

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### effects of functional virtual reality intervention on biomechanic indexes and proprioception 6 month after high tibial osteotomy operation

#### Protocol summary

##### Study aim

Determining the effect of virtual reality intervention on biomechanical indices and proprioception in individuals after proximal tibial osteotomy surgery

##### Design

Clinical trial on 28 samples, with two groups: intervention and control, double-blind and randomized with categorized block method

##### Settings and conduct

Interventions are conducted at the Red Crescent Comprehensive Rehabilitation Center, with 12 sessions of 45 minutes each per person, three days a week. The participants and the trained occupational therapist are blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 30-50 years who have undergone unilateral proximal tibial osteotomy surgery, at least 3 months to 1-year post-surgery, completion of a written and informed consent form. Exclusion criteria: Any neurological or neuromuscular disorder that affects balance, use of medications that impair balance, presence of cognitive or psychological disorders, presence of infection or open wounds in the studied limb, patient's withdrawal from the study.

##### Intervention groups

In the intervention group, routine rehabilitation interventions, along with virtual reality exercises aimed at increasing balance, proprioception, and postural stability, designed and programmed by the researcher and executed using a virtual reality device, are also performed for 45 minutes. In the control group, patients receive routine rehabilitation exercises along with balance and proprioception exercises with similar repetition and intensity for 45 minutes under the supervision of a trained occupational therapist.

##### Main outcome variables

Quality of life score, Static and Dynamic balance, and proprioception after 4 weeks of intervention in intervention and control groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250903067109N1**

Registration date: **2026-01-31, 1404/11/11**

Registration timing: **prospective**

Last update: **2026-01-31, 1404/11/11**

Update count: **0**

##### Registration date

2026-01-31, 1404/11/11

##### Registrant information

##### Name

Reyhane Zare

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 930 728 7175

##### Email address

reyhane.zare@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-02-20, 1404/12/01

##### Expected recruitment end date

2026-05-22, 1405/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

effects of functional virtual reality intervention on biomechanic indexes and proprioception 6 month after high tibial osteotomy operation

#### Public title

effects of functional virtual reality intervention on biomechanic indexes and proprioception after high tibial osteotomy operation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Performing proximal tibial osteotomy surgery for the first time unilateral surgery homogeneity of groups in terms of surgical method and the time elapsed since surgery Patients should be in the age range of 30-50 years Willingness to participate in research and understand information related to the research content ability to answer the questions in persian Cognitively, being in the 24-30 range based on the MMSE scale Ability to walk and maintain balance while standing without any assistive device At least 3 months and at most one year should have passed since the surgery. No complications after surgery, such as non-union, delayed union, and infection No neurological problems No accompanying neurological diseases or other orthopedic disorders that impair balance. Avoid using balance-disrupting medications during the assessment and intervention period No other surgery on the lower limb in the past year

##### Exclusion criteria:

Damage to the operated bone such that a second surgery is required. The presence of issues such as embolism that have disrupted the normal course of treatment Unwillingness to continue cooperation

#### Age

From **30 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **28**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each person provides one sample

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, a stratified block randomization method will be used. Participants will first be stratified based on their Body Mass Index (BMI) to control for its potential confounding effect on the study outcomes. Within each BMI stratum, randomization will be performed using block of four to ensure balanced allocation between the intervention and control groups. The allocation sequences within each block will be randomly generated

using Random Allocation Software, with a fixed block size of 4. The randomization and allocation process will be conducted by an independent researcher who is not involved in data collection or intervention implementation.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

This study will be conducted in a double-blind design. In this trial, both the participants and the outcome assessors will be blinded to the type of intervention received. Allocation to the intervention and control groups will be performed using coded randomization, and each participant will receive a unique identification code. The intervention will be prepared or presented in identical forms to prevent any visual or procedural differences between groups. The allocation codes will remain concealed from the principal investigator and data analyst until the completion of data analysis and will only be disclosed in case of serious adverse events requiring unblinding.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice-chancellor in research affairs- Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti university of medical Science, arabi St., Daneshjoo Blvd., velenjak, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2024-11-10, 1403/08/20

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1403.444

## Health conditions studied

### 1

#### Description of health condition studied

post-operative rehabilitation of patients with high tibial osteotomy.

#### ICD-10 code

M21.16

## ICD-10 code description

Varus deformity, not elsewhere classified, knee

## Primary outcomes

### 1

#### Description

Static balance

#### Timepoint

The beginning of the study before intervention and 4 weeks after using the intervention

#### Method of measurement

force plate

### 2

#### Description

Dynamic balance

#### Timepoint

The beginning of the study before intervention and 4 weeks after using the intervention

#### Method of measurement

STAR test

### 3

#### Description

Quality of life

#### Timepoint

The beginning of the study before intervention and 4 weeks after using the intervention

#### Method of measurement

Knee injury and Osteoarthritis Outcome Score questionnaire (KOOS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will perform routine rehabilitation interventions in addition to virtual reality exercises aimed at improving balance, proprioception, and postural stability, which are designed and programmed by the researcher and executed using a virtual reality device, for 4 weeks, with 3 sessions of 45 minutes each per week. In this group, in addition to routine balance rehabilitation interventions, interventions using the SENA intelligent rehabilitation system at the Red Crescent Comprehensive Rehabilitation Center and the related device will also be carried out. The Kinect camera of this tool determines the patient's joint angles and presents them as an avatar on the screen, providing various dynamic balance exercises. Using the balance board, which is connected to the device via a cable, also enables static balance exercises. During the exercises, a target is usually set for

the patient, represented by colored balls, and the patient hits the targets by moving their feet or shifting their center of gravity. The size of the target, the time to reach it, and the number of hits can change the level of the games and determine the difficulty of the exercises according to the therapist's judgment and the patient's progress. Additionally, during the exercises, appropriate auditory and visual feedback is provided through the display based on the individual's performance.

#### Category

Rehabilitation

### 2

#### Description

Control group: In the control group, patients receive routine rehabilitation exercises in addition to balance and proprioception exercises such as standing and walking on uneven surfaces, postural stability exercises, and gait training exercises with similar repetition and intensity for 4 weeks, three 45-minute sessions per week under the supervision of a trained occupational therapist. Routine rehabilitation includes full weight bearing on the affected knee, strengthening the muscles around the knees, especially the vastus medialis and quadriceps, lateral and forward step-up exercises, weight transfer exercises from one leg to the other using a foam roll and balance board, walking on the foam roll, and other uneven surfaces.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Biomechanics Laboratory, Faculty of Rehabilitation, Shahid Beheshti University

##### Full name of responsible person

Reyhane Zare

##### Street address

biomechanics laboratory, Shahid Beheshti Faculty of Rehabilitation Sciences, in front of Bu Ali hospital, Damavand St. , Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1616913111

##### Phone

+98 21 7754 2057

##### Email

info@sbm.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Shahid Beheshti University of Medical Sciences, Arabi St, Daneshjoo Blvd, Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835113

**Phone**

+98 21 2243 9907

**Fax****Email**

pcu@sbmu.ac.ir

**Web page address**[https://isid.research.ac.ir/Afshin\\_Zarghi](https://isid.research.ac.ir/Afshin_Zarghi)**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reyhane Zare

**Position**

Occupational therapy Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Shahid Beheshti Faculty of Rehabilitation Science, in front of Bu Ali hospital, Damavand street

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 7754 2057

**Fax****Email**

reyhane.zare@sbmu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

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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