Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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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

2024-01-24, 1402/11/04

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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Tarbiat Modares
Full name of responsible person
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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
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

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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