

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)

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+98 11 3313 2601

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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

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

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

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

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Contact

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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