Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Developing a machine-based training program for using Wii Fit to evaluate patient's balance and physical function after anterior cruciate ligament reconstruction

Protocol summary

Study aim
The overall objective of this study was to develop a machine-based training program using the Nintendo Wii Fit to evaluate the balance and physical performance of patients after reconstructing the anterior cruciate ligament.

Design
In this study,20 subjects after random allocation in two groups will be treated in parallel. First, a summary of the research program is presented for them, then the checklist of the research, which includes questions about demographic information and the medical history is completed. Then, other clinical, functional and balance evaluations will be performed

Settings and conduct
This study will be performed on patients after ACL reconstruction surgery at the physical therapy clinic, Tarbiat Modares University.

Participants/Inclusion and exclusion criteria
Male patients aged between 20-30 years who at least 3 months have passed since their ACL reconstruction surgery without any chronic diseases and injuries that affect the study.

Intervention groups
1-Wii Fit System Machine Based Rehabilitation Group ; 2-Conventional Exercise Therapy Group ;

Main outcome variables
Pain; Active knee flexion range of motion; The circumference of the thigh; Physical Function;Static & Dynamic Balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191013045090N1**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date
2020-03-03, 1398/12/13

Registrant information

Name
Arezoo Abasi

Name of organization / entity
Tarbiat Modares University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Developing a machine-based training program for using Wii Fit to evaluate patient's balance and physical function after anterior cruciate ligament reconstruction

Public title
Developing a machine-based training program in rehabilitation after reconstruction of the anterior cruciate ligament
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral ACL injury with specialist physician diagnosis and MRI approval At least 3 months after ACL reconstruction surgery (With Bone-Patellar-Tendon-Bone Surgery Type) Male Full consent to participate in the research Having a referral from an orthopedic specialist Complete cardiovascular health of patients with physician approval Balanced state of mind
Exclusion criteria:
Unfinished treatment programs and assessment The occurrence of any sudden systemic disorder during rehabilitation according to the patient The patient's willingness to withdraw from the study and unfinished treatment Performing exercises outside the prescribed schedule according to the patient Receive any treatment other than the treatment plans prescribed in this research plan Injury to other ligaments and knee joint structures with orthopedic specialist approval Previous surgery or injury in the knee of the opposite side and other joints of the lower extremities with orthopedic specialist approval Taking painkillers, anti-inflammatory drugs, etc Chronic illness or other known condition that may affect research research
Age
From **20 years** old to **30 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
The study samples will be divided into study groups (Interfering with Wii Fit, treatment with conventional therapy) by a quadruple-block random sampling among eligible patients undergoing ACL reconstruction.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the evaluator of research outcomes will be blinded to treatment groups. The person who does the statistical analysis of the data will also be blind to the treatment modalities and treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tarbiat Modares University
Street address
Tarbiat Modares University, Jalal Al ahmad Street, Tehran
City
Tehran
Province
Tehran
Postal code
14115-111
Approval date
2019-07-07, 1398/04/16
Ethics committee reference number
IR.MODARES.REC.1398.124

Health conditions studied

1

Description of health condition studied
Anterior cruciate ligament tear
ICD-10 code
ICD-10 code description
Sprain of anterior cruciate ligament of knee

Primary outcomes

1

Description
Static Balance
Timepoint
Pre and Post Intervention
Method of measurement
Balance Error Scoring System Test

2

Description
Dynamic Balance
Timepoint
Pre and Post Intervention
Method of measurement
Modified Star Excursion Balance Test

3

Description
Physical Function
Timepoint
Pre and Post Intervention
Method of measurement

Single leg hop for time & One leg hop for distance

Secondary outcomes

1

Description
Pain Intensity
Timepoint
Pre and Post Intervention
Method of measurement
Visual Analogue Scale

2

Description
Knee range of motion
Timepoint
Pre and Post Intervention
Method of measurement
Goniometery

3

Description
Thigh Atrophy
Timepoint
Pre and Post Intervention
Method of measurement
Measurement of thigh circumference with Cm tape measure

Intervention groups

1

Description
Intervention group:]It is a game-based rehabilitation program based on expert opinions and with the Wii Fit system to improve the balance for patients after reconstruction of the anterior cruciate ligament and Includes seven Ski Slalom, Ski Jump, Table Tilt, Balance Bubble, Perfect 10, Penguin Slide, Skateboard Adena on Wii system.
Category
Rehabilitation

2

Description
Control group: The common rehabilitation program treatments used in physiotherapy clinics for patients after reconstruction of the anterior cruciate ligament.Patients' exercise therapy programs in the control group will include:• Static exercises for quadriceps, hamstring, gluteal muscles and SLR. .•Closed chain exercises to increase knee mobility.• Proprioseptive exercises on the balance board.• Functional exercises such as using a stationary bike or treadmill.• Stretching exercises for the lower extremities .• Lower extremity muscle strengthening exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Physiotherapy - Tarbiat Modares University
Full name of responsible person
Anoshirvan Kazemnejad lili
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Sponsors / Funding sources

1

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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
Tarbiat Modares University
Proportion provided by this source
10
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
Tarbiat Modares University

Full name of responsible person
Arezoo Abasi

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Medical Informatics

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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
Due to ethical standards, The participants have been promised that the information of this research will remain confidential in their written consent form.

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Not applicable

Title and more details about the data/document
Part of the data, such as information about the main outcomeس can be shared.

When the data will become available and for how long
One year after the publication of articles related to the research project

To whom data/document is available
The researchers and specialists working in universities and health centers

Under which criteria data/document could be used
Analysis of the data delivered after obtaining permission from the researchers

From where data/document is obtainable

Arezoo Abasi Medical Informatics Dept., Faculty of Medicine,Tarbiat Modares University -Jalal Al ahmad Street - Tehran - Iran, Postal code 14115-111

What processes are involved for a request to access data/document

The applicant of the data file should send a request to the researcher via an email and the researcher will inform the applicant after negotiating with other research colleagues, and this process will take a maximum of one month.

Comments