

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8788 8828

###### Email address

arezoo\_abasi@modares.ac.ir

##### 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

Rehabilitation

## 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

Goniometry

### 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. • Proprioceptive 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

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Physiotherapy - Tarbiat Modares University

##### Full name of responsible person

Anoshirvan Kazemnejad lili

##### Street address

Tarbiat Modares University -Jalal Al ahmad Street - Tehran - Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

14115-111

##### Phone

+98 21 82880

##### Email

pres@modares.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tarbiat Modares University

##### Full name of responsible person

Anoshirvan Kazemnejad lili

##### Street address

Tarbiat Modares University -Jalal Al ahmad Street - Tehran - Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

14115-111

##### Phone

+98 21 8288 3875

##### Email

kazem\_an@modares.ac.ir

#### 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

#### Street address

Tarbiat Modares University -Jalal Al ahmad Street -  
Tehran - Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

14115-111

#### Phone

+98 21 8288 3875

#### Email

arezoo\_abasi@modares.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tarbiat Modares University

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Arezoo Abasi

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Masters student

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#### Email

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tarbiat Modares University

#### Full name of responsible person

Arezoo Abasi

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Masters student

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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 outcome *س* 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**