

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of 8-week of neuromuscular training with and without cognitive dual-task on proprioception, balance, strength and functional performance of athletes with anterior cruciate ligament deficiency

#### Protocol summary

##### Study aim

Investigating the effect of adding dual cognitive and motor tasks on the rehabilitation and preventive output of athletes who are transferred from a controlled rehabilitation environment to an uncontrolled playground environment

##### Design

The statistical population of the present study will be male football players aged 18 to 35 years in Mazandaran province who have a history of anterior cruciate ligament injury and rupture. Injury will be diagnosed under the supervision of a sports medicine specialist through MRI images. From the study population, 36 subjects will be selected who will be placed in three groups of 12 people.

##### Settings and conduct

The tests and exercises of the present study will be performed at the Academy of Sacrifice Health and Rehabilitation, and the Clinic of the Sports Medicine Board of Mazandaran Province.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the research: 1. People with a history of grade 2 anterior cruciate ligament rupture in the past year 2. Soccer athletes 3. Having a BMI between 18 and 24 4. Not participating in lower limb rehabilitation programs in the last 6 months 5. Having a damaged knee joint up to 80 to 90% of the isokinetic strength of a healthy knee Exclusion variables: 1. History of complex and multi-ligament injuries of the knee joint 2. History of knee joint surgery 3. The presence of any abnormalities of the lower limbs and spine 4. Feeling of pain in the knee joint 5. Feeling of significant instability and relaxation in the knee joint 6. Sensory and neurological problems

##### Intervention groups

The first intervention group, neuromuscular exercises  
The second intervention group, neuromuscular exercises with dual tasks  
Matched control group, custom exercises

##### Main outcome variables

muscle strength; neuromuscular and sensorimotor coordination; balance; Specialized functional performance

#### General information

##### Reason for update

Subject: Request for Correction of Randomized and Blinding Information Dear reviewer, With greetings and respect, I would like to inform you that I have mistakenly entered the blinding and randomization details and kindly request permission to correct them. Sincerely, Masoud barzegar

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220602055058N1**  
Registration date: **2022-12-16, 1401/09/25**  
Registration timing: **retrospective**

Last update: **2025-05-21, 1404/02/31**

Update count: **1**

##### Registration date

2022-12-16, 1401/09/25

##### Registrant information

###### Name

Masoud Barzegar

###### Name of organization / entity

The University of Kharazmi

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3313 2601

###### Email address

msdbarzegar@gmail.com

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2022-03-06, 1400/12/15

### Expected recruitment end date

2022-08-21, 1401/05/30

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

The effect of 8-week of neuromuscular training with and without cognitive dual-task on proprioception, balance, strength and functional performance of athletes with anterior cruciate ligament deficiency

## Public title

The effect of neuromuscular training and cognitive tasks on functional performance of athletes with anterior cruciate ligament injury

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

lack of surgery, having 80-90% isokinetic strength of healthy opposite knee, lack of neurovascular problems and pain

### Exclusion criteria:

Joint range of motion problems, pain, swelling, major meniscus rupture

## Age

From **18 years** old to **35 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **39**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using permuted block randomization (6 blocks with a size of 7), three treatment arms will be independently allocated to participants in a 1:1:1 ratio (after initial screening). The random sequence list will be generated by computer (Pocock SJ. Clinical Trials: A Practical Approach. Wiley; 1983) and the website <https://www.randomizer.org>. This process will be overseen by a blinded assessor to ensure allocation concealment.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The outcome assessor will be blinded to group allocation. Participants will not be blinded to the study or their assigned group; however, they will be blinded to the

specific intervention they receive (an unavoidable risk of bias exists in this study, as neither the intervention administrators nor the patients can be fully blinded to the treatment). Prior to assessments, the outcome assessor will receive standardized training on variable evaluation protocols to prevent any discussion or exchange of information between the assessor and participants during the trial.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

پژوهشگاه تربیت بدنی و علوم ورزشی

##### Street address

Tehran - Ostad Motahhari St. - Mir Emad St. - Fifth Alley - No. 3

##### City

tehran

##### Province

Tehran

##### Postal code

1587958711

#### Approval date

2022-02-20, 1400/12/01

#### Ethics committee reference number

IR.SSRI.REC.1400.1340

## Health conditions studied

### 1

#### Description of health condition studied

knee injury

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

1. Neuromuscular exercises with dual cognitive tasks2. Neuromuscular exercises without dual cognitive tasks1. Deep sense2. Equilibrium3. Power4. Performance

#### Timepoint

Winter 1400 to Summer 1401

#### Method of measurement

1. Consent form and personal information2. Digital scale for measuring weight3. Tape meter for measuring height4. Isokinetic device for measuring muscle

strength5. Lower limb function test (LESS and Hopping tests)6. Goniometer to measure joint angle in depth sense test (position sense) in closed chain7. Digital camera to record video images in frontal and sagittal motion screens8. AutoCAD software for measuring detailed angle9. Quinoa software for outputting kinematic data10. Adhesive tape for dynamic balance test Y (Y)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: First - neuromuscular exercises. Second - neuromuscular exercises with dual tasks. Third-control

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Physiotherapy Clinic

#### Full name of responsible person

Masoud Barzegar

#### Street address

Farhang

#### City

sari

#### Province

Mazandaran

#### Postal code

4849176751

#### Phone

+98 11 3330 5709

#### Email

msdbarzegar@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Masoud Barzegar

#### Street address

khaghani

#### City

tehran

#### Province

Tehran

### Postal code

4849176751

### Phone

+98 935 287 5051

### Email

msdbarzegar@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Iranian academic center for education culture and research

### Proportion provided by this source

80

### 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

Iranian academic center for education culture and research

#### Full name of responsible person

Masoud Barzegar

#### Position

student

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Sport Medicine

#### Street address

Farhang

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Masoud Barzegar

**Position**  
student  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iranian academic center for education culture and research  
**Full name of responsible person**  
Masoud Barzegar  
**Position**  
student  
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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

training

### When the data will become available and for how long

one year

### To whom data/document is available

barzegar

### Under which criteria data/document could be used

progression

### From where data/document is obtainable

ever

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

total

### Comments