

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

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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

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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