

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Rehabilitation Education on surgical outcomes in patients Who undergo a Total knee Replacement

Protocol summary

Study aim

Determining the effect of rehabilitation education on surgical outcomes in patients undergoing knee replacement

Design

non-randomized clinical trial with control group. Continuous non-probabilistic approach. Sample size: 48 subjects in each group

Settings and conduct

The environment of this research is the orthopedic sections of the Milad Hospital (orthopedics of men and women). Firstly, all eligible patients were placed in the control group and after completing the sampling in this group, the intervention group entered the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: aged 50-70 years old Suffering from knee osteoarthritis undergoing total knee replacement No affection to acute anxiety disorder, depression and psychological problems and not taking psychoactive drugs before and after surgery. Having no history of joint replacement or surgery on the knee Having a BMI of less than 30 kg / m² Having reading and writing skills Non-arrival conditions: Pre-surgery infection that affects the outcome of the research Failure to co-operate with the patient in exercising and training Patients unable to walk and unable to attend exercises There are some underlying problems in the patient that make it impossible to attend rehabilitation sessions such as: severe heart and respiratory disease

Intervention groups

In the intervention group: intervention training (one day before surgery) and (24 and 48 hours after operation until discharge) and then (6 weeks after intervention), anxiety and womac questionnaire were completed before and 6 weeks after the intervention In the control group: routine training was done and the anxiety and womac questionnaires were completed before and 6 weeks after the study.

Main outcome variables

Anxiety, Knee pain and Stiffness, and Physical Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091124002769N6**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **retrospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Mansoureh Ashghaly Farahani

Name of organization / entity

Iran University Medical Sciences ,Nursing & Miwifery Faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-09-22, 1396/06/31

Expected recruitment end date

2017-11-20, 1396/08/29

Actual recruitment start date

2017-09-22, 1396/06/31

Actual recruitment end date

2017-12-10, 1396/09/19

Trial completion date

empty

Scientific title

The effect of Rehabilitation Education on surgical outcomes in patients Who undergo a Total knee Replacement

Public title

The effect of Rehabilitation Education in patients Who undergo a Total knee Replacement

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

50-70 years old Men and women with osteoarthritis undergoing total knee replacement No affection to acute anxiety disorder, depression and psychological problems and not taking psychoactive drugs before and after surgery. (According to the patient's statements and the diagnosis of physical and mental health by referring to the patient's medical records) Having no history of joint replacement or surgery on the knee Having a BMI of less than 30 kg / m Having reading and writing skills (and in case of no literacy, one of the literate carers should be involved in the patient's education process)

Exclusion criteria:

Pre-surgery infection that affects the outcome of the research Failure to co-operate with the patient in exercising and training Patients unable to walk and unable to attend exercises There are some underlying problems in the patient that make it impossible to attend rehabilitation sessions such as: severe heart and respiratory disease

AgeFrom **50 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **96**Actual sample size reached: **96****Randomization (investigator's opinion)**

Not randomized

Randomization description**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 Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-06-23, 1396/04/02

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311689001

Health conditions studied**1****Description of health condition studied**

knee replacement in osteoarthritis patient

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthrosis

Primary outcomes**1****Description**

Anxiety

Timepoint

before & 6 weeks after intervention

Method of measurement

Spielberg state anxiety questionnaire

2**Description**

pain, stiffness and physical function

Timepoint

before & 6 weeks after intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 4 educational sessions including: the

day before Intervention , 24 hours after surgery (after leaving the bed), 48 hours after surgery, and then during discharge, using lecture, group and individual training, question and answer, and Role play and Complete the questionnaires before intervention and 6 weeks after intervention.

Category

Rehabilitation

2**Description**

Control group: receiving routine training Intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Milad Hospital

Full name of responsible person

Mansoureh Ashgholi Farahani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Sayed Kazem Malekoti Deputy Director of Research in
Iran University of Medical Sciences

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Iran University of Medical Sciences, Shahid Hemmat
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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Batoul Atabaki

Position

MS student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Participants data file (without name and profile and confidential) Consent Form Conscious

When the data will become available and for how long

After the publication of the article

To whom data/document is available

For all scholars

Under which criteria data/document could be used

For use in research

From where data/document is obtainable

Atabaki batoul sheyda.atabaki@yahoo.com
09014196618

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

Send a request with a note of purpose and how to use the documentation

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

MS student

Latest degree

Bachelor

Other areas of specialty/work

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