

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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		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.	
Public title	effects of functional virtual reality intervention on biomechanic indexes and proprioception after high tibial osteotomy operation	Blinding (investigator's opinion)	Double blinded
Purpose	Treatment	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.
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	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
Age	From 30 years old to 50 years old	Health conditions studied	1 Description of health condition studied post-operative rehabilitation of patients with high tibial osteotomy. ICD-10 code M21.16
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		

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

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

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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
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

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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