Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of dual task balance training with single task balance training in subjects with anterior cruciate ligament reconstruction: A randomized controlled trial

Protocol summary

Study aim

Main objective: The effect of balance training with secondary cognitive task in comparison with balance training separately on postural control, activity level and functional ability of individuals with unilateral anterior cruciate ligament reconstruction.

Design

A randomized clinical trial with a control group with parallel, double-blind, randomized groups on 26 patients divided into two groups by blocking.

Settings and conduct

Referred patients will be evaluated and if they meet the necessary conditions and after obtaining informed consent, they will be included in the study. First, the initial evaluation of the tests will be performed from the patients and the results will be recorded. Patients will be randomly assigned (using closed envelopes) to control and intervention groups. Patients will be evaluated and treated in private clinic and Ghaem hospital in Mashhad.

Participants/Inclusion and exclusion criteria

This project is performed on people with anterior cruciate ligament reconstruction aged 16 to 50 years, patients must be at least 6 weeks past ACL reconstruction surgery (at least 40 seconds on the injured leg can stand), at least 120 degree range of motion for knee flexion and can walk without any helps.

Intervention groups

In both groups, patients will receive FES for 15 minutes and a series of conventional physiotherapy treatments will be performed for 15 minutes including strengthening, stretching and mobilizing knee joint sets. Then balance exercises are performed by the patient under the supervision of the physiotherapist. In the intervention group, balance exercises are performed simultaneously with the secondary cognitive task and in the control group, balance exercises are performed separately.

Main outcome variables

Star Excursion Balance Test Single leg Stance on Force Platform Tegner Activity Scale The Knee Injury and Osteoarthritis Outcome Score (KOOS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220705055372N1**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Mohammad Reza Amirinejad Robot

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of dual task balance training with single task balance training in subjects with anterior cruciate ligament reconstruction: A randomized controlled trial

Public title

The effect of balance training with cognitive task

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Participants age between 16 and 50 At least 6 weeks have passed since ACL reconstruction surgery (at least 40 seconds on the injured leg can stand) Have minimal inflammation There is a minimum range of motion of 120 degrees for knee flexion Able to walk without any help Sensory and motor function of the lower extremity of the person is healthy

Exclusion criteria:

Patient has neurological problems, heart and respiratory diseases Have a history of neuromuscular diseases and surgery in the lower extremities The patient has vision problems and vestibolar disorders The rate of pain during evaluation on the VAS scale is greater than 2 The patient should take a reduced consciousness and hypnotic drug Patients have osteoporosis, knee osteoarthritis and fractures in the lower extremities

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block allocation method with volume 4 will be used. All possible 4 permutations will be listed in two groups. (Permutations 1 to 6 as follows) A is the intervention group and B is the control group. 1-AABB 2-ABAB 3-BAAB 4-BABA 5-BBAA 6-ABBA Then, from the random numbers table with random starting point, 6 will be selected between 1 and 6 by accident (either using software or randomaize.com site).For example, if the 6 random numbers obtained are 3 5 4 3 4 6, it will mean that the first four are similar to block 3, the second four are similar to block 5 and ... They'll be allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, evaluators, analyzer were kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Yazdan Building , Sadeghiyeh18, Sadeghiyeh Blvd,

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Razavi Khorasan

Postal code

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Approval date

2022-06-28, 1401/04/07

Ethics committee reference number

IR.MUMS.FHMPM.REC.1401.063

Health conditions studied

1

Description of health condition studied

People or patients with anterior cruciate ligament reconstruction

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes

1

Description

Star Excursion Balance Test

Timepoint

This assessment is done before and after treatment.

Method of measurement

This tool is used as a widely used dynamic test for clinical and research trials that evaluate a person's dynamic balance and this test requires strength, flexibility and depth perception. While standing on one leg (injured leg), the tester must move the other leg along eight directions and the person's displacement will be measured and will be calculated as the person's score.

Secondary outcomes

1

Description
Single Leg Stance on Force Platform
Timepoint
This assessment is done before and after treatment.
Method of measurement
The force plate is a tool that measures information about the state of the body and uses oscillation amplitude to evaluate this information. This amplitude is obtained from the minimum and maximum distance from the pressure center recorded by the device, and the lower the amplitude, the better the stability. Another parameter of the force plate is the sway speed, which is defined as the total displacement of the center of pressure on the total time the person has been on the device, and the lower the sway speed, the better the state stability of the individual.

2

Description
Tegner Activity Scale
Timepoint
This assessment is done before and after treatment.
Method of measurement
This scale is used to record the activity level of both groups. The numerical amplitude of this scale is in the range of 0-10. The higher the score on this scale, the higher the activity level.

3

Description
Knee Injury and Osteoarthritis Outcome Score (KOOS)
Timepoint
This assessment is done before and after treatment.
Method of measurement
A questionnaire used to assess the outcome of knee injuries and knee joint function. This questionnaire includes 5 dimensions related to pain, symptoms related to illness, life activities, recreational sports activities and quality of life. The score of this questionnaire is between 0-100, which means the maximum disability score and the score of 100 means that the person has no disability.

Intervention groups

1

Description
Intervention group: patients receive 60 minutes of treatment for 4 weeks and 3 sessions per week in a total of 12 sessions. In the intervention group, patients are initially treated with conventional physiotherapy for 30 minutes and then perform balance exercises that coincide with cognitive task for 30 minutes.
Category
Rehabilitation

2

Description
Control group: patients receive 60 minutes of treatment for 4 weeks and 3 sessions per week in a total of 12 sessions. In the control group, patients are initially treated with conventional physiotherapy for 30 minutes and then perform balance exercises separately for 30 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Mahmood Mohammadzade Shabestari
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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
Mashhad 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available