instrument; have not received treatment in the last 3 months; age 18-60 years old. Exit criteria: history of previous surgeries on musculoskeletal structures (eg, bones, joint structures, nerves) in any lower limb; history of fracture in any of the lower limbs.

##### Intervention groups

This clinical trial includes an intervention group and a control group. In the intervention group, vibrating ankle orthosis is used. And in the control group, an ankle orthosis without vibration will be used.

##### Main outcome variables

Peroneus longus and brevis muscle reaction time;

proprioception; posture control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181021041400N2**

Registration date: **2023-02-20, 1401/12/01**

Registration timing: **prospective**

Last update: **2023-02-20, 1401/12/01**

Update count: **0**

##### Registration date

2023-02-20, 1401/12/01

##### Registrant information

##### Name

Behnam Hajiaghaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 0947

##### Email address

hajiaghaei.b@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-12, 1402/02/22

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of vibratory and non-vibratory orthosis on sensorimotor function in people with chronic ankle instability

### Public title

Comparison of the effects of two types of vibrating and non-vibrating ankle orthoses on balance, proprioception, and reaction time of ankle muscles in people with chronic ankle instability

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

History of at least 1 ankle sprain 1.1. The first sprain must have occurred at least 12 months prior to study participation. 1.2. The sprain is accompanied by inflammatory symptoms (pain, swelling, etc.). The last injury must have occurred more than 3 months before participating in the study. Feeling of emptying and ankle instability 2.1. At least 2 episodes of giving way in the 6 months prior to study participation. 2.2. A score of less than 24 on the Cumberland Instability Instrument Have not received treatment in the last 3 months. Age 60-18 years old

#### Exclusion criteria:

History of previous surgeries on musculoskeletal structures (eg, bones, joint structures, nerves) in any lower limb History of fracture in any lower limb Acute injury to musculoskeletal structures of other joints of the lower limb in Past 3 months that has affected joint integrity and function resulting in at least 1 day away from daily activity

### Age

From **18 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **57**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be done in blocks with 2, 4, and 6 blocks. Also, random concealment is done by using sealed opaque envelopes with a random sequence. the first randomization is created and based on the opaque envelope sample size. Random number cards are placed inside the envelope. Then the participants choose the envelopes.

### 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 Iran University of Medical Sciences

##### Street address

Next to the Milad Tower; Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2023-01-02, 1401/10/12

#### Ethics committee reference number

IR.IUMS.REC.1401.794

## Health conditions studied

### 1

#### Description of health condition studied

Chronic ankle instability

#### ICD-10 code

S93.4

#### ICD-10 code description

Sprain and strain of ankle

## Primary outcomes

### 1

#### Description

Reaction time of peroneus longus and brevis muscle during external perturbation.

#### Timepoint

Before the start of the study and 4 weeks after using the orthosis.

#### Method of measurement

Surface electromyography 8 canals Myon brand

### 2

#### Description

Postural control

#### Timepoint

Before the start of the study and 4 weeks after using the orthosis

#### Method of measurement

Force plate AMTI, Germany

### 3

#### **Description**

Proprioception

#### **Timepoint**

Before the start of the study and 4 weeks after using the orthosis

#### **Method of measurement**

Biodex Multi-Joint Systems, Germany

## **Secondary outcomes**

### 1

#### **Description**

Quality of life

#### **Timepoint**

Before starting and 4 weeks after using the orthosis

#### **Method of measurement**

Foot and Ankle Ability Measure (FAMM) questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: Ankle orthosis with Vibration. This type of orthosis consists of a supporting part and a vibrating part. Its supporting part is made of neoprene and thermoplastic and covers up to 10 centimeters above the wrist. The vibration section also consists of vibration motors. This vibration will be applied to the outer part of the ankle. The vibration frequency will be 100 Hz. Each participant will wear the orthosis for 6 hours per day for 4 weeks, but will only receive vibration for 30 minutes while walking.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Ankle orthosis without Vibration. This type of orthosis is made of only one supporting part. The supporting part is made of neoprene and thermoplastic and covers up to 10 centimeters above the wrist. Each participant will wear this orthosis for 6 hours every day for 4 weeks.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

School of Rehabilitation Sciences , Iran University of Medical Sciences

##### **Full name of responsible person**

Behnam Hajiaghaei

##### **Street address**

Iran University of Medical Sciences, Faculty of Rehabilitation sciences, ShahNazari St, Mother Sq, Mirdamad Blvd

##### **City**

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##### **Postal code**

1545913487

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##### **Email**

hajiaghaei.b@iums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Hossein Keyvan

##### **Street address**

Next to the Milad Tower; Hemmat Highway

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##### **Phone**

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##### **Email**

research@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Iran University of Medical Sciences

#### **Proportion provided by this source**

50

#### **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**

Iran University of Medical Sciences

##### **Full name of responsible person**

Maryam Ashkar

##### **Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Orthotics and prosthetics

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

Behnam Hajiaghaei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Orthosis and Prosthesis

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Behnam Hajiaghaei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Orthotics and Prosthetics

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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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available