Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Name
Abdollah Tayebi

Name of organization / entity

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Iran (Islamic Republic of)

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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
Age
From **17 years** old to **45 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target 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, Ahvaz Jundishapur University of Medical Sciences and Health Services, Ground Floor
City
Ahvaz
Province
Khouzestan
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
ABDOLLAH TAYEBI
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College Town - Rehabilitation College
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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HOSSAIN KOHZAD MAHAMADI
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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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Person responsible for updating data

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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