

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of biofeedback on proprioception , balance , strength of the quadriceps and knee function following anterior cruciate ligament reconstruction

Protocol summary

Study aim

Determining the effect of biofeedback on proprioception, balance and function following anterior cruciate ligament reconstruction

Design

In this randomized double-blind clinical trial study, patients were randomly divided into two groups of 20 based on a random number table: biofeedback technique and routine rehabilitation exercises and control of routine rehabilitation exercises.

Settings and conduct

Patients who are candidates for anterior cruciate ligament reconstruction referred to Akhtar Hospital will be randomly divided into two groups of 20 in one of the intervention / control groups.

Participants/Inclusion and exclusion criteria

This study will be performed on patients with anterior cruciate ligament reconstruction in Tehran in 2021-2022 and patients will not enter the study with the dissatisfaction of participating in the study.

Intervention groups

Intervention group (Biofeedback techniques and common rehabilitation exercises) : Patients will practice in a standing position, mini-squat, knee extension with maximum isometric contraction in front of a computer that provides visual and auditory feedback, and individuals should increase the maximum threshold for muscle contraction. The intervention is held for 4 weeks and three sessions per week for each person and the duration of each session is 45 minutes. Control group: Patients perform common rehabilitation exercises including weightlifting, SLR and quad set exercises for 4 weeks and three sessions per week, each lasting 45 minutes.

Main outcome variables

Proprioception, balance and anterior cruciate ligament function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211113053048N1**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **prospective**

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

Ali Asghar Jameh Bozorgi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7754 2057

Email address

aas.bozorgi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-05, 1400/09/14

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of biofeedback on proprioception , balance , strength of the quadriceps and knee function following anterior cruciate ligament reconstruction

Public title

The effect of biofeedback on proprioception, balance, strength of the quadriceps and knee function following anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Unilateral anterior cruciate ligament injury Age 30-18 years Patients who have undergone at least 16 sessions of physical therapy and are able to walk without a cane, without pain and inflammation, and with full range of motion of the knee. At least ten weeks have passed since surgery No neuromuscular disease, length difference between limbs, addiction to drugs and alcohol and any complication of the peripheral and central nervous system that disturbs the balance Patients who do not have cognitive, visual or auditory problems Patients who did not receive biofeedback therapy or similar during the intervention. Do not take medication that affects balance Consent to participate in the project

Exclusion criteria:

Dissatisfaction with participating in the project

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups based on a table of random numbers. First, we define the framework of our statistical community, determine the exact number of people in the community, and code them in order. If the total number of people in a community is a two-digit or three-digit number or more, the codes and numbers assigned to members of the community must be the same. To select sample people from the table, we randomly start from a table point in the row or column direction. Point selection can be done by closing the eyes and placing a finger or the tip of a pen on the table. We only select smaller numbers. The selected number is in fact the individual code of the community that is selected as a sample.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients (intervention or control) will receive encoded sealed envelopes. The coding will be done by

one of the project partners and the evaluator and the patient will be blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1014

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

Anterior Cruciate Ligament Reconstruction

ICD-10 code

S83.512A

ICD-10 code description

Sprain of anterior cruciate ligament of left knee, init ·

Primary outcomes**1****Description**

Proprioception

Timepoint

Before and after treatment

Method of measurement

Using a digital camera, the patient must estimate the angles defined for the injured knee.

2**Description**

Balance

Timepoint

Before and after treatment

Method of measurement

Using the plate machine, the static balance is measured in four positions: standing on two legs with open eyes, standing on two legs with closed eyes, standing on one with open eyes, standing on one with closed eyes, and dynamic balance of activities. Used to transfer weight along the anterior-posterior, internal, or external surfaces of a computer screen.

3

Description

Strength of the quadriceps

Timepoint

Before and after treatment

Method of measurement

Quadriceps muscle strength using a dynamometer

4

Description

knee function

Timepoint

Before and after treatment

Method of measurement

KOOS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: (Biofeedback techniques and common rehabilitation exercises) : Patients will practice in a standing position, mini-squat, knee extension with maximum isometric contraction in front of a computer that provides visual and auditory feedback, and individuals should increase the maximum threshold for muscle contraction. The intervention is held for 4 weeks and three sessions per week for each person and the duration of each session is 45 minutes.

Category

Treatment - Devices

2

Description

Control group: Patients perform common rehabilitation exercises including weightlifting, SLR and quad set exercises for 4 weeks and three sessions per week, each lasting 45 minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Ali Asghar Jameh Bozorgi P.H.D

Street address

In front of Bouali Hospital, Damavand Street (New Tehran), Tehran

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aas.bozorgi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai P.H.D

Street address

Parvaneh St., Yaman St., Shahid Chamran Expressway

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19615-1179

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Email

aliziai@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Asghar Jameh Bozorgi \.Ā._

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Position

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Person responsible for updating data

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Position

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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

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Research centers and faculty members

Under which criteria data/document could be used

At the request of the researcher and faculty members

From where data/document is obtainable

Send email to the scientific respondent

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

Within two months from the time of requesting and sending the email, the documents will be sent to the mentioned people

Comments