Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effects of Motor_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 (ACL) 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. Individuals in intervention group will do progressive balance training simultaneously with motor 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 ligement reconstruction surgery 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

In this study intervention group will do balance training and motor tasks simultaneously (Dual Task). However, control group will just do balance training (Single Task).

Main outcome variables

Center of pressure(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 , ellipse sway area and KOOS questionnaire score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180925041138N2**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **prospective**

Last update: **2019-06-09, 1398/03/19**
Update count: **0**

Registration date

2019-06-09, 1398/03/19

Registrant information

Name

Jalal Ahadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 5359

Email address

ahadij@tbzmed.ac.ir

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 Motor_Balance Dual-Task Training and Single Task Balance Training on Static Balance of People with Anterior Cruciate Ligament Reconstruction (ACL_R)

Public title
Effect of Dual_Task Balance Training on Balance of People with Anterior Cruciate Ligament Reconstruction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral Anterior Cruciate Ligament Reconstruction Surgery by Hamstring Tendon Allograft Full Weight Bearing Ability on Reconstructed limb At Least 120 Degree Reconstructed Knee Range of Motion
Exclusion criteria:
History of Neurological, Vestibular and Visual Disorder History of Injury or Surgery of the Spine History of Injury or Surgery of the Other Segments of Reconstructed Limb 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
2019-02-25, 1397/12/06
Ethics committee reference number
IR.TBZMED.REC.1397.946

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
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

4

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

5

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

6

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

7

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

8

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

9

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

10

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

11

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

12

Description
Ellipse sway area
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 standing (single leg) 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 doing motor tasks including Moving the ball between two hands, throwing the ball to a target, pouring water of glasses into each other, taking and returning the ball with hand, bouncing the ball with intact foot, following the lines drawn on wall with a laser pen (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 motor 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

Street address

No. 692, Golshahr Street, Elgoli Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3314

Email

info@cdrm-en.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

Street address

No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3334 4280

Email

research-vice@tbzmed.ac.ir

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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166615669

Phone

+98 41 3337 5359

Email
Ahadij@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Jalal Ahadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy department, Rehabilitation Sciences Faculty, Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166615669
Phone
+98 41 3337 5359
Email
Ahadij@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Jalal Ahadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Physiotherapy department, Rehabilitation Sciences Faculty, Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166615669
Phone
+98 41 3337 5359
Email
Ahadij@tbzmed.ac.ir

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