Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
Phone
+98 21 4428 3829
Email address
hashemi.ghz@gmail.com

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 osteoarthrosis

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-diziness and vestibular disorders that affect patients balance 5-having joint infections,amboly 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.

City

Tehran

Province

Tehran

Postal code

1463864463

Phone

+98 21 4480 1802

Email

hashemi.ghz@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Zahra mosallanezhad

Street address

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0109

Email

webmaster@uswr.ac.ir

Web page address

https://www.uswr.ac.ir/

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

Street address
dakyar Ave., daneshjo Blvd.,Evin

City
tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 7173 2833

Email
webmaster@uswr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
zahra mosalla nezhad

Position
associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 7173 2000

Email
zmosallanezhad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Ghazal Hashemi Zenooz

Position
Physiotherapyst

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
number 34,sepehr7 alli,sepehr street,marzdaran blvd

City
Tehran

Province
Tehran

Postal code
1463815141

Phone
44801802

Email
hashemi.ghz@gmail.com

Web page address

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