Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of a comprehensive exercise program with arch support insole on foot alignment and kinematic variables of gait in individuals with flexible flatfoot

Protocol summary

Study aim
To determine the effects of a comprehensive exercise program with arch support insole on foot alignment and kinematic variables of gait in individuals with flexible flatfoot

Design
The study design will be a Randomized Clinical Trial (RCT)

Settings and conduct
During the study, high school students will visit the University of Tehran, Biomechanics Laboratory, Faculty of Sport Sciences. These individuals will be included in the study if they are eligible for flatfoot deformity and will be randomly divided into 3 groups using sealed envelopes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male high school students, have an age range of 13 to 15 years. All subjects have flat flexible feet. Exclusion criteria: Having any physical injury, pathological symptoms and any congenital abnormality in the lower limbs and pelvis.

Intervention groups
"Intervention Group 1": This group performs comprehensive exercises (3 sessions per week, and each session is about 30 minutes) with arch support insole (fabricated) for 8 weeks. "Intervention Group 2": This group will use only arch support insole (fabricated) for 8 weeks. "Control group": This group does not perform any of the intervention group programs.

Main outcome variables
Navicular drop(cm), medial longitudinal arch angle(degree), eversion angle(degree), Stride length(cm), Step length(cm), width length(cm), foot progression angle(degree), Stride time(s), step time(s), double support time(s), single support time(s), Cadence (steps/min), hallux Relative to the forefoot(degree), forefoot Relative to the hindfoot(degree), hindfoot relative to tibia(degree) and tibia relative to the laboratory(degree).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250506065623N1**
Registration date: **2025-08-25, 1404/06/03**
Registration timing: **retrospective**

Last update: **2025-08-25, 1404/06/03**
Update count: **0**

Registration date
2025-08-25, 1404/06/03

Registrant information

Name
Seyyed Ghasem Hosseini

Name of organization / entity
University of Tehran

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-27, 1404/04/06

Expected recruitment end date
2025-07-14, 1404/04/23

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of a comprehensive exercise program with arch support insole on foot alignment and kinematic variables of gait in individuals with flexible flatfoot

Public title
The effects of exercise with arch support insole on flexible flatfoot
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male high school students, have an age range of 13 to 15 years. All subjects have flat flexible feet with a navicular drop greater than 10 mm, a medial longitudinal arch angle less than 130 degrees, and a eversion angle greater than or equal to 5 degrees.
Exclusion criteria:
Having any physical injury in the past four months Having pathological symptoms in the lower limbs Having a body weight outside the normal range Having any congenital abnormality in the lower limbs Having any congenital abnormality in the pelvis
Age
From **13 years** old to **15 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
After the initial assessments, the people will be randomly assigned to one of the three groups of comprehensive exercise program with arch support insole, only use of arch support insole and control group (method: simple randomization - unit: individual). An envelope containing blue paper, an envelope containing red paper and another envelope containing yellow paper (randomization tool: sealed envelope) will be given to each person. Each person choosing the envelope containing blue or red or yellow paper will be assigned to the comprehensive exercise program with arch support insole group or only use of arch support insole group or control group, respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, University of Tehran, Faculty of Sport and Health Sciences
Street address
Faculty of Physical Education and Sport Sciences, North Kargar street
City
Tehran
Province
Tehran
Postal code
1439813117
Approval date
2025-04-28, 1404/02/08
Ethics committee reference number
IR.UT.SPORT.REC.1404.040

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
navicular drop (cm)
Timepoint
Measurement of navicular drop (cm) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
ruler

2

Description
medial longitudinal arch angle (degree)
Timepoint
Measurement of medial longitudinal arch angle (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
goniometer

3

Description
eversion angle (degree)
Timepoint
Measurement of eversion angle (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
goniometer

4

Description
Stride length (cm)
Timepoint
Measurement of Stride length (cm) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

5

Description
Step length (cm)
Timepoint
Measurement of Step length (cm) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

6

Description
width length (cm)
Timepoint
Measurement of width length (cm) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

7

Description
foot progression angle (degree)
Timepoint
Measurement of foot progression angle (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

8

Description
Stride time (s)
Timepoint
Measurement of Stride time (s) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

9

Description
step time (s)
Timepoint
Measurement of Step time (s) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

10

Description
double support time (s)
Timepoint
Measurement of double support time (s) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

11

Description
single support time (s)
Timepoint
Measurement of single support time (s) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

12

Description
Cadence (steps/min)
Timepoint
Measurement of Cadence (steps/min) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

13

Description
hallux Relative to the forefoot (degree)
Timepoint
Measurement of hallux Relative to the forefoot (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.
Method of measurement
A3-dimensional motion analysis system

14

Description

forefoot Relative to the hindfoot (degree)

Timepoint

Measurement of forefoot Relative to the hindfoot (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.

Method of measurement

A3-dimensional motion analysis system

15

Description

hindfoot relative to tibia(degree)

Timepoint

Measurement of hindfoot relative to tibia(degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.

Method of measurement

A3-dimensional motion analysis system

16

Description

tibia relative to the laboratory (degree)

Timepoint

Measurement of tibia relative to the laboratory (degree) at the beginning of the study, before the start of the 8-week intervention, and immediately after the end of the intervention.

Method of measurement

A3-dimensional motion analysis system

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention Group 1": This group performs comprehensive exercises with arch support insole under the supervision of the researcher. Comprehensive exercises program includes active exercises (dorsiflexion and plantarflexion), short foot exercises (lesser toe extension, toe spread, doming and hallux extension), gluteal muscle strengthening exercises (hip abduction, hip extension) and calf stretches. Exercises progress after 2 weeks with alteration in the position (i.e., sitting, standing and single-leg stance) and/or an increase in hold time and number of repetitions. The intervention is performed at three sessions per week for 8 weeks. The three session per week are prescribed to occur on Monday, Wednesday and Friday. The medical insole used is a custom insole that is made for each individual through three-dimensional (3D)-printed and computer-aided design/computer-aided manufacturing (CAD/CAM) technology from semi-rigid foam in an orthopedic Clinic in Tehran. The necessary measurements will be performed as a pre-test for all subjects, and after 8 weeks of intervention, the measurements will be repeated as a post-test.

Category

Rehabilitation

2

Description

"Intervention Group 2": This group will use only a pair of custom arch support insole for 8 weeks. These insoles are designed with an internal longitudinal arch that aligns with the individual’s foot arch corresponding to the size of each participant’s foot through three-dimensional (3D)-printed and computer-aided design/computer-aided manufacturing (CAD/CAM) technology from semi-rigid foam at an orthopedic Clinic in Tehran. The necessary measurements will be taken as a pre-test for all subjects, and after 8 weeks of intervention, the measurements will be repeated as a post-test.

Category

Rehabilitation

3

Description

"Control group": The control group does not perform any of the intervention group programs. The necessary measurements will be taken as a pre-test for all subjects, and after 8 weeks, the measurements will be repeated as a post-test. In order to comply with research ethics, after the completion of the research work, if the corrective exercises and the use of arch support insole were effective, we will give the control group the exercises and the use of arch support insole.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tehran

Full name of responsible person

Seyyed Ghasem Hosseini

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Email
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Web page address
https://profile.ut.ac.ir/~moradih
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Tehran
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
University of Tehran
Full name of responsible person
Seyyed Ghasem Hosseini
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available