Clinical Trial Protocol
Iranian Registry of Clinical Trials
07 Aug 2023

Effects of combined exercises and short foot exercise with isometric hip abduction on navicular drop and postural control in individuals with pes planus

Protocol summary

Study aim
Determining the effect of combined exercises and short foot exercises with isometric hip abduction on navicular drop and postural control in patients with flat feet

Design
Clinical trial without control group, with parallel, single-blind, randomized. Randlist software will be used for randomization.

Settings and conduct
The exercises will be done in Arak University and the study groups will do their respective exercises daily for six weeks. Three sessions of supervised exercises and three sessions of home exercises will be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Age 18 to 28 years with body mass index of 18 to 25 kg per square meter, Navicular drop more than 10 mm without leg length difference of more than 1 centimeter, No lower limb or back injury in 6 months before the study. The absence of neurological diseases affecting balance and the dominant foot will be the right foot for all subjects. Exclusion criteria include: Any numbness or tingling, fracture, dislocation, skin disease on the sole of the foot or vascular disease, lower limb arthritis, nerve dysfunction, lower limb injury, history of hip and ankle surgery, use of orthotics, and leg length difference. From 1 centimeter.

Intervention groups
Short foot exercise group with isometric hip abduction: Subjects will perform sensory motor training of short foot simultaneously with isometric hip contraction (with the help of Traband). Short foot exercise group: They will perform short-foot sensory motor training. Combination Exercise Group: They will do a series of strengthening, stretching and balance exercises.

Main outcome variables
Navicular drop; Posture control

General information

Reason for update
Due to the time-consuming process of review, our initial estimated date for starting the work is before the trial registration date in the system. (The estimated date is September 10, 2022, and the review was completed on September 28, 2022). Unfortunately, neither we nor the honorable referee noticed this inadvertent error, so please correct the date to September 30 if possible. With respect

Acronym
IRCT registration information
IRCT registration number: IRCT20220409054456N1
Registration date: 2022-09-28, 1401/07/06
Registration timing: registered_while_recruiting

Last update: 2023-06-06, 1402/03/16
Update count: 1

Registration date
2022-09-28, 1401/07/06

Registrant information
Name
Aftab zarali
Name of organization / entity
The University of Araku
Country
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
Scientific title
Effects of combined exercises and short foot exercise with isometric hip abduction on navicular drop and postural control in individuals with pes planus

Public title
Effects of combined exercises and short foot exercise with isometric hip abduction on navicular drop and postural control in individuals with pes planus

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index 18 to 25 kg/m2 navicular drop more than 10 mm No injury to the lower limbs or back in the 6 months before the study The dominant foot will be the right foot for all subjects No leg length difference of more than 1.1 cm

Exclusion criteria:
Those who do lower extremity exercises separately People with numbness or tingling, fractures, dislocations, plantar fasciitis, or vascular disease Having lower limb arthritis Neurological dysfunction Suffering from a lower limb injury, a history of hip and ankle surgery, foot deformity or malformation Use of orthosis Limb length difference more than 1/1 cm

Age
From 18 years old to 28 years old

Gender
Female

Phase
N/A

Groups that have been masked
- Data analyser

Sample size
Target sample size: 45

Randomization (investigator’s opinion)
Randomized

Randomization description
The randomization method is parallel. The randomization unit is individual. Randlist software is used to randomly assign subjects to study groups. Randomization was done in the software as follows: At first, the number of subjects and groups is given to the software, then a code is assigned to each subject by this software. Finally a group is randomly assigned to each code by the software.

Blinding (investigator’s opinion)
Single blinded

Blinding description
The data analyser will not be aware of the group classification. The information of the groups will be provided to the data analyst in the form of number 1, 2 and 3 and for each participant with a code.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary IIds
empty

Ethics committees

Ethics committee
Name of ethics committee
Ethics committee of araku University
Street address
Basij Square, Karbala Boulevard, Arak University
City
Arak
Province
Markazi
Postal code
۴۸۵۷۷۱۸۴۸۳
Approval date
2022-03-02, 1400/12/11

Ethics committee reference number
IR.ARAKU.REC.1401.010

Health conditions studied

Health condition studied
Pes Planus
ICD-10 code
M21.4
ICD-10 code description
Flat foot [pes planus] (acquired)

Primary outcomes

Primary outcome
Description
navicular drop

Timepoint
Before and after of intervention

Method of measurement
Entrance test Navicular drop test, Foot scan,

Secondary outcome
Description
Postural control

Timepoint
Before and after of intervention

Method of measurement
Secondary outcomes

1
Description
Knee range of motion
Timepoint
Before and after intervention
Method of measurement
Goniometer

2
Description
Static balance
Timepoint
Before and after intervention
Method of measurement
Foot scan

3
Description
Dynamic balance
Timepoint
Before and after intervention
Method of measurement
Y test. Foot scan

4
Description
Ankle range of motion
Timepoint
Before and after intervention
Method of measurement
Goniometer

5
Description
Joint proprioception
Timepoint
Before and after intervention
Method of measurement
Goniometer

6
Description
Muscles strength of the ankle
Timepoint
Before and after intervention
Method of measurement
Dynamometer

7
Description
Muscles strength of the knee
Timepoint

8
Description
Gait
Timepoint
Before and after intervention
Method of measurement
Foot scan

9
Description
Quality of Life
Timepoint
Before and after intervention
Method of measurement
Questionnaire

10
Description
Pain
Timepoint
Before and after intervention
Method of measurement
Questionnaire

Intervention groups

1
Description
Intervention group: combined exercises
Category
Rehabilitation

2
Description
Intervention group: and short foot exercise with isometric hip abduction
Category
Rehabilitation

3
Description
Control group: Short Foot Exercise
Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
Arak University
Full name of responsible person
Zahra Raeisi

Street address
Arak University, Karbala Boulevard, Basij Square, Arak

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Province
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azarali2515@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University

Full name of responsible person
Hamed Safikhani

Street address
Karbala Boulevard, Basij Square, Arak University.

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e-dabir@araku.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source

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 scientific inquiries

Contact

Name of organization / entity
Arak University

Full name of responsible person
Zahra Raeisi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport rehabilitation and corrective movements

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Karbala Boulevard, Basij Square, Arak University

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Person responsible for updating data

Contact

Name of organization / entity
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Zahra Raeisi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sport rehabilitation and corrective exercises

Street address

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University

Full name of responsible person
Aftab Zarali
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
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
Not applicable

Data Dictionary
Not applicable