

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of Kinesiotape on the Performance of the Musculoskeletal System in Women with Flexible Flatfeet in Conditions with and without Fatigue

Protocol summary

Study aim

Investigation of the performance variables of the musculoskeletal system extracted from biomechanical data in functional activities in women with flat feet before and after the functional fatigue protocol in two kinesiotape and sham tape groups

Design

The way of dividing people into two kinesiotape or sham tape groups will be according to block randomization. The sample size is 46. There is no trial phase. A clinical trial with a control group with parallel groups. Bilaterally blind.

Settings and conduct

The place of performance is in the research center for the treatment of movement disorders at Tarbiat Modares University. The random arrangement in the group is Kinsiotape and sham tape. The participants and the person responsible for data collection are unaware of the study group allocation. The intervention will be in two sessions, one week apart.

Participants/Inclusion and exclusion criteria

Entry conditions: Active non-athletes women suffering from bilateral flat feet normal body mass index (18.5-24.9) Age 18-30 Conditions of non-entry: history of any lasting orthopedic or neurological injury The difference in the actual length of the lower body is more than 1.5 centimeter Significant congenital malformations

Intervention groups

It includes Kinesiotape (intervention) or sham tape (control). The first session will be done in the condition without fatigue in two situations with and without tape and the second session will be done in the condition with fatigue in two situations with and without the jump tape. Our fatigue protocol consists of 5 sets of consecutive lateral jumps.

Main outcome variables

Biomechanical variables related to the performance of the musculoskeletal system during functional activities such as jumping and walking

General information

Reason for update

Updating to provide accurate and up-to-date information about the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049511N4**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **prospective**

Last update: **2025-04-25, 1404/02/05**

Update count: **1**

Registration date

2022-11-28, 1401/09/07

Registrant information

Name

Sahar Boozari

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 5053

Email address

s.boozari@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

2023-04-25, 1402/02/05

Actual recruitment end date

2024-01-24, 1402/11/04

Trial completion date

Scientific title

Effect of Kinesiotape on the Performance of the Musculoskeletal System in Women with Flexible Flatfeet in Conditions with and without Fatigue

Public title

Effect of Elastic Bands on the Human Body Performance in Women with Flatfeet

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Active non-athlete women (light aerobic activity three times a week), suffering from bilateral flexible flatfeet Normal Body Mass Index (18.5-24.9) Age 18-30

Exclusion criteria:

History of any lasting orthopedic or neurological damage in the lower limbs and spine The difference in the actual length of the lower body is more than 1.5 centimeter Significant congenital malformations in the lower limbs Body mass index more than 24.9 Pain in the lower limbs or spine during the research period Obvious deformities such as hallux valgus, genu varus, genu valgum, and internal rotation of the thigh

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **24**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done by the block randomization method. In the first session, people are randomly assigned to either kinesiotape or sham tape groups. The number of blocks will be 4 and 6, and randomly be placed in sealed envelopes. For the random assignment, code 1 for the kinesiotape group and code 0 for the sham tape group are placed in the envelopes. subjects will choose a closed envelope and are placed in the kinesiotape or sham tape group based on the selected code.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the kinesiotape group, the Kinesiotape, which is an elastic therapeutic tape, is attached to the posterior tibialis muscle, the transverse arch, and the inner longitudinal arch of the foot with a special tension to correct the arch and improve muscle function. For the sham group, a piece of tape is attached to the inside of the ankle, that is, in a place other than the treatment

area and without tension. Study participants are not aware of whether they are in the kinesiotape or sham group and are not familiar with the treatment. The engineer responsible for data recording also does not have information about how to stick the Kinesiotape, which is a therapeutic task and is blinded to the people in the two groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.MODARES.REC.1401.109

Health conditions studied

1

Description of health condition studied

Flexible flatfoot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Biomechanical variables related to body movement activities such as walking and jumping

Timepoint

Before and after the functional fatigue protocol

Method of measurement

Force plate device

Secondary outcomes

1

Description

Navicular drop value

Timepoint

Before and after kinesio tape

Method of measurement

Difference between the distance of the navicular tuberosity to the ground in the sitting and standing positions

Intervention groups

1

Description

Intervention group: intervention includes kinesiotape. In the first session, after learning how to jump, the subject performs the jump in the condition without tape. Then the tape is attached to the subject and this time the jump is done with the tape. Two situations with and without tape will be randomly selected for people. After a week, the second session will begin. In the second session, the fatigue protocol will be applied randomly in two conditions with and without tape. Our fatigue protocol consists of 5 sets of consecutive jumps, and when the person cannot continue the protocol, it means that the person is tired.

Category

Treatment - Other

2

Description

For the sham tape group, a kinesiotape piece is used on the inside of the ankle. In the first session, after learning how to jump, the subject performs the jump in the condition without tape. Then the tape is attached to the subject and this time the jump is done with the tape. Two situations with and without tape will be randomly selected for people. After a week, the second session will begin. In the second session, the fatigue protocol will be applied randomly in two conditions with and without tape. Our fatigue protocol consists of 5 sets of consecutive jumps, and when the person cannot continue the protocol, it means that the person is tired.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Treatment Center for Movement Disorders of Tarbiat Modares University

Full name of responsible person

Sahar Boozari

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al ahmad Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 5053

Fax

+98 21 8800 6544

Email

s.boozari@modares.ac.ir

Web page address

<http://ptmodares.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Tarbiat Modares

Full name of responsible person

Amir Abdollahzadeh

Street address

Tarbiat Modares University, Jalal Al Ahmad, Pol Nasr, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 2009

Fax

+98 21 8288 3101

Email

Res@modares.ac.ir

Web page address

<https://res.modares.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 Tarbiat Modares

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

The University of Tarbiat Modares

Full name of responsible person

Zeynab Nickpey

Position

Master's Student in Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al ahmad Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 5053

Fax

+98 21 8800 6544

Email

zeynabnickpey@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

Sahar Boozari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Iran, Tehran, Jalal Al ahmad Highway, Nasr Bridge, Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 5053

Fax

+98 21 8800 6544

Email

s.boozari@modares.ac.ir

Web page address

http://ptmodares.ir

Person responsible for updating data

Contact

Name of organization / entity

The University of Tarbiat Modares

Full name of responsible person

Sahar Boozari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Iran, Tehran, Jalal Al ahmad Highway, Nasr Bridge, Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 5053

Fax

+98 21 8800 6544

Email

s.boozari@modares.ac.ir

Web page address

http://ptmodares.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared after people are not identified.

When the data will become available and for how long

After the results are published, the access phase started six months later

To whom data/document is available

Researchers in academic and research organizations will also have access to the data.

Under which criteria data/document could be used

to do scientific research

From where data/document is obtainable

to do scientific research, Sahar Boozari, Jalal Al Ahmad Highway, Tarbiat Modares University,

s.boozari@modares.ac.ir, 00982182885053

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

Send the project plan, and if approved, it will be sent

following a complete evaluation of the persons and organizations involved in the project.

Comments