

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Impact of Different Methods of Constraint-led Approach and Visual-Motor Training on Selected Neuroplasticity, psychology and Functional Variables in the Patients with the History of Anterior Cruciate Ligament Reconstruction

Protocol summary

Study aim

The Impact of Different Methods of Constraint-led Approach and Visual-Motor Training on Selected Neuroplasticity, psychology and Functional Variables in the Patients with the History of Anterior Cruciate Ligament Reconstruction

Design

The study consists of two parallel groups and one control group. The sample size is based on previous selected articles on 45 people

Settings and conduct

FMRI test at National Brain Mapping Laboratory and Biomechanical Test at Biomechanics Laboratory of Shahid Beheshti Rehabilitation School and two months of training at the University Stadium

Participants/Inclusion and exclusion criteria

Age between 18 and 45 years Having general health at the discretion of the physician No pain or swelling in the knee area Have at least four years of experience in sports 6 months to a year after surgery

Intervention groups

Intervention Group 1: Investigating the Impact of Visual Motor training Intervention group 2: The effect of different methods of the Constraint-led Approach Intervention group 3: The control group is without any training intervention

Main outcome variables

Help improve rehabilitation for patients by reconstructing the anterior cruciate ligament and repairing the brain (neuroplasticity) and improving psychological factors such as fear of injury and kinophobia and functional factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046598N1**

Registration date: **2020-05-10, 1399/02/21**

Registration timing: **retrospective**

Last update: **2020-05-10, 1399/02/21**

Update count: **0**

Registration date

2020-05-10, 1399/02/21

Registrant information

Name

Fateme Gholami

Name of organization / entity

The University Of Kharazmi

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2600

Email address

std_gholami_f@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

2020-01-25, 1398/11/05

Actual recruitment end date

2020-02-05, 1398/11/16

Trial completion date

2020-02-05, 1398/11/16

Scientific title

The Impact of Different Methods of Constraint-led Approach and Visual-Motor Training on Selected Neuroplasticity, psychology and Functional Variables in the Patients with the History of Anterior Cruciate Ligament Reconstruction

Public title

The effect of Visual-Motor Training on Neuroplasticity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having general health at the discretion of the physician
Perform surgery on the anterior cruciate ligament 6 months to a year after surgery

Exclusion criteria:

No pain or swelling in the knee area
Lack of lower limb abnormalities

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته ملی اخلاق در پژوهش های زیست پزشکی

Street address

Tehran, Ghods Town (West), between Flamak South and Zarafshan, Simai St., Iran, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th Floor

City

Tehran

Province

Tehran

Postal code

71869_11817

Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.KHU.REC.1398.049

Health conditions studied

1

Description of health condition studied

Patients with anterior cruciate ligament reconstruction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Restoration of cerebral areas, including the motor cortex after training, improves performance in knee flexion / extension, and valgus .reduces fear of injury and kinophobia after exercise

Timepoint

After 8 weeks of training

Method of measurement

عوامل عملکردی با: موشن و FMRI نورویلاستیسیتی: اندازه گیری با فورس پلیت و همچنین عوامل روانشناختی با پرسشنامه

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: visual training is a movement that is the basis of jumping and landing exercises with balance movement and resistance and visual disturbance and with the use of tools such as Traband, Busobal, balance board. The second intervention group: the constraints_led approach that change the environment and homework in these exercises as well as the person himself, for example, the person exercises with fatigue and without fatigue or in a bright and dark environment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Behnam Physiotherapy Clinic

Full name of responsible person

Dr. Soheil Mansour Sohani

Street address

Tehran, Shariati St., Ershad dead end

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University student

Latest degree

Bachelor

Other areas of specialty/work

Corrective exercise and sport injury

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kharazmi

Full name of responsible person

amir letafatkar

Street address

Hesari st

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+98 21 8832 9220

Email

letafatkaramir@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Kharazmi

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

The University Of Kharazmi

Full name of responsible person

Fateme Gholami

Position

Person responsible for scientific inquiries

Contact

Name of organization / entity

the University of Kharazmi

Full name of responsible person

Fateme Gholami

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Corrective exercise and sport injury

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Part of the data related to people's information, including the area undergoing surgery and reconstruction, age, height and bmi, and their level of athletic activity

When the data will become available and for how long

The course starts up to 5 to 8 months after printing the results

To whom data/document is available

Researchers studying at academic institutions or physicians and physiotherapists

Under which criteria data/document could be used

People can ask the researcher for information or data by informing them

From where data/document is obtainable

researcher : std_gholami-f@gmail.com

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

If the results are out of print, they will be available to people

Comments