

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effects of local, functional, and mental fatigue protocols on isokinetic strength, balance, and performance in healthy athletes and with anterior cruciate ligament reconstruction

Protocol summary

Study aim

Comparison of the effects of local, functional, and mental fatigue protocols on quadriceps to hamstring strength ratio at speeds of 60, 180, and 300 degrees per second, static and dynamic balance, and landing performance in healthy athletes and with anterior cruciate ligament reconstruction.

Design

The clinical trial will have a group of 12 athletes with ACL reconstruction, and a group of 12 healthy athletes. These samples will be selected purposively.

Settings and conduct

The location of the study is the Corrective Exercise Laboratory, Faculty of Sport and Health Sciences, University of Tehran. The study will be conducted in the form of a pre-test and post-test. The study variables will be measured before and after applying the fatigue protocols.

Participants/Inclusion and exclusion criteria

Male athletes with anterior cruciate ligament reconstruction of the dominant leg have a non-contact ACL injury mechanism. The surgical method for anterior cruciate ligament (ACL) reconstruction will involve an open procedure using a hamstring autograft. Post-rehabilitation, the participants must have a physical activity level of 6 or higher according to the Tegner Activity Scale upon return to sports. Full range of motion in the knee Body mass index (BMI) between 18 and 25 will be required.

Intervention groups

Interventions include local, functional, and mental fatigue protocols. The local fatigue protocol is applied using an isokinetic machine. The functional fatigue protocol is applied using the L Drill fatigue protocol. The mental fatigue protocol is applied using the Stroop protocol.

Main outcome variables

Types of local, functional, and mental fatigue can affect muscle strength, landing performance, joint position sense, and balance, and this effect can differ between healthy and ACL reconstruction groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045729N2**

Registration date: **2025-06-24, 1404/04/03**

Registration timing: **prospective**

Last update: **2025-06-24, 1404/04/03**

Update count: **0**

Registration date

2025-06-24, 1404/04/03

Registrant information

Name

Mohammad Hamzeh

Name of organization / entity

The University of Tehran

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-06, 1404/05/15

Expected recruitment end date

2026-01-05, 1404/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of local, functional, and mental fatigue protocols on isokinetic strength, balance, and performance in healthy athletes and with anterior cruciate ligament reconstruction

Public title

Comparing the effects of local, functional, and mental fatigue protocols on muscle strength, balance and performance in healthy athletes and with anterior cruciate ligament reconstruction.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The samples were from athletes in sports with shearing, jumping, and landing movement patterns who had regular sports activity and at least 3 years of experience. The mechanism of ACL injury is non-contact and occurs in jumping and landing movement patterns or shearing movements. The surgical procedure is anterior cruciate ligament reconstruction with hamstring autograft. Have completed various levels of rehabilitation and rehabilitation courses. The physical activity level of individuals after the rehabilitation process and return to sports should be a score of 6 or higher based on the Tegner questionnaire. Full range of motion in knee flexion and extension movements Body mass index between 18 - 25

Exclusion criteria:

Any neurological, cardiovascular, metabolic, rheumatic or vestibular disease. Frequent use of painkillers and drugs that affect the person's balance Consumption of any caffeine, energy drinks, or alcohol 24 hours before performing the fatigue protocol Performing intense physical activity 24 hours before the implementation of the fatigue protocol Having any history of injury or surgery to the hip, ankle, foot, or opposite knee injury Having any mental health problems, such as depression or anxiety

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: **24**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Tehran University - Faculty of Sport Sciences and Health

Street address

Faculty of Physical Education and Sport Sciences, between 15th and 16th St., North Kargar st., Tehran, Islamic Republic

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Approval date

2025-05-11, 1404/02/21

Ethics committee reference number

IR.UT.SPORT.REC.1404.074

Health conditions studied**1****Description of health condition studied**

Anterior Cruciate Ligament Reconstruction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Quadriceps to hamstring strength ratio

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the study (after each fatigue protocol applied at 7-day intervals).

Method of measurement

Isokinetic

Secondary outcomes

1

Description

Knee Flexion and Extensor Peak Torque

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the study (after each fatigue protocol applied at 7-day intervals).

Method of measurement

Isokinetic

2

Description

Landing performance

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the study (after each fatigue protocol applied at 7-day intervals).

Method of measurement

Landing Error Scoring System

3

Description

Joint Position Sense

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the study (after each fatigue protocol applied at 7-day intervals).

Method of measurement

Isokinetic

4

Description

Postural Stability

Timepoint

At the beginning of the study (before the start of the intervention) and 7, 14 and 21 days after the start of the study (after each fatigue protocol applied at 7-day intervals).

Method of measurement

Biodex Balance System

Intervention groups

1

Description

Intervention group one: Local fatigue: To induce localized fatigue, the Biodex isokinetic dynamometer (System 4 Pro™ model) will be used. In this experiment, each participant will undergo six test stages. The first three stages involve determining the maximum torque at three angular velocities: 60, 180, and 300 degrees per second. The criterion for achieving fatigue at each speed is a reduction in torque to below 50% of the individual's maximal voluntary torque at that specific speed.

Category

Other

2

Description

Intervention group two: Functional fatigue : To induce functional fatigue, a functional agility short-term fatigue protocol will be used. This protocol consists of the following four components: Step-up L-drill
Countermovement jump Agility ladder drill. Based on previous studies, participants are required to complete all four sets of the protocol consecutively in order to induce a state of fatigue. The entire sequence is estimated to last approximately six minutes.

Category

Other

3

Description

Intervention group three: Mental fatigue: The mental fatigue protocol will be conducted using the Stroop test. To induce mental fatigue, a 30-minute Stroop task will be employed. The Stroop mental fatigue task is essentially a color-word interference test administered during the mental fatigue session. In this task, color words ("red," "blue," "green," and "yellow") are presented on a screen in either congruent or incongruent formats. Participants are encouraged to exert maximal effort to complete as many items as possible within the 30-minute period. The Stroop task will be administered using the DMDX software on the same display and at the same distance.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Laboratory of corrective exercise Faculty of Sports and Health Sciences University of Tehran

Full name of responsible person

Ali Mirabedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

The University of Tehran

Proportion provided by this source

5

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 Tehran

Full name of responsible person

Mohammad Hamzeh Shalamzari

Position

Ph.D Student

Latest degree

Ph.D.

Other areas of specialty/work

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying individuals.

When the data will become available and for how long

The access period begins 8 months after the results are published.

To whom data/document is available

The data is accessible to all scientific and industrial people.

Under which criteria data/document could be used

The data is accessible to all scientific and industrial people.

From where data/document is obtainable

To receive the data, they can apply to the following email address: m.hamzeh13755@ut.ac.ir Also, they can contact Mohammad Hamzeh at the following number: 00989138790757

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

After sending the applicant's email and code assigned to the subject at the time of testing, his data will be sent.

Comments