Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparison of the effects of intrinsic and extrinsic foot muscle fatigue on lower limb joint kinetics and kinematics in female athletes with dynamic knee valgus

Protocol summary

Study aim

Comparing the effects of intrinsic-biased and extrinsic-biased foot muscle fatigue on lower-extremity kinetics and kinematics in female athletes with dynamic knee valgus.

Design

A randomized clinical trial with two parallel groups (intrinsic and extrinsic foot muscle fatigue), without a control group, involving 20 physically active women with dynamic knee valgus, with simple random allocation using the RAND function in Excel.

Settings and conduct

Study setting: Faculty of Physical Education and Sport Sciences, Allameh Tabataba’i University, Tehran; Study population: Women with dynamic knee valgus in Tehran; Blinding: No blinding will be performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18–30 years; presence of dynamic knee valgus based on the single-leg squat test; regular physical activity at moderate or vigorous intensity. Exclusion Criteria: History of lower-limb surgery or injury within the previous six months; neurological or musculoskeletal disorders; pain during testing and inability to complete the muscle fatigue protocol.

Intervention groups

First Intervention Group: Participants will stand on one leg on a balance pad and repeatedly raise and lower their heels every two seconds until fatigue of the extrinsic foot muscles is induced. Second Intervention Group: Participants will sit and use a Pilates resistance band to flex the big toe downward, followed by the other four toes, until fatigue of the intrinsic foot muscles is induced.

Main outcome variables

Kinetics and Kinematics of the Lower Extremity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180626040244N9**
Registration date: **2026-11-03, 1405/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-03, 1405/08/12**
Update count: **0**

Registration date

2026-11-03, 1405/08/12

Registrant information

Name
Rahman Sheikhhoseini
Name of organization / entity
Allameh Tabataba'i University
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Iran (Islamic Republic of)
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+98 21 4839 4134
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rahmanhoseini@atu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-03, 1405/08/12

Expected recruitment end date

2026-12-03, 1405/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison of the effects of intrinsic and extrinsic foot muscle fatigue on lower limb joint kinetics and kinematics in female athletes with dynamic knee valgus

Public title
Effect of Foot Muscle Fatigue on the Biomechanical Responses of the Lower Extremity in Women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Being between 18 and 30 years of age Demonstration of dynamic knee valgus based on the results of the single-leg squat test Engaging in sports activities involving at least 90 minutes of vigorous-intensity physical activity or 150 minutes of moderate-intensity physical activity per week.

Exclusion criteria:
A history of lower-limb surgery or injury within the past six months Having any neurological or musculoskeletal disorder Experiencing pain during test performance. Inability to complete the muscle fatigue protocol.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple randomization method, using sealed envelopes, is employed to assign participants to different groups. Each intervention type is written on a card and placed in a sealed envelope. Participants are listed in the order of their enrollment in the study. After each participant is enrolled, the envelopes are shuffled randomly, and each participant is asked to select one envelope at random. The number of envelopes is determined based on the expected sample size, ensuring that each selected envelope is not re-entered into the randomization process. This method ensures that the number of participants in each experimental group is approximately equal, thereby reducing the risk of discrepancies in group sizes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Allameh Tabataba'i University

Street address
West Azadi sports complex entrance, Hakim highway

City
Tehran

Province
Tehran

Postal code
1485743411

Approval date
2024-12-21, 1403/10/01

Ethics committee reference number
IR.ATU.REC.1403.170

Health conditions studied

1

Description of health condition studied
Dynamic knee valgus

ICD-10 code
M21.069

ICD-10 code description
Valgus deformity, not elsewhere classified, unspecified knee

Primary outcomes

1

Description
Lower extremity kinematics in 3 motion planes

Timepoint
Before the intervention and immediately after the intervention.

Method of measurement
8 Vicon motion capture cameras, a Kistler force plate

2

Description
Lower extremity kinetics in 3 motion planes

Timepoint
Before the intervention and immediately after the intervention.

Method of measurement
8 Vicon motion capture cameras, a Kistler force plate

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (Extrinsic Muscle Fatigue): Participants in this group stand on one leg on a balance pad and slowly raise and lower the heel of the supporting foot. This movement is performed every two seconds at a controlled rhythm until fatigue of the extrinsic foot muscles is induced.
Category
Prevention

2

Description
Intervention group 2 (Intrinsic Muscle Fatigue): Participants sit on a chair and use a Pilates resistance band to flex the big toe downward, followed by the other four toes, at the metatarsophalangeal joints. This exercise is repeated for several sets until fatigue of the intrinsic foot muscles is induced.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Physical Education and Sport Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Allameh Tabataba'i University
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
Allameh Tabataba'i 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
Allameh Tabataba'i
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Position
professor
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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
After the article is published, raw data without identifying the participants will be available by email to the corresponding author of the article.
When the data will become available and for how long
After the article is published, raw data without identifying the participants will be available by email to the corresponding author of the article.
To whom data/document is available
Any author who needs raw data, with a reason
Under which criteria data/document could be used
Any researcher can request data.
From where data/document is obtainable
By email to the correspondence author
What processes are involved for a request to access data/document
By email to the correspondence author
Comments