

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Name

Akram Ghahramanian

Name of organization / entity

Tabriz university of medical sciences, Faculty of Nursing and Midwifery

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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-Marofi

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-Marofi

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-Marofi

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

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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

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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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