Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized controlled trial of comparison of the self-efficacy and pain control in the patients undergoing total knee arthroplasty with and without empowerment program

Protocol summary

Summary

Purpose of this single-blind randomized controlled trial is determination the effectiveness of the empowerment program on pain control and self-efficacy in patients undergoing knee arthroplasty referring to the Shohada, Shahid Mahallati and Alinasab hospitals in Tabriz, Iran. After convenience sampling, 98 patients will be randomly assigned to two groups using random allocation software. Inclusion criteria include the male and female patients aged 18 and over, who are being undergone total knee arthroplasty. In intervention group, an empowerment program based on linton cognitive behavior and Bandura behavior changing models will be used and it will be done for 6 weeks (one session before surgery and 5 sessions after surgery). The control group will receive no intervention. The study outcomes include self-efficacy and pain control which data related to them are gathered by a member of the research team through conducting interviews with the participants in both groups and using study tools, before and after completion of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101224484N1**
Registration date: **2016-03-15, 1394/12/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-15, 1394/12/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences, Tabriz, East Azarbayjan, Iran, Islamic Republic Of

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-07-01, 1395/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial of comparison of the self-efficacy and pain control in the patients undergoing total knee arthroplasty with and without empowerment program

Public title

Self-efficacy and pain control in the patients undergoing total knee arthroplasty

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Male and female patients aged 18 and over, patients undergoing total knee arthroplasty, patients with no history of chronic diseases and no drug addiction. Exclusion criteria: patient’s death, complications during and after surgery
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The person who collects data of outcome variables, doesn't know which patient belongs to which group. Participants are selected using convenience sampling and randomly allocated to two groups of intervention and control by randomization allocation software.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Golgasht Ave., Daneshgah St., Tabriz, East Azarbayjan, Iran
City
Tabriz
Postal code
Approval date
2015-09-20, 1394/06/29
Ethics committee reference number
TBZMED.REC.1394.526

Health conditions studied

1

Description of health condition studied
Knee arthroplasty
ICD-10 code
Z96.651
ICD-10 code description
Presence of right artificial knee joint

Primary outcomes

1

Description
Self-efficacy
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Pain Self-Efficacy Questionnaire

Secondary outcomes

1

Description
Pain control
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Short-form McGill Pain Questionnaire

Intervention groups

1

Description
In the intervention group, an empowerment program based on Linton cognitive-behavior and Bandura behavior changing models will be used which is implemented for 6 weeks (one session before surgery and 5 sessions after surgery). In control group there will be no intervention.
Category
Behavior

2

Description
The control group receives no intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada hospital
Full name of responsible person
Nazila Mir-Maroofi
Street address
Shohada hospital, Golshahr St., Tabriz, East Azerbaijan, Iran

City
Tabriz

2

Recruitment center
Name of recruitment center
Shahid Mahallati hospital
Full name of responsible person
Nazila Mir-Maroofi
Street address
Kuchebagh St., Tabriz, East Azerbaijan, Iran
City
Tabriz

3

Recruitment center
Name of recruitment center
Alinasab hospital
Full name of responsible person
Nazila Mir-Maroofi
Street address
Eram St., Tabriz, East Azerbaijan, Iran
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Rashidi
Street address
Golgasht Ave., Daneshgah St., Tabriz, East Azarbayjan, Iran
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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
Vice Chancellor for Research of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty