Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Impact of Home-Based Exercise Training and Clinic-Based Physiotherapy on the Mobility Status of Patients Following Knee Joint Replacement Surgery

Protocol summary

Study aim

Determining the effect of home-based exercise training with clinic-based physiotherapy on the movement status of patients after total knee surgery.

Design

Clinical trial, with a control group, with parallel groups, without blinding, randomized on 80 patients. The participants will be randomly assigned to two control and intervention groups using the computer software (RAS) using permutation blocks in 10 blocks of 8.

Settings and conduct

Study population: All patients who are candidates for knee joint replacement in Shahid Chamran Hospital in Shiraz and Beheshti Hospital in Kashan. Rehabilitation exercises can be done in two forms: home-based sports exercises or clinic-based physical therapy. From the second day after the knee joint replacement surgery, the intervention group will undergo home-based exercise training, in which the patient and his companion will be taught how to perform exercise by an experienced physiotherapist in a face-to-face meeting. The intervention group will perform these exercises twice a day for a period of 1 month. In the control group; Patients will undergo clinic-based physiotherapy protocol from the third day after surgery for 15 sessions every 2 days by referring to the specified clinic. Then, the demographic information questionnaire and the Lysholm questionnaire will be completed by the patients and with the help of the surgeon in the stage before the surgery and 2 months after the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum age of 60 years for patients Exclusion criteria: Having internal diseases, nervous system, skeletal system (such as the spine) Failure to complete physical therapy or exercise sessions

Intervention groups

Intervention group: patients receiving home-based exercise Control group: patients receiving clinic-based physiotherapy protocol

Main outcome variables

Knee motion position

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230928059543N3**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date

2024-07-25, 1403/05/04

Registrant information

Name

Armin Fereidouni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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arminfereidoni@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Impact of Home-Based Exercise Training and Clinic-Based Physiotherapy on the Mobility Status of Patients Following Knee Joint Replacement Surgery

Public title
The effect of exercise on the movement status of patients after knee joint replacement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Age range from 40 to 90 years Literate to read and write

Exclusion criteria:
Failure to complete the questionnaire Failure to complete physical therapy sessions or exercise according to self-report Bleeding and infection after surgery Abnormal pain and joint and prosthesis malfunction Patients not going to the doctor after the interventions Failure to do exercises at home by people who have received clinic-based physiotherapy. The presence of severe deformities or a history of surgery in the lower limbs and spine Suffering from specific psychological diseases according to self-report according to MMSE mental state questionnaire Presence of internal diseases (such as gout), diseases of the nervous and central system (such as stroke and MS)

Age
From **60 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of participants by permutation blocks in 10 blocks of 8 and using Random Allocation Software (RAS) version 4/9 (Internet address: https://random-allocation-software.software.informer.com) /2.0/) will be assigned to two groups of home-based exercise or clinic-based physical therapy. Researchers will use the block randomization method for random allocation, the unit of randomization will be the individual (we do not have stratified randomization), and the tool will be the RAS version 4.9 software. There is no blinding in this study.

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 Committee of kashan University of Medical Sciences

Street address
5.7 side alley; 5 alley; Dolate-sharghy Blvd.; Shiraz

City
shiraz

Province
Fars

Postal code
716775595

Approval date
2024-07-01, 1403/04/11

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1403.021

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
T84.9

ICD-10 code description
Unspecified complication of internal orthopedic prosthetic device, implant and graft

Primary outcomes

1

Description
Movement status

Timepoint
The patient's movement status will be completed by the patients and with the help of the surgeon through the Lysholm questionnaire in the stage before the surgery and 2 months after the surgery.

Method of measurement
Lyshulm questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving home-based exercise training. These exercises include: home-based exercise intervention: from the second day after the knee joint replacement surgery, the home-based exercise group will undergo home-based exercise twice a day for a period of 1 month. The physiotherapist will teach the patient and his companion how to perform physical exercises in a face-to-face meeting at the patient's home. At the same time as the training, it will be filmed by the patient's companion, so that the patient and his companion can see it at home and while doing sports), also during this period of 1 month, the physiotherapist through a phone call on the exercises Patient-centered exercise monitors. Full knee extension exercise • The patient sits on a bed or a flat surface. • It straightens the operated leg as completely as possible. • A folded or rolled towel is placed under the heel of the patient's foot. Another person stands next to the patient and the operated leg, he puts one of his hands on the patient's thigh 10-15 cm above the knee and the other on the patient's leg 10-15 cm below the knee. It applies to the patient's operated knee. Of course, in case of applying pressure and feeling pain in the patient's leg, it is sufficient to apply pressure to the extent that the patient feels the pain. He applies pressure for 5 seconds and releases it. Performs range of motion exercises • The patient is placed on the edge of the bed. The height of the bed should be such that the patient's leg remains hanging. The patient places the healthy (non-operated) leg on the operated leg and straightens and raises the leg as much as possible and keeps this position for 5 seconds. and leaves • Then in the same position (healthy leg on the operated leg) he bends the operated leg as much as possible and in this he takes help from the healthy leg to apply pressure to reach the maximum amount of bending. This exercise also requires 5 seconds of maintaining the position. • The patient performs this exercise twenty to thirty times twice a day (28). Exercise to strengthen the quadriceps muscle • This exercise is divided into two parts of three weeks • The first three weeks: the patient sits on a chair, raises the operated leg in a position that is straightened as much as possible and is in line with the chair He stays in this position for 10 seconds and then lowers his leg. The patient repeats this exercise thirty times twice a day. Second three weeks: This time the exercise becomes a little more difficult. The patient places the non-operated leg on the operated leg and while we see the greatest level of straightening in the leg, he raises the operated leg up to the level of the chair. This exercise should also be done thirty times twice a day

Category

Rehabilitation

2

Description

Control group: This group receives clinic-based physiotherapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
chamran hospital

Full name of responsible person
Armin fereidouni

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Recruitment center

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shahid eheshti

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Gholam Ali Hamidi

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Khordad 15 Square - Shahdari St. University campus: Kashan - Qutb Ravandi Boulevard – Doctor

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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
Kashan 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
Shiraz University of Medical Sciences
Full name of responsible person
Armin Fereidouni
Position
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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
There is more information.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Study data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Performing statistical analysis on the data will not be allowed except in the case of systematic review articles.

Data Access Paths: Data will only be sent to academic researchers via the corresponding author's email. Only academic researchers working on a study similar to this study can submit an application. There are no other conditions.

From where data/document is obtainable

People can get the study data by sending an email to Armin Feridouni (author responsible for the article). Email: arminfereidoni@yahoo.com

What processes are involved for a request to access data/document

Ten days after receiving the email by the responsible author, the data will be available to the requesting person.

Comments