

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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)

###### Phone

+98 86 3366 3112

###### Email address

saide.sha.3@gmail.com

##### 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  $\geq 3$  Patients with BMI  $\geq 3$  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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Quds Hospital, Palestine Street

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**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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**Web page address**

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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

### Contact

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## Person responsible for updating data

### Contact

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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**