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
Iran (Islamic Republic of)
Phone
+98 66 4266 5135
Email address
azarali2515@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
Expected recruitment end date
2022-12-10, 1401/09/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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 IDs
empty

Ethics committees

1

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

1

Description of health condition studied
Pes Planus

ICD-10 code
M21.4

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

Primary outcomes

1

Description
navicular drop

Timepoint
Before and after of intervention

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

2

Description
Postural control

Timepoint
Before and after of intervention

Method of measurement
### Secondary outcomes

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee range of motion</td>
<td>Before and after intervention</td>
<td>Goniometer</td>
</tr>
<tr>
<td>Static balance</td>
<td>Before and after intervention</td>
<td>Foot scan</td>
</tr>
<tr>
<td>Dynamic balance</td>
<td>Before and after intervention</td>
<td>Y test, Foot scan</td>
</tr>
<tr>
<td>Ankle range of motion</td>
<td>Before and after intervention</td>
<td>Goniometer</td>
</tr>
<tr>
<td>Joint proprioception</td>
<td>Before and after intervention</td>
<td>Goniometer</td>
</tr>
<tr>
<td>Muscles strength of the ankle</td>
<td>Before and after intervention</td>
<td>Dynamometer</td>
</tr>
<tr>
<td>Muscles strength of the knee</td>
<td>Before and after intervention</td>
<td>Dynamometer</td>
</tr>
</tbody>
</table>

### 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**: Arak University  
   **Name of recruitment center**: Arak University  
   **Full name of responsible person**
Zahra Raeisi

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

**City**
Arak

**Province**
Markazi

**Postal code**
۴۸۵۷۷۱۸۴۸۳

**Phone**
+98 66 4266 5135

**Fax**

**Email**
azarali2515@gmail.com

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**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,

**City**
Arak

**Province**
Markazi

**Postal code**
۴۸۵۷۷۱۸۴۸۳

**Phone**
+98 86 3262 1024

**Email**
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

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
Arak University

**Full name of responsible person**
Aftab Zarali

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**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

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

**City**
Arak

**Province**
Markazi

**Postal code**
۴۸۵۷۷۱۸۴۸۳

**Phone**
+98 86 3262 1024

**Email**
Z-raisi13@yahoo.com

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**Person responsible for updating data**

**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 exercises

**Street address**
Karbala Boulevard, Basij Square, Arak University,
Karbala Boulevard ,Basij Square ,Arak University
City
Arak
Province
Markazi
Postal code
۴۸۵۷۷۱۸۴۸۳
Phone
+98 86 3262 1024
Email
Z-raisi13@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
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