# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**
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**Name of organization / entity**

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Iran (Islamic Republic of)

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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. W 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
**Street address**
Shahid Hemmat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
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 kinesiphobia

## 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**
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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**
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**
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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**