# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

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Mansoureh Ashghaly Farahani
**Name of organization / entity**
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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
**Age**
From **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**
۱۴۴۹۶۱۴۵۳۵
**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 afterintervention
**Method of measurement**
Spielberg state anxiety questionnaire

### 2

**Description**
pain, stiffness and physical function
**Timepoint**
before & 6 weeks afterintervention
**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**

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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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**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**