Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of kinesio typing and ankle resistance training with Bosu ball on pain, balance and big toe angle of women with Hallux Valgus.

Protocol summary

Study aim
Determining the effect of kinesiotype with and without ankle strengthening exercises with bosu ball on pain, balance and big toe angle of women with hallux valgus.

Design
A clinical trial with two experimental groups and one control group, one blind, randomized, will be conducted on 45 women with hallux valgus and flat foot.

Settings and conduct
Group (kinesiotype): It will be applied on the big toe for four weeks (three sessions per week) for a maximum of 24 hours. Before using kinesiotype, passive stretching is done using massage for two minutes focusing on the muscles to be taped, and also according to the elasticity of the tape, the amount of elasticity (while applying on on the big toe) increases. Group (kinesiotype and ankle strengthening exercises with bosu ball): for four weeks (three sessions a week), the researcher applied kinesiotype on the subject's big toe for 24 hours, and these people should also perform ankle strengthening exercises with bosu ball give The control group will not receive any intervention. This trial will be conducted in the sports hall in Arak city.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1: Women who have mild and moderate hallux valgus (15 to 30 degrees) with flat feet. 2: Absence of any orthopedic problems in the lower limbs. 3: Absence of any congenital diseases in the lower limbs.

Intervention groups
Experimental group 1: kinesiotype and ankle strengthening exercises with Bosu ball, experimental group 2: kinesiotype and group 3: control

Main outcome variables
Kinesiotype and ankle strengthening exercises with bosu ball have an effect on pain, balance and big toe angle in women with hallux valgus.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230619058528N1**
Registration date: **2023-10-15, 1402/07/23**
Registration timing: **prospective**

Last update: **2023-10-15, 1402/07/23**
Update count: **0**

Registration date
2023-10-15, 1402/07/23

Registrant information

Name
Zahra Geramipour

Name of organization / entity
The univesity of arak

Country
Iran (Islamic Republic of)

Phone
+98 86 3403 9071

Email address
zahragerami938@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-22, 1402/07/30

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of kinesio typing and ankle resistance training with Bosu ball on pain, balance and big toe angle of women with Hallux Valgus.

Public title
The effect of kinesio typing and ankle strengthening exercises with bosu ball on hallux valgus

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women who have flat feet in addition to mild and moderate hallux valgus (15 to 30 degrees). Absence of any inflammatory disease in the lower limbs such as rheumatoid arthritis and gout... Absence of any orthopedic problems such as fractures and dislocations in the lower limbs Absence of any congenital diseases in the lower limbs

Exclusion criteria:

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The research community will consist of women with hallux valgus and flat feet. The number of samples was obtained using G-power software for all three groups of 45 people (15 control people, 15 kinesiotype people and 15 ankle strengthening exercises). The groups were selected by simple random.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants are unaware of the division of control and experimental groups.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University

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

City
Arak

Province
Markazi

Postal code
3848177584

Approval date
2023-04-19, 1402/01/30

Ethics committee reference number
IR.ARAKU.REC.1402.010

Health conditions studied

1

Description of health condition studied
Hallux valgus

ICD-10 code
M20.1

ICD-10 code description
Hallux valgus (acquired)

Primary outcomes

1

Description
Hallux valgus angle

Timepoint
At the beginning of the study and after 4 weeks of intervention

Method of measurement
Using a goniometer

Secondary outcomes

1

Description
The balance

Timepoint
At the beginning of the study and after four weeks of intervention

Method of measurement
Singel_Leg Balance test

2

Description
The pain

Timepoint
At the beginning of the study and after four weeks of intervention

Method of measurement
Visual Analogue Scale

3

Description

Flat foot

Timepoint

At the beginning of the study and after four weeks of intervention

Method of measurement

The amount of navicular bone loss

Intervention groups

1

Description

1: intervention group (kinesiotype and kinesiotype with ankle strengthening exercises) 2: control group

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hygieia Corrective Movement Center

Full name of responsible person

Azadeh Ghasemi

Street address

Hygieia Correctional Movement Center, Golha Alley, Abbas Abad St, Arak Town

City

Arak

Province

Markazi

Postal code

3819655357

Phone

+98 86 3402 2840

Email

zahragerami938@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University

Full name of responsible person

Shahnaz Shahrjardi

Street address

Faculty of Sport Sciences, Department of Sports Pathology, karbala Boulevard, Basij Square, Sardasht, Arak University, Arak

City

Atak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3262 9024

Email

shahjerdi_shahnaz@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University

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

Arak University

Full name of responsible person

Shahnaz Shahrjardi

Position

PhD in sports medicine

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Faculty of Sport Sciences, Department of Sports Pathology, karbala Boulevard, Basij Square, Sardasht, Arak University, Arak

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3262 9024

Fax

Email

shahjerdi_shahnaz@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University

Full name of responsible person

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City
Arak
Province
Markazi
Postal code
3848177584
Phone
+98 86 3262 9024
Fax
Email
shahjerdi_shahnaz@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Arak University
Full name of responsible person
Shahnaz Shahrjardi
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Faculty of Sport Sciences, Department of Sports Pathology, karbala Boulevard, Basij Square, Sardasht, Arak University, Arak
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Province
Markazi
Postal code
3848177584
Phone
+98 86 3262 9024
Fax
Email
shahjerdi_shahnaz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
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
Title and more details about the data/document
All data will be accessible after the publication of the research.
When the data will become available and for how long
Since 2023
To whom data/document is available
All people from university researchers, professors and people with hallux valgus can receive this research.
Under which criteria data/document could be used
A person who intends to study this research can send a message to the researcher via email, and the person can also use the information in the article.
From where data/document is obtainable
First, email: shahrjerdi.shanaz@gmail.com, then call the following number: 09161520974, and finally, you can visit the Arak University library located in Sardasht, Karbala Boulevard, in front of the flour factory.
What processes are involved for a request to access data/document
The applicant can receive the documents after sending an email to the researcher and receiving confirmation from the researcher.
Comments