

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of kinesiotyping 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 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 university of arak

Country

Iran (Islamic Republic of)

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+98 86 3403 9071

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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 taping 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 taping 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 kinesiotape 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 (kinesiotape and kinesiotape 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

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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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