Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≤90% on the activities of daily living subscale of Foot and Ankle Ability Measure (FAAM); and having self-assessed disability scores ≤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 teat.
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)

Phone
+98 21 2222 0947

Email address
azadinia.f@iums.ac.ir

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 ≤90% on the activities of daily living subscale on the Foot and Ankle Ability Measure (FAAM); and having self-assessed disability scores ≤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
۱۴۴۹۶۱۴۵۳۵

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
Street address
Shahnazari st., Mother Sq., Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 8051
Email
azadinia.fatemeh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Dr. Reza Falak

Street address
Hemat highway, next to Milad tower

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8670 2503

Email
falak.r@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
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

Street address
Shahnazari st., Mother Sq., Mirdamad Blvd

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
azadinia.fatemeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Azadinia

Position
Associate Professor

Latest degree
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Other areas of specialty/work
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Postal code
1545913487

Phone
+98 21 2222 8051

Email
azadinia.fatemeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Azadinia

Position
Associate Professor

Latest degree
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Email
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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