Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effects of Cognitive_Balance Dual-Task Training and Single Task Balance Training on Static Balance of People with Anterior Cruciate Ligament Reconstruction (ACL_R)

Protocol summary

Study aim

The main purposes of this study are the comparison of some of center of pressure (COP) parameters in static balance task while standing on reconstructed limb before and after intervention in each group and between groups, also survey of correlation between COP parameters and level of functional disability measured by KOOS questionnaire in people with anterior cruciate ligament reconstruction.

Design

Clinical trial with parallel control group, double blind and randomized grouping, 15 people in each group

Settings and conduct

This study will be carried out at the Biomechanics Lab of rehabilitation sciences faculty of Tabriz University of Medical Sciences. Individuals in intervention group will do progressive balance training simultaneously with cognitive tasks for 20 minutes 3 sessions a week for 6 weeks. The control group will just do balance training. Participants, researcher, and data recorder and analyzer will be blind to groups.

Participants/Inclusion and exclusion criteria

In this study the people with unilateral anterior cruciate ligament reconstructed by hamstring tendon allograft and ability of full weight bearing on reconstructed limb and at least 120 degree reconstructed knee range of motion will participate; and they will be eliminated if they have a history of neurological, vestibular and visual disorder, injury or surgery of the spine or other segments of involved limb or other ligaments of the reconstructed knee.

Intervention groups

Intervention group will do balance training and cognitive tasks simultaneously (Dual Task). However, control group will just do balance training (Single Task).

Main outcome variables

COP parameters include sway amplitude, velocity, path length and Mean Square (RMS) amplitude and velocity of COP in anterior-posterior and medial-lateral direction, total path length of COP ,Root , ellipse sway area and KOOS questionnaire score.

General information

Reason for update

Acronym

Anterior Cruciate Ligament Reconstruction (ACL_R)

IRCT registration information

IRCT registration number: **IRCT20180925041138N1**
Registration date: **2019-05-31, 1398/03/10**
Registration timing: **prospective**

Last update: **2019-05-31, 1398/03/10**
Update count: **0**

Registration date

2019-05-31, 1398/03/10

Registrant information

Name

Jalal Ahadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3337 5359

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Cognitive_Balance Dual-Task Training and Single Task Balance Training on Static Balance of People with Anterior Cruciate Ligament Reconstruction (ACL_R)

Public title
Affect of Dual_Task Balance Training on Balance of People with Anterior Cruciate Ligament Reconstruction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral ACL Reconstruction Surgery by Hamstring Tendon Allograft Full Weight Bearing Ability on Reconstructed limb At Least 120 Degree Reconstructed Knee Range of Motion
Exclusion criteria:
The History of Neurological, Vestibular and Visual Disorder The History of Injury or Surgery of the Spine The History of Injury or Surgery of the Other Segments of Reconstructed Limb The History of Injury or Surgery of the Other Ligaments of Reconstructed Knee
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study people with inclusion criteria will be divided into control and Intervention groups according to simple randomization way by Random Software Allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study all of the participants will be unaware of group of study they belong to. Also researcher, outcomes assessors and data analyzer will be unaware the group each participants belong to. Inevitably, the trainer physiotherapist base on intervention type will not be blind. However, he will not be allowed to outcome assessment and data analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166615669
Approval date
2019-01-21, 1397/11/01
Ethics committee reference number
IR.TBZMED.REC.1397.865

Health conditions studied

1

Description of health condition studied
Anterior Cruciate Ligament Reconstruction
ICD-10 code
S83.51
ICD-10 code description
Sprain of anterior cruciate ligament of knee

Primary outcomes

1

Description
Mean Anterior - Posterior Sway amplitude of Center of Pressure
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

2

Description
Mean Medial - Lateral Sway amplitude of Center of Pressure
Timepoint
Before starting balance training and at the end of treatment (18 session later)

Method of measurement
Force Plate Instrument

3

Description
Total path length of Center of Pressure
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

4

Description
Root-mean-square amplitude of center of pressure in anterior - posterior direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

5

Description
Root-mean-square amplitude of center of pressure in medial - lateral direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

6

Description
Root-mean-square velocity of center of pressure in anterior - posterior direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

7

Description
Root-mean-square velocity of center of pressure in medial - lateral direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

8

Description
Ellipse sway area
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

9

Description
Center of pressure velocity in anterior - posterior direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

10

Description
Center of pressure velocity in medial - lateral direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

11

Description
Path length of center of pressure in anterior - posterior direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

12

Description
Path length of center of pressure in medial - lateral direction
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

Secondary outcomes

1

Description
The Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire
Timepoint
Before starting balance training and at the end of treatment (18 session later)
Method of measurement
Force Plate Instrument

Intervention groups

1

Description
Intervention group: Anterior cruciate reconstructed patients during rehabilitation in balance training phase will do progressive balance training including single leg standing on reconstructed limb, standing on bi-direction balance board in med-lat direction, standing on bi-direction balance board in ant-post direction, standing on bi-direction balance board with foam surface(10 cm thickness), standing on multi-direction balance board, standing on multi-direction balance board with foam surface(10 cm thickness) simultaneously with cognitive tasks including backward counting of numbers at a specified interval, saying the days of the week in reverse and alternative ways, saying the names started with special letters, reverse words spelling (Dual Task) for 20 minutes, 3 sessions a week for 6 weeks.

Category
Rehabilitation

2

Description
Control group: Anterior cruciate reconstructed patients during rehabilitation in balance training phase will do progressive balance training including single leg standing on reconstructed limb, standing on bi-direction balance board in med-lat direction, standing on bi-direction balance board in ant-post direction, standing on bi-direction balance board with foam surface(10 cm thickness), standing on multi-direction balance board, standing on multi-direction balance board with foam surface(10 cm thickness) without any cognitive tasks (Single Task) for 20 minutes, 3 sessions a week for 6 weeks.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada medical research & training hospital

Full name of responsible person
Dr. Amin Moradi

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No. 692, Golshahr street, Elgoli Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Jalal Ahadi

Position
Assistance Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Physiotherapy department, Rehabilitation Sciences Faculty, Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available