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

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Iran (Islamic Republic of)

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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

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 homogenity 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 date 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 afairs- Shahid Beheshti University of Medical Sciences

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

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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 begining of the study before intervention and 4 weeks after using the intervention
Method of measurement
force plate

2

Description
Dynamic balance
Timepoint
The begining of the study before intervention and 4 weeks after using the intervention
Method of measurement
STAR test

3

Description
Quality of life
Timepoint
The begining of the study before intervention and 4 weeks after using the intervention
Method of measurement
Knee injury and Osteoarthritis Outcome Score questionaire (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
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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
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Position
Occupational therapy Master's student
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Other areas of specialty/work
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Person responsible for updating data

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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