

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

the effect of adding virtual reality- based rehabilitation to conventional physiotherapy on functional level,pain and balance in patients after total knee arthroplasty

Protocol summary

Study aim

The effect of adding virtual reality-based rehabilitation to conventional physiotherapy on functional level, pain and balance in patients after total knee arthroplasty

Design

The study is two arm parallel randomized trial with blinded,outcome assessor , on 40 patients after knee joint replacement surgery. randomization will be used by Block randomization method.

Settings and conduct

patients after total knee joint replacement in Erfan, Sina and Nikan hospitals referred to Sabay Salamat Physiotherapy Center in 1402. The patients were randomly divided into intervention and control groups.control group will receive standard physiotherapy after knee replacement surgery and intervention group , will receive , virtual reality based exercises . this study, is outcome assessor blind,the implementation and evaluation method is designed to blind the evaluator, so the therapist will be different from the evaluator

Participants/Inclusion and exclusion criteria

Patients are eligible for inclusion and exclusion criteria if a total knee replacement after idiopathic,post traumatic osteoarthritis was implemented.The criteria s include age between 45-65 years,Body Mass Index lesser than 31, Ability to weight bearing on affected limb,Absence of redicular pain, cognitive disorders,imbalance and previous history of surgery in affected limb.

Intervention groups

Each patient will allocate to an experimental(VR; virtual reality group) or to a control group. The control group will receive standard physiotherapy after joint replacement, including modalities that reduce pain and inflammation, joint replacement exercises according to the knee joint replacement rehabilitation guidelines, such as range of motion and strength exercises , the control group will receive therapeutic exercises with virtual

reality .

Main outcome variables

Womac questionnaire,VAS scale,static and dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230524058283N1**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

Registration date

2023-08-10, 1402/05/19

Registrant information

Name

Ghazal Hashemi Zenooz

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-07, 1402/09/16

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effect of adding virtual reality- based rehabilitation to conventional physiotherapy on functional level,pain and balance in patients after total knee arthroplasty

Public title
the effect of adding virtual reality- based rehabilitation to conventional physiotherapy on functional level,pain and balance in patients after total knee arthroplasty

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 45-65years Ability to weight bearing on affected limb To 7 days after surgery Body mass index lower than 31 Total knee arthroplasty with primary diagnosis of osteoarthritis
Exclusion criteria:
1-history of previous surgery in operated leg for instant tibial osteotomy or fixation 2-history of former total knee or hip arthroplasty 3-neurologic or cognitive disorders that affect patients walking ability 4-dizziness and vestibular disorders that affect patients balance 5-having joint infections,ambly and prosthesis loosening 6-painfull contra-lateral knee joint arthrosis 7-visual dysfunctions 8-problems that disturb patients corporation with virtual environment for instant demance,psychological disorders and ...

Age
From **45 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Block method was used for randomization in the present study.we will choose 10 blocks of 4 patients. Randomization Block method has been designed to randomize the distribution of people into the studied groups in such a way that the sample size of the groups is equal. 10 blocks of 4 patients were selected. In each block, an equal number of people was assigned to each group. 10 blocks, were determined, and then blocks of both intervention and control groups were randomized. For example, when a participant entered the study, he was asked to select a block from blocks 1 to 10 and then either A or B. After block selection, the order of the other three subjects was determined randomly.then the information will deliver to secreter in closed envelopes

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comitee of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2023-05-10, 1402/02/20

Ethics committee reference number

IR.USWR.REC.1402.024

Health conditions studied

1

Description of health condition studied

total knee arthroplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient functional level with Western Ontario and McMaster universities Osteoarthritis index(WOMAC)

Timepoint

After and before treatment,1 month after treatment

Method of measurement

Western Ontario and McMaster universities Osteoarthritis index(WOMAC) questionnaire

Secondary outcomes

1

Description

Pain
Timepoint
Before and after treatment
Method of measurement
Visual Analogue Scale

2

Description
Static balance
Timepoint
Before and after treatment

Method of measurement
Body center of pressure displacement and velocity parameters in standing position

3

Description
dynamic balance
Timepoint
before and after treatment
Method of measurement
functional reach test

Intervention groups

1

Description
"Intervention group": virtual reality based rehabilitation by Kinect. Patients will do their exercises in front of Kinect's Infra Red cameras from 5th to 10th session with duration of 20 minutes. This technology provides real time visual feedback during exercises.

Category
Rehabilitation

2

Description
"Control group": Patients will be treated with standard physiotherapy after total knee arthroplasty surgery that include different modalities for reducing pain and inflammation and doing exercises in all sessions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Saba Salamat Physiotherapy
Full name of responsible person
Ghazal Hashemi Zenooz
Street address
No. 10, 1st. Alborz Alley, Alborz St., Marzdaran Blvd.
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
zahra mosallanezhad
Position
associate professor
Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Latest degree

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Other areas of specialty/work

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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

patients privacy

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

No - There is not 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