Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

Comparison of the Effect of the Combination of Neurocognitive Challenges and Fatigue on the Biomechanical Pattern of Athletes with and without Anterior Cruciate Ligament (ACL) Reconstruction During Single-leg Landing

Protocol summary

Study aim

Compare the effect of the combination of cognitive challenges and fatigue on the biomechanical pattern and coordination variability in athletes with and without a history of anterior cruciate ligament surgery during single-leg landing.

Design

The research includes 2 groups who are subjected to 4 intervention conditions. The present study does not have randomization and blinding, because the participants know their sample and receive all the interventions.

Settings and conduct

All data will be collected during one session in the laboratory of the Kharazmi University-Karaj Branch.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Male athletes in the age range of 18 to 30 years old, healthy, and with a history of anterior cruciate ligament surgery. 2. Experience in participating in sports that require cutting, turning, jumping, and landing movements. Exclusion criteria: 1. A history of anterior cruciate ligament injury and lower limb surgery in the past year (except for injury in the group with a history of anterior cruciate ligament surgery) 2. Neurocognitive and vision disorders in participants 3. Pain in the lower limbs 4. Sleep disorders

Intervention groups

All participants are examined in four conditions: 1. No intervention, 2. Fatigue condition, 3. Cognitive load condition, and 4. Fatigue and cognitive condition during single-leg landing.

Main outcome variables

The kinematic pattern includes: hip flexion, knee flexion, trunk flexion, ankle dorsiflexion, knee valgus, knee adduction and internal rotation, and lateral trunk flexion. A kinetic pattern including peak ground reaction force and external moment of knee abduction and extension and hip abduction and external rotation. Coordination variability including trunk-thigh, thigh-knee, knee-ankle, thigh-ankle and trunk-knee couplings.

General information

Reason for update

Acronym

ACL

IRCT registration information

IRCT registration number: **IRCT20210602051477N2**
Registration date: **2025-03-02, 1403/12/12**
Registration timing: **prospective**

Last update: **2025-03-02, 1403/12/12**
Update count: **0**

Registration date

2025-03-02, 1403/12/12

Registrant information

Name

Majid Hamoongard

Name of organization / entity

The University of Kharazmi

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-03, 1404/01/14

Expected recruitment end date
2025-04-20, 1404/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of the Combination of Neurocognitive Challenges and Fatigue on the Biomechanical Pattern of Athletes with and without Anterior Cruciate Ligament (ACL) Reconstruction During Single-leg Landing

Public title
The effect of cognitive challenge and fatigue on the risk of anterior cruciate ligament injury
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Male athletes in the age range of 18 to 30 years old, healthy and with a history of anterior cruciate ligament surgery (at least 9 months have passed since the surgery and the rehabilitation period has been completed) Experience in participating in sports that require cutting, turning, jumping and landing movements (futsal, volleyball, handball and basketball)
Exclusion criteria:
A history of anterior cruciate ligament injury and lower limb surgery in the past year (except for injury in the group with a history of anterior cruciate ligament surgery) Neurocognitive and vision disorders in participants Pain in the lower limbs sleep disorders The presence of cartilage, meniscal and other knee ligament injuries in the group with a history of anterior cruciate ligament surgery
Age
From **18 years** old to **30 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
The current study includes two groups of healthy athletes with a history of anterior cruciate ligament (ACL) surgery, who have completed the rehabilitation period under the supervision of a physiotherapist, and 9 months have passed since their surgery. All participants will undergo 4 immediate interventions to evaluate their biomechanical functions, and this will provide a better understanding of injury risk factors in the design of ACL injury prevention programs.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committees of kharazmi university
Street address
No. 43, Shahid Moftah St., Enghelab Blvd., Tehran Town
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Postal code
15719-14911
Approval date
2025-01-15, 1403/10/26
Ethics committee reference number
IR.KHU.REC.1403.155

Health conditions studied

1

Description of health condition studied
Participants with a history of anterior cruciate ligament surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Knee biomechanics (Kinematic and kinetics)
Timepoint
Biomechanical factors will be measured simultaneously with the intervention's effect on a cross-sectional and one-time basis.
Method of measurement
A motion capture system (Kestrel 8.0 motion analysis, US) 8 cameras and a force plate (Bertec corporation, Columbus, OH) 60x40 will simultaneously record data.

Secondary outcomes

1

Description
Coordination variability of lower extremity

Timepoint
Coordination variability will be done simultaneously with the effect of the intervention on a one-time basis.

Method of measurement
A motion capture system (Kestrel 8.0 motion analysis, US) 8 cameras and a force plate (Bertec corporation, Columbus, OH) 60x40 will simultaneously record data.

Intervention groups

1

Description
Intervention group: In the first intervention when the athlete performs a single-leg landing task, visual cognitive load is imposed on him. cognitive load includes using a color frame with blue, red, yellow, and green words to display to the subjects during the landing task. Participants will be asked to call out the color of the word aloud if the meaning of the word and the color of its font were similar, and to otherwise use the phrase " false."

Category
Prevention

2

Description
Intervention group: In the second intervention group, performance fatigue protocol will be used to impose physiological load on athletes during single-leg landing. first, the maximum vertical jump height of each subject will be measured. the protocol will consist of a combination of five consecutive vertical jumps at an altitude above 70 percent of the maximum jump height of each subject, followed by a series of back-and-forth speed races with maximum effort. subjects will be asked to perform the above method until their vertical jump height in five consecutive jumps reaches below 70 percent of the maximum height of each subject. Heart rate will be used to monitor the intensity of the fatigue protocol, so that the heart rate should be about 90 percent of each person's maximum heart rate.

Category
Prevention

3

Description
Intervention group: The athletes will first perform the functional fatigue protocol followed by the single-leg landing task along with the cognitive challenge simultaneously. First, the maximum vertical jump height of each subject will be measured. the protocol will consist of a combination of five consecutive vertical jumps at an altitude above 70 percent of the maximum jump height of each subject, followed by a series of back-and-forth speed races with maximum effort. subjects will be asked to perform the above method until their vertical jump height in five consecutive jumps reaches below 70 percent of the maximum height of each subject. Heart rate will be used to monitor the intensity of the fatigue protocol, so that the heart rate should be about 90 percent of each person's maximum heart rate. Cognitive load includes using a color frame with blue, red, yellow, and green words to display to the subjects during the landing task. Participants will be asked to call out the color of the word aloud if the meaning of the word and the color of its font were similar, and to otherwise use the phrase " false."

Category
Prevention

4

Description
Control group: Participants in the control group will perform the single-leg landing task only. The subjects will be asked to jump down a 30 cm high box with one leg followed by a maximum vertical jump on the same leg. The subjects will be told to do as much as possible to achieve an overhead goal by raising both hands (similar to a sport-specific task) at 300 cm height. If the subjects jump over the box instead of landing, if the other foot touches the ground, or if it loses its balance and falls during the test, the test will be repeated. No cognitive challenges and fatigue conditions are imposed on athletes.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kharazmi University

Full name of responsible person
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Sponsors / Funding sources

1

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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
Kharazmi 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
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Full name of responsible person
Majid Hamoongard

Position
Ph.D Student

Latest degree
Master

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file of the participants, the study protocol, the informed consent form and the study report after the completion of the research and the publication of the articles extracted from it will be published as attached files of the article as well as the results as an average of the entire population and anonymously.

When the data will become available and for how long

The period of access to protocols and results will begin about 6 months after the results are published.

To whom data/document is available

Researchers working in scientific institutions and universities, trainers working in sports clubs and physiotherapists, and health professionals.

Under which criteria data/document could be used

The research results will be in the form of articles published in scientific journals, and researchers and experts can access and use the results in this way.

From where data/document is obtainable

Applicants can email the responsible author of the article to receive the results of the study after its publication or submit their request through other scientific databases such as Research Gate. Email address: majidhamoongard@gmail.com

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

Applicants can email the corresponding author to receive the results of the study after it is published, and a response will be given as soon as possible.

Comments