

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effects of balance training with and without cognitive task and external focus of attention on postural control in individuals with anterior cruciate ligament reconstruction-A duoble blinded randomized control trial

Protocol summary

Study aim

Determine an appropriate balance exercise program for individuals with anterior cruciate ligament reconstruction.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients. G-POWER software was used for randomization.

Settings and conduct

In this study, which is a two-way blind randomized trial. Patients are evaluated by another physiotherapist. The data analyzer will also be unaware of the specifics of the groups. After the call, people will be evaluated by an experienced physiotherapist. The first step is to perform general and local stability tests of their postural control using force plate device and balance control using Y balance test. The second stage involves training intervention The third step is to repeat the postural control tests and the dynamic balance assessment test

Participants/Inclusion and exclusion criteria

Inclusion criteria 1)Age between 17 and 45 years 2) More than 6 months after surgery 3)The subjects did not participate in another treatment exercise during the last six weeks. Exclusion criteria 1)Existence of untreated meniscus tear in the operated leg 2)Have a history of lateral ligament injury or surgery 3)Have a history of surgery or traumatic injury to the opposite knee 4)Have a history of surgery or traumatic injury to either of the ankle and hip joints 5)Complain about instability 6)Have a history of neurological diseases, vestibular disorders and vision 7)Have a history of posterior cruciate ligament rupture .

Intervention groups

1: Individuals who perform routine balance exercises 2: Individuals who perform common balance exercises with external focus 3: Individuals who perform common

balance exercises with cognitive tasks

Main outcome variables

Average power frequency Approximate entropy
Maximum Lyapanov exponent Amplitude and velocity of pressure center oscillations

General information

Reason for update

Acronym

کنترل پاسچر ، بازسازی رباط صلیبی قدامی زانو، تکلیف شناختی ، تمرکز توجه ، تمرینات تعادلی

IRCT registration information

IRCT registration number: **IRCT20211004052666N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-05, 1400/08/14

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of balance training with and without cognitive task and external focus of attention on postural control in individuals with anterior cruciate ligament reconstruction-A duoble blinded randomized control trial

Public title

The effects of balance training with and without cognitive task and external focus of attention on postural control in individuals with anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1) At least 6 months after the anterior cruciate ligament reconstraction of the knee 2) Age between 17 and 45 years old 3)The subjects in the study did not participate in another treatment exercise during the last six weeks.

Exclusion criteria:

Existence of untreated meniscus tear in the operated leg
Have a history of lateral ligament injury or surgery
Have a history of surgery or traumatic injury to the opposite knee
Have a history of surgery or traumatic injury to either of the ankle and hip joints
Complain about instability
Have a history of neurological diseases, vestibular disorders and vision
Have a history of posterior cruciate ligament rupture
Have a history of diabetes, taking medication that affects balance and confusion
Existence of musculoskeletal problems in the back and neck

AgeFrom **17 years** old to **45 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample sizeTarget sample size: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

They will be selected from the available population by simple non-probability sampling method and then randomly divided into three groups. And after obtaining informed consent, people enter the study. The advantage of this method is that while keeping the number of people in the three groups equal, the balance

of groups in terms of the distribution of influential variables (gender in this study) is also maintained. For this purpose, first by Random allocation computer software (version 1.1 of Isfahan University of Medical Sciences, Iran) a random order of three letters A (first group) and B (second group) and C (third group) with random numbers 4 and 5 And 6 will be built. The blocks are then hidden by an opaque envelope. In order to minimize bias, select, and ensure that the allocation of individuals in groups is concealed, the randomization process will be performed by a person who will not participate in any of the other stages of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind randomized trial in which patients are evaluated by a physiotherapist who is unaware of the assignments of individuals in groups. The data analyst is also unaware of the specifics of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences and Health Services

Street address

University City, Vice Chancellor for Research and Technology, Ahwaz Jundishapur University of Medical Sciences and Health Services, Ground Floor

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Postal code

15794-61357

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.AJUMS.REC.1400.335

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

individuals with (knee) anterior cruciate ligament reconstruction

ICD-10 code

M23.61

ICD-10 code description

Other spontaneous disruption of anterior cruciate ligament of knee

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

Sway of center of pressure

Timepoint

Measurement of pressure center sway before intervention, after 8 weeks of intervention and 4 weeks after the end of the study

Method of measurement

Force plate apparatus

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Group 1: People with anterior cruciate ligament reconstruction who perform regular balance exercises

Category

Rehabilitation

2**Description**

Group 2: People with anterior cruciate ligament reconstruction who perform routine balance exercises with external attention focus exercises

Category

Rehabilitation

3**Description**

Intervention group: Group 3: People with ligament reconstruction Anterior cruciate ligament that combines common balance exercises with cognitive exercises

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ahvaz University of Medical Sciences - Rehabilitation College

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

HOSSAIN KOHZAD MOHAMMADI

Position
CONSULTANT

Latest degree
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Other areas of specialty/work
Physiotherapy

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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

Informed consent forms, koos questionnaire, tegner, and personal information collection form are given. And only information about the main outcome is shared.

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

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The applicant must be a researcher working in an academic institution

From where data/document is obtainable

To receive information, you need to contact Dr. Kouhzad Mohammadi, in charge of the project, by email: Correspondence should be sent to www.kouhzad@yahoo.com.

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

Request an email from the developer and receive a response within one to two months

Comments