Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Immediate Effects of Foot Insole and Kinesio Taping on Postural Stability Using the Double-Leg to Single-Leg Stance Transition Test in Adults with Flexible Flatfoot

Protocol summary

Study aim

Aim: To compare the effects of Kinesio taping and arch-support foot orthosis on postural stability during the transition from double-leg to single-leg stance.

Design

This is a randomized crossover. Thirty participants will be randomly assigned to one of six possible intervention sequences using a permuted block randomization method with a fixed block size of six.

Settings and conduct

This study will be conducted at the School of Rehabilitation Science, Iran University of Medical Sciences. Using a randomized crossover design, each participant will be assessed under three conditions: a control condition (no intervention), a tape condition, and an insole condition. Sequence of these three conditions will be randomized according to one of six possible orders. A minimum washout period of 24 hours will be considered between sessions. Because of obvious nature of interventions is not possible to blind participants or outcome assessors, however, the statistician will not aware of assigned groups.

Participants/Inclusion and exclusion criteria

Inclusion: Age between 18 and 35 years, ability to stand and walk, bilateral flatfoot, BMI less than 30, FPI-6 score ≥ 6, Navicular Drop ≥ 10 mm, literate (able to read and write), moderate activity level based on the IPAQ questionnaire. Exclusion: Foot deformities and vestibular disorders, use of medications or substances affecting the central nervous system, history of surgery within the last 6 months, high intensity physical activity within 12 hours before the test.

Intervention groups

Each participant will be assessed under three conditions: control (no intervention), insole, and kinesio tape, in a randomized order across three separate sessions.

Main outcome variables

COP displacement and velocity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260810070608N1**
Registration date: **2026-08-24, 1405/06/02**
Registration timing: **prospective**

Last update: **2026-08-24, 1405/06/02**
Update count: **0**

Registration date

2026-08-24, 1405/06/02

Registrant information

Name

Amir mohammad Shooryabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-05, 1405/06/14

Expected recruitment end date

2027-03-11, 1405/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Immediate Effects of Foot Insole and Kinesio Taping on Postural Stability Using the Double-Leg to Single-Leg Stance Transition Test in Adults with Flexible Flatfoot

Public title
Effect of interventions on flatfoot

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18–35 years Ability to stand and walk Bilateral flatfoot BMI less than 30 Foot Posture Index (FPI-6) score ≥ +6 Navicular Drop Test ≥ 10 mm Able to read and write in Persian Moderate physical activity level (IPAQ questionnaire)

Exclusion criteria:
Foot deformities (hallux valgus, hammer toe, etc.) and vestibular disorders Use of medications/substances affecting the central nervous system History of musculoskeletal injury within the last 6 months High-intensity physical activity within 12 hours before test

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will employ a randomized, three-period, three-treatment crossover design. Eligible participants will be randomly assigned to one of six possible intervention sequences (IBT, ITB, BIT, BTI, TIB, TBI) in a 1:1:1:1:1:1 allocation ratio using a permuted block randomization method with a fixed block size of six. Each block will contain all six sequences exactly once in a randomly determined order. Five complete blocks will be generated to achieve the target sample size of 30 participants. To ensure allocation concealment, group assignments will be placed in sequentially numbered, opaque, sealed envelopes by an independent administrator. Envelopes will be opened sequentially only after participant enrollment and completion of all baseline procedures, immediately before the first intervention session.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Rehabilitation Sciences, Iran University of Medical Sciences

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School of Rehabilitation Sciences, Nezam Alley, Shahnazari St. Madar Sq. Mirdamad Blv.

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Tehran

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Postal code
۱۳۴۸۷۱۵۴۵۹

Approval date
2026-07-22, 1405/04/31

Ethics committee reference number
IR.IUMS.REHAB.REC.1405.016

Health conditions studied

1

Description of health condition studied
Flexible flatfoot

ICD-10 code
M21.4

ICD-10 code description
Flat foot [pes planus] (acquired)

Primary outcomes

1

Description
The mean of COP displacement

Timepoint
Assessments will be performed immediately after a 30-minute period(familiarization) following the application of each intervention, across 3 sessions with different conditions, each separated by an interval of at least 24 hours from the previous session.

Method of measurement
Force plate, model 9260AA6, manufactured by Kistler

2

Description
Mean absolute COP velocity

Timepoint
Assessments will be performed immediately after a 30-minute period(familiarization) following the application of each intervention, across 3 sessions with different

conditions, each separated by an interval of at least 24 hours from the previous session.

Method of measurement

Force plate, model 9260AA6, manufactured by Kistler

3

Description

Mean peak absolute COP velocity

Timepoint

Assessments will be performed immediately after a 30-minute period(familiarization) following the application of each intervention, across 3 sessions with different conditions, each separated by an interval of at least 24 hours from the previous session.

Method of measurement

Force plate, model 9260AA6, manufactured by Kistler

4

Description

Mean COP displacement during contralateral push-off phase

Timepoint

Assessments will be performed immediately after a 30-minute period(familiarization) following the application of each intervention, across 3 sessions with different conditions, each separated by an interval of at least 24 hours from the previous session.

Method of measurement

Force plate, model 9260AA6, manufactured by Kistler

5

Description

Mean COP excursion range during contralateral push-off phase

Timepoint

Assessments will be performed immediately after a 30-minute period(familiarization) following the application of each intervention, across 3 sessions with different conditions, each separated by an interval of at least 24 hours from the previous session.

Method of measurement

Force plate, model 9260AA6, manufactured by Kistler

Secondary outcomes

1

Description

temporal parameters during transition task including mean time to new stability point, mean duration of contralateral limb push-off phase

Timepoint

Assessments will be performed in each session, under one of (control/no intervention; insole; kinesio tape) conditions, a 24-hours washout period will be considered between sessions. There will be a 30-minute familiarization time with interventions in each session.

Method of measurement

force plate

Intervention groups

1

Description

Insole condition. Due to the crossover design of this study, this group represents one of the 3 conditions available. All 30 participants in the study receive this condition according to the sequence group to which they are assigned. This study has a total of 6 sequence groups, which determine the order in which the conditions (insole, Kinesio tape, no intervention) are received in each session.To evaluate the immediate effect of the condition, the participant performs the test 30 minutes after receiving the condition (familiarization period).

Category

Treatment - Other

2

Description

Kinesio tape condition. Due to the crossover design of this study, this group represents one of the 3 conditions available. All 30 participants in the study receive this condition according to the sequence group to which they are assigned. This study has a total of 6 sequence groups, which determine the order in which the conditions (insole, Kinesio tape, no intervention) are received in each session.To evaluate the immediate effect of the condition, the participant performs the test 30 minutes after receiving the condition (familiarization period).

Category

Treatment - Other

3

Description

No intervention condition. Due to the crossover design of this study, this group represents one of the 3 conditions available. All 30 participants in the study receive this condition according to the sequence group to which they are assigned. This study has a total of 6 sequence groups, which determine the order in which the conditions (insole, Kinesio tape, no intervention) are received in each session.To evaluate the immediate effect of the condition, the participant performs the test 30 minutes after receiving the condition (familiarization period).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Amir Mohammad Shooryabi

Position
MSc Student in Orthotics and Prosthetics

Latest degree
Bachelor

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
No - There is not a plan to make this available
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 articles.
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