

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of needs-based education on postoperative complications of patients with knee arthroplasty

Protocol summary

Study aim

Effect of needs-based assessment of postoperative complications following knee replacement

Design

A total of 76 patients were enrolled in the study. To prevent the contact between patients in the intervention and control groups, the sampling was done as follows, patients in the intervention group were selected according to the list of operations for successive weeks until the number of samples was completed and then the control group sampling was continued up to completion of the number of samples.

Settings and conduct

The study is a semi-experimental clinical trial. The research environment in this study was orthopedic section of Qods Hospital in Arak. Patients in both groups completed the questionnaires before surgery. After the completion of the intervention, postoperative complications were recorded during the period of hospitalization by assessing the patient's record and after discharge within one month after the operation.

Participants/Inclusion and exclusion criteria

Age over 18 years
The absence of immunosuppressive agents and diabetes
Lack of full participation in training sessions
Patients with $3 \leq \text{ASA}$
Patients with $\text{BMI} \geq 3$

Intervention groups

Patients in both groups completed the demographic and needs assessment questionnaires before surgery. Sample training was given in the intervention group after determining the educational priorities. While the control group received only routine training. One month after the operation, the questionnaire was completed again by patients

Main outcome variables

Complications in patients with knee replacement surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180913041022N1**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **retrospective**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Saeedeh Shakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-31, 1396/11/11

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date

2018-03-20, 1396/12/29

Actual recruitment end date

2018-06-04, 1397/03/14

Trial completion date

2018-07-02, 1397/04/11

Scientific title

Effect of needs-based education on postoperative complications of patients with knee arthroplasty

Public title

Effect of needs-based education on postoperative complications of patients with knee arthroplasty

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with knee joint disease (recorded in the file) Have reading and writing skills Age over 18 years Not having previous experience in training programs Not having previous joint replacement history Replacement candidate for one knee Lack of cognitive, visual acuity and hearing impairment The absence of immunosuppressive diseases such as AIDS and hepatitis, heart disease (MI, CHF) and diabetes

Exclusion criteria:

Unwillingness to continue participating in the study Exit the patient from the hospital with personal consent before discharging by a doctor Lack of full participation in training sessions Patients with ASA ≥ 3 Patients with BMI ≥ 3 Contact of each patient in the control group with each patient in the intervention group (in case of re-admission)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

A researcher-made questionnaire was used in this study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Iran University of Medical Sciences, Valiasr St., Shahid Rashid Yasemi St

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶-۱۴۵۳۵

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9311686015

Health conditions studied

1

Description of health condition studied

Complications after knee replacement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post knee joint surgery complications

Timepoint

Measurement of three common postoperative complications at the end of hospitalization time and one month after surgery during the first week of contact with the patient, the first referral of the patient to the office during the second week, the second week by contact with the patient, The second visit to the office during the fourth week, the third week and the fourth week by contact with the patient

Method of measurement

Assessing the patients' file, physician information, telephone to patients

2

Description

The patients' educational needs

Timepoint

Before surgery and one month after surgery

Method of measurement

A researcher-made questionnaire called the need-assessment questionnaire for knee replacement subjects

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group completed the demographic and needs assessment questionnaires before surgery. Sample training was done

so that prior to the beginning of the training, a questionnaire on the needs assessment of the educational priorities was determined based on the educational needs of the patient, then each person was trained according to his needs. Individual and face-to-face training was provided for 3 days from day before surgery or the same day until the day of discharge per day for 15-20 minutes at patient's tolerance and capacity, and a manual was provided to patients in the intervention group. Patient education was also conducted by telephoning and meeting the patient's needs by answering his questions and ambiguities by availability of the researcher (telephone number was provided to the patients) at the time of discharge and telephone answering. And the researcher himself also contacted the patient every week and ensure patient follow up and answer the patient's questions.

Category

Other

2**Description**

Control group: Patients in the preoperative control group completed the demographic information and needle assessment questionnaire. Patients in the control group received only regular training.

Category

Other

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

Quds Hospital

Full name of responsible person

Shakeri Saeedeh

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<http://rozaneh81.mihanblog.com/page/1>

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malekoti

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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

Saeedeh Shakeri

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Information about the questionnaire, statistical information, and outcomes are available

When the data will become available and for how long

Starting the access period from 1399

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For researchers working in academic and scientific institutions, students and research centers

From where data/document is obtainable

Responsive email address of Saeedeh Shakeri
saide.sha.3@gmail.com

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

Your application will be processed within one month after your request has been made

Comments