

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of ankle support orthosis and kinesiotape on force control, muscle strength, and kinesiphobia in subjects with chronic ankle instability: A randomized controlled trial

Protocol summary

Study aim

to investigate the effect of external ankle supports (i.e. ankle support orthosis, Kinesiotape) in subjects with chronic ankle instability.

Design

Parallel group, Randomized controlled trial with outcome assessor blinded

Settings and conduct

All the assessments, interventions, and data collection steps will be carried out at the School of sport sciences and health, Shahid Beheshti University. The outcome assessor and statistician will be blinded.

Participants/Inclusion and exclusion criteria

aged 18 - 40. at least one significant ankle sprain at least 12 months ago that resulted in pain, swelling, and physical activity restriction for at least 1 day. have not sprained their ankle within the six weeks prior to study onset. feeling of instability, at least two episodes of giving way in the past 6 months. Ankle instability Instrument: answer "yes" to at least 5 yes/no questions (This should include question 1, plus 4 others) Cumberland Ankle Instability Tool. Score of ≤ 24 . 20 min or greater of moderate physical activity level at least 3 days. having no mechanical instability

Intervention groups

Three groups: ankle support orthosis group, Kinesiotape group, control group

Main outcome variables

Force sense Force steadiness

General information

Reason for update

Acronym

CAI

IRCT registration information

IRCT registration number: **IRCT20200315046784N3**

Registration date: **2023-11-28, 1402/09/07**

Registration timing: **prospective**

Last update: **2023-11-28, 1402/09/07**

Update count: **0**

Registration date

2023-11-28, 1402/09/07

Registrant information

Name

Fatemeh Azadinia

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-07-02, 1403/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ankle support orthosis and kinesiotape on force control, muscle strength, and kinesiphobia in subjects with chronic ankle instability: A randomized controlled trial

Public title

Effect of external ankle support in patients with chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

aged 18 - 40. at least one significant ankle sprain at least 12 months ago that resulted in pain, swelling, and physical activity restriction for at least 1 day. have not sprained their ankle within the six weeks prior to study onset. feeling of instability, at least two episodes of giving way in the past 6 months. Ankle instability Instrument: answer "yes" to at least 5 yes/no questions (This should include question 1, plus 4 others) Cumberland Ankle Instability Tool. Score of ≤ 24 . 20 min or greater of moderate physical activity level at least 3 days. having no mechanical instability.

Exclusion criteria:

History of lower extremity injury, fracture, surgery or acute trauma in either lower extremity in the previous 3 months, or time since the last sprain of less than 3 months. diabetes, neuropathies, neurological pathology. consumption of muscle relaxant during research period. not receiving of ankle orthosis, kinesiotape, and physical therapy over the last 6 months. leg length discrepancies. rheumatoid arthritis. congenital deformities.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 51, however, to take account of potential withdrawals, 60 patients (n=20 per group) will be recruited for the study. First, create and seal 20 treatment A envelopes, 20 treatment B envelopes, and 20 treatment C envelopes. To create a block of 6, we will select 2 treatment A envelopes, 2 treatment B envelopes, and 2 treatment C envelopes. We will shuffle these 6 envelopes thoroughly, and place this block of 6 in a separate pile. Then, we will prepare additional blocks of 6 until all 20 treatment A, B, and C envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 10 individuals piles of shuffled blocks of 6.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will be blinded to group allocation, because all dependent variables will be measured without the orthosis and or kinesiotape, and the patients will remove their orthosis / kinesiotape before referring for post-intervention assessment. Furthermore, all data will be encoded to prevent bias and to blind the statistician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Iran University of Medical Sciences

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Shahid Hemmat Highway

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Tehran

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1449614535

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.IUMS.REC.1402.376

Health conditions studied**1****Description of health condition studied**

chronic ankle instability

ICD-10 code

M25.37

ICD-10 code description

Other instability, ankle and foot

Primary outcomes**1****Description**

Force sense

Timepoint

before and after 4 weeks

Method of measurement

Isokinetic Dynamometer

2

Description

Force steadiness

Timepoint

before and after 4 weeks

Method of measurement

Isokinetic Dynamometer

Secondary outcomes

1

Description

evertor muscles strength eccentric and concentric contractions

Timepoint

before and after 4 weeks

Method of measurement

Isokinetic dynamometer

2

Description

Kinesiophobia/ fear of movement

Timepoint

before and after 4 weeks

Method of measurement

Tampa scale of kinesiophobia

Intervention groups

1

Description

Intervention group: Group A will be received an ankle support orthosis. The patients will be asked to wear the orthosis for 4 weeks.

Category

Treatment - Devices

2

Description

Intervention group: Group B: kinesiotape will be re-applied every 3 days, for 4 weeks.

Category

Treatment - Devices

3

Description

Control group: no-intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of sport sciences and health, Shahid Beheshti University

Full name of responsible person

Fatemeh Azadinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Reza Falak

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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

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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Azadinia

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Our research findings will be shared with all researchers, and practitioners. We will publish our research findings in scientific journals

When the data will become available and for how long

All documents can be shared 1 year after article publication

To whom data/document is available

Researchers and health practitioners

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article.

From where data/document is obtainable

Fatemeh azadinia

What processes are involved for a request to access data/document

Send email to corresponding author.

Comments