

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3262 2846

##### Email address

m.hamzeh13755@ut.ac.ir

##### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955975

**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

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1439955975

##### **Phone**

+98 21 7308 8351

##### **Fax**

+98 21 8802 1527

##### **Email**

infosport@ut.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The University of Tehran

**Full name of responsible person**

Hooman Minoonejad

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955975

**Phone**

+98 21 7308 8351

**Email**

h.minoonejad@ut.ac.ir

**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**

Corrective Exercise and Sport Injuries

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955975

**Phone**

+98 21 6111 8928

**Email**

m.hamzeh13755@ut.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

The University of Tehran

**Full name of responsible person**

Hooman Minoonejad

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Corrective Exercise and Sport Injuries

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955975

**Phone**

+98 21 6111 8928

**Email**

h.minoonejad@ut.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

The University of Tehran

**Full name of responsible person**

Mohammad Hamzeh Shalamzari

**Position**

Ph.D Student

**Latest degree**

Master

**Other areas of specialty/work**

Corrective Exercise and Sport Injuries

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1439955975

**Phone**

+98 21 6111 8928

**Email**

m.hamzeh13755@ut.ac.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**

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**