Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparing the effect of a 12-week gait retraining and short foot exercises on foot pronation in individuals with pronated foot: a randomised control trial

Protocol summary

Study aim
Can changing center of pressure and Foot progression angle impact rearfoot eversion and navicular drop in individuals with pronated foot

Design
Randomized control trial, Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct
Laboratory setting, randomized into 2 groups, only assessors will be blinded, not being aware of datas belong to which group

Participants/Inclusion and exclusion criteria
Inclusion: Healthy Statically Pronated foot >4 degrees Flat foot, static navicular drop>0.9 cm No injuries in past 6 month Active individuals, walking 3 times a week for at least 20 minutes Exclusion:En Injured Non-flat foot Non-pronated foot Sedentary life style Any disease

Intervention groups
Gait retraining: lateralizing COP and toe-in walking Short foot exercise

Main outcome variables
Peak rearfoot eversion, time to peak rearfoot eversion, rearfoot eversion at TD, rearfoot eversion excursion, medial longitudinal arch angle

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230801058998N1**
Registration date: **2024-10-04, 1403/07/13**
Registration timing: **retrospective**
Last update: **2024-10-04, 1403/07/13**
Update count: **0**

Registration date
2024-10-04, 1403/07/13

Registrant information

Name
Fateme Khorramroo

Name of organization / entity
University of tehran

Country
Iran (Islamic Republic of)

Phone
+98 21 2632 3962

Email address
negar_moj2004@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-25, 1403/07/04

Expected recruitment end date
2024-10-03, 1403/07/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparing the effect of a 12-week gait retraining and short foot exercises on foot pronation in individuals with pronated foot: a randomised control trial

Public title
Effect of a 12-week gait retraining for flat foot

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy Pronated foot >4 degrees Flat foot static navicular drop>0.9 cm No injuries in past 6 month Active individuals, walking 3 times a week for at least 20 minutes

Exclusion criteria:

Injured or any disease Non-flat foot Non-pronated foot Sedentary life style

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **1**

Kinematic data during gait

Randomization (investigator's opinion)

Randomized

Randomization description

After the baseline measurement, the participants will be divided randomly into the intervention group (INT) or control group (CON). A research assistant willgenerate the randomization schedule using a computer program and handed the results of allocation to the participants in a sealed envelope, ensuring that the researchers involved in outcome measurement and data analysis are unaware of the allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor and data and statistical analyzer will be blinded from knowing intervention groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of faculty of sport scienth and health, university of Tehran

Street address

North kargar street, faculty of sport scienth and health, university of Tehran

City

Tehran

Province

Tehran

Postal code

1664918948

Approval date

2024-09-25, 1403/07/04

Ethics committee reference number

IR.UT.SPORT.REC.1403.078

Health conditions studied

1

Description of health condition studied

Flat foot, pronated foot, pes planus

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Peak rearfoot eversion (◦)

Timepoint

First week and after 12 weeks

Method of measurement

Kinematic analysis using vican cameras

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After receiving the code of ethics, through an announcement, active sports women aged 18 to 40 with flat, flexible soles and arched feet are invited to this study. Tests for women will be conducted by a female test taker. By using the navicular drop test, it is ensured that these people have flat soles and arch of the back of the feet. Based on the entry criteria, 30 people will sign the consent form. The tools include a consent form, scale, meter, treadmill, Vikan 3D motion analysis system, marker. Data collection will be done in Mofaqian's laboratory using 6 Vicon cameras (Vicon MX-T40S) and 4 Vicon cameras (Vero (v2.2)). In order to measure the internal longitudinal arch of the sole of the foot, three markers will be attached to the inner part of the heel, the prominence of the navicular bone, and the head of the first metatarsal. The angle between these three markers in the middle distance of walking and running is considered as the angle of the internal longitudinal arch of the sole of the foot. In an

announcement, active sports women aged 18 to 40 with flat flexible soles are invited to this study. By using the navicular drop test, it is ensured that these people have a flat sole and the arch angle of the back of the foot in a static state. Based on the entry criteria, 30 people will sign the consent form. After a five-minute warm-up period, the markers will be attached to the subjects' bodies. To measure the foot arch, three markers will be attached to the big toe bone, navicular bone and heel bone. To adjust the speed of walking and running to provide feedback and generalize it to all subjects, the speed of the treadmill for all subjects is set to 3 km/h for walking and 9 km/h for running. In the first session after warming up, all subjects They are asked to walk on the treadmill for two minutes, and the data of the last 20 seconds will be collected. The average angle of foot advancement and center of pressure of the sole of the foot in the first five steps is considered as the normal walking angle of the foot. The same process will be done while running. The foot advancement angle is the angle between the line connecting the markers on the heel bone and the second metatarsal head with the longitudinal axis of the treadmill. This line will be marked with a white stripe. In the second session, the subjects of the walking retraining group are asked to change the leg advancement angle within 5 degrees less than the normal leg angle (inward) through visual feedback and put the center of pressure on the outer edge of the leg. For this purpose, MATLAB code will be used to give visual feedback of the position of foot markers. Then the subject will be asked to try to place his foot in line with the light of the lasers while walking and running. Visual feedback and how to display the angle of leg progress is done using a video projector that displays the image of linear laser lines (treadmill tape) on a white screen placed in front of the subject. 12 weeks of training will be done.gait retraining sessions start with 15 minutes and reach to 40 minutes in the wekk 12.

Category

Rehabilitation

2

Description

Control group: After receiving the code of ethics, through an announcement, active sports women aged 18 to 40 with flat, flexible soles and arched feet are invited to this study. Tests for women will be conducted by a female test taker. By using the navicular drop test, it is ensured that these people have flat soles and arch of the back of the feet. Based on the entry criteria, 30 people will sign the consent form. The tools include a consent form, scale, meter, treadmill, Vikan 3D motion analysis system, marker. Data collection will be done in Mofaqian's laboratory using 6 Vicon cameras (Vicon MX-T40S) and 4 Vicon cameras (Vero (v2.2)). In order to measure the internal longitudinal arch of the sole of the foot, three markers will be attached to the inner part of the heel, the prominence of the navicular bone, and the head of the first metatarsal. The angle between these three markers in the middle distance of walking and running is considered as the angle of the internal longitudinal arch of the sole of the foot. In an announcement, active sports women aged 18 to 40 with flat flexible soles are invited to this study. By using the navicular drop test, it is ensured that these people have a flat sole and the arch angle of the back of the foot in a static state. Based on the entry criteria, 30 people will sign the consent form. Short foot exercises will be done for 12 weeks , 3 session each week including: Heel raise, Towel curls, Foot doming, Toe spread, Balance board, Foot relaxes. Starting from 1 set of 10 repeats and end in week 12 with 3 sets of 25 repetitions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Movafaghian laboratory

Full name of responsible person
Zahra Rafiei

Street address
Movafaghian laboratory, Khark street, Enghelab street

City
تهران

Province
Tehran

Postal code
1664918948

Phone
+98 21 6671 6100

Email
Gaitlab@sharif.edm

Web page address
http://www.mowafaghian.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Tehran

Full name of responsible person
Shahrzad Tahmasebi

Street address
17th Kargar

City
Tehran

Province
Tehran

Postal code
1664918948

Phone
+98 21 6111 8807

Email
shahzadtahmaseb@ut.ac.ir

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
Seyed Hamed Mousavi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine

Street address
17th north Kargar

City
Tehran

Province
Tehran

Postal code
1664918948

Phone
+98 21 6111 8807

Email
Musavihamed@ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Tehran

Full name of responsible person
Fateme Khorramroo

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
17th kargar

City
Tehran

Province
Tehran

Postal code
1664918948

Phone
+98 21 2632 3962

Email
negar_moj2004@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of Tehran

Full name of responsible person
Fateme Khorramroo

Position
Master

Latest degree
Master

Other areas of specialty/work
Sport Medicine

Street address
17th kargar

City
Tehran

Province
Tehran

Postal code
1664918948

Phone
+98 21 2632 3962

Email
negar_moj2004@yahoo.com

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
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Final Outcome

When the data will become available and for how long
3 month after publication

To whom data/document is available
Everyone

Under which criteria data/document could be used
For research and rehabilitation

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

One week time to gather the needed data

Comments