

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Supportive Ankle Orthoses and Balance Training on Gait Initiation and postural control in Individuals with Chronic Ankle Instability

Protocol summary

Study aim

To investigate the effect of supportive ankle orthosis and balance training on gait initiation and postural control in individuals 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 Rehabilitation Sciences, Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria

criteria are in-line with the recommendations made by the International Ankle Consortium. Age range 18 to 40 years old. a history of at least 1 ankle sprain which had limited patients activity at that day and had been associated with inflammatory signs. self-reported history of the first ankle sprain more than 12 months ago. The last sprain has occurred at least 3 month ago. history of at least two episodes of 'giving way' and 'feelings of ankle joint instability' during the last 6 months. Cumberland Ankle Instability Tool (CAIT) score ≤ 24 . Having self-assessed disability scores of $\leq 90\%$ on the activities of daily living subscale of Foot and Ankle Ability Measure (FAAM); and having self-assessed disability scores $\leq 80\%$ on the sports subscale of Foot and Ankle Ability Measure (FAAM).

Intervention groups

Four Groups: Semi-rigid ankle orthosis, balance training, combine two intervention (e.g. semi-rigid orthosis + balance training), control group

Main outcome variables

Primary outcome: Star Excursion Balance test.
Secondary outcomes: parameters extracted of Gait initiations, time to boundary, kinesiophobia, self reported ankle instability, self reported foot and ankle ability measure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200315046784N5**

Registration date: **2024-11-02, 1403/08/12**

Registration timing: **prospective**

Last update: **2024-11-02, 1403/08/12**

Update count: **0**

Registration date

2024-11-02, 1403/08/12

Registrant information

Name

Fatemeh Azadinia

Name of organization / entity

Country

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

2024-11-04, 1403/08/14

Expected recruitment end date

2025-07-05, 1404/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Supportive Ankle Orthoses and Balance Training on Gait Initiation and postural control in Individuals with Chronic Ankle Instability

Public title

Effect of supportive ankle orthoses and balance training in chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

criteria are in-line with the recommendations made by the International Ankle Consortium 18 to 40 years old a history of at least 1 ankle sprain which had limited patients activity at that day and had been associated with inflammatory signs self-reported history of the first ankle sprain more than 12 months ago the last sprain has occurred at least 3 month ago history of at least two episodes of 'giving way' and 'feelings of ankle joint instability' during the last 6 months Cumberland Ankle Instability Tool (CAIT) score ≤ 24 having self-assessed disability scores of $\leq 90\%$ on the activities of daily living subscale on the Foot and Ankle Ability Measure (FAAM); and having self-assessed disability scores $\leq 80\%$ on the sport subscale on the FAAM.

Exclusion criteria:

reluctance to continue participating in the project not wearing of the prescribed orthosis during physical activities missing 3 or more non-consecutive sessions or 2 consecutive sessions allergic skin reaction because of wearing semi-rigid ankle support orthosis acute injury during 4-week project period a history of lower limb surgery a history of lower limb fracture which has required realignment acute injuries of lower limb musculoskeletal structures over the past 3 months chronic disorders of lower limb, neurological disorders, vestibular disorders Diabetic neuropathy and or other disorders affecting balance control receiving treatment strategies for their chronic ankle instability over the past 3 months

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: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1:1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 52, however, to take account of potential withdrawals, 64 patients (n=16

per group) will be recruited for the study. First, create and seal 16 treatment A envelopes, 16 treatment B envelopes, 16 treatment C envelopes, and 16 treatment D envelopes. To create a block of 8, we will select 2 treatment A envelopes, 2 treatment B envelopes, 2 treatment C envelopes, and 2 treatment D envelopes. We will shuffle these 8 envelopes thoroughly, and place this block of 8 in a separate pile. Then, we will prepare additional blocks of 8 until all 16 treatment A, B, and C envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 8 individuals piles of shuffled blocks of 8.

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 the patients will remove their orthosis 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

Research Ethics Committees of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2024-06-02, 1403/03/13

Ethics committee reference number

IR.IUMS.REC.1403.209

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

reach distance in Star Excursion Balance Test

Timepoint

before and after 4 weeks intervention

Method of measurement

the reach distance per centimeter

Secondary outcomes

1

Description

Center of Pressure (COP) based measures of gait initiation, reaction time, time of each phase of the gait initiation

Timepoint

before and after 4 weeks intervention

Method of measurement

force platform

2

Description

Time to boundary measures postural control in single leg stance

Timepoint

before and after 4 weeks intervention

Method of measurement

force platform

3

Description

self-reported physical function

Timepoint

before and after 4 weeks intervention

Method of measurement

Foot and Ankle Ability Measure

4

Description

self-reported functional ankle instability

Timepoint

before and after 4 weeks intervention

Method of measurement

Cumberland Ankle Instability Tool

5

Description

Kinesiophobia

Timepoint

before and after 4 weeks intervention

Method of measurement

TAMPA scale of kinesiophobia

Intervention groups

1

Description

Intervention group: semi-rigid supportive ankle orthosis

Category

Rehabilitation

2

Description

Intervention group: balance training

Category

Rehabilitation

3

Description

Intervention group: supportive ankle orthosis in addition to balance training

Category

Rehabilitation

4

Description

Control group: no-intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences, Iran University of Medical Sciences

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