

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 $\geq +6$ 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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Postal code

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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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree

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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