Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Iran (Islamic Republic of)

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+98 21 2222 0947

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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
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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
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Sponsors / Funding sources

1

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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
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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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