Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness based training on intensity of pain and situational anxiety control of patient undergoing knee replacement surgery

Protocol summary

Study aim
Determining the effect of mindfulness-based training on pain intensity and situational anxiety control of patients undergoing knee joint replacement surgery

Design
A clinical trial study with two intervention and control groups -randomized - on 76 patients

Settings and conduct
This study includes patients waiting for knee joint replacement surgery in Hefdeh Shahrivar and Imam Khomeini hospitals in Amol. First in the office, Spielberger, Pittsburgh, and McGill questionnaires are given to the intervention and control groups. During two thirty-minute sessions, which the first session is before hospitalization in the office and the second session is on the day of hospitalization, the four mindfulness techniques are taught to the intervention group. It was decided by nursing office that each group should be hospitalized in two departments of orthopedics and its support department ENT, so that there is no interference and communication between them, and at the same time they receive the same care .After the first session, the audio file of the training will be given to the patient for practice, and during the hospitalization after surgery, the patients questions will be answered. On the morning of the surgery, the Spielberger questionnaire is completed again by both groups. On the second, third, and fourteenth day after surgery, McGill and Pittsburgh questionnaires are completed by both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: candidates for unilateral joint replacement surgery Exclusion criteria: Any event that leads to the removal of the sample from the action list

Intervention groups
Four mindfulness techniques which include: focus on breathing - body scan - visualization - mental stretching are taught to the intervention group and the control group receives training and routine care.

Main outcome variables
anxiety; pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250122064489N1**
Registration date: **2025-02-09, 1403/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-09, 1403/11/21**
Update count: **0**

Registration date
2025-02-09, 1403/11/21

Registrant information

Name
Maede Solimani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4326 1686

Email address
ma.sileimani@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-01, 1403/11/13

Expected recruitment end date
2026-06-22, 1405/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of mindfulness based training on intensity of pain and situational anxiety control of patient undergoing knee replacement surgery

Public title
The effect of mindfulness based training on pain and anxiety of knee replacement surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The candidate for joint replacement surgery must be unilateral and have the same treatment protocol Willingness to participate in the study Hospitalization at least one day before surgery Having the ability to listen, understand and answer your questions Not having a history of mental problems, such as not suffering from anxiety disorders listed in the patient's file Having a smart phone Having mild to moderate anxiety
Exclusion criteria:
Incomplete completion of questionnaires Any event that leads to the removal of the sample from the action list Any event that leads to disruption of communication and understanding of the patient's pain
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization in the present study, the Randomization Block method will be used in the form of a double blog. The unit of randomization will be a person (we do not have stratified randomization). In a matte box, 76 cards are placed on which 38 cards have the letter A and 38 cards have the letter B written on them. so that it is not possible for anyone to see the cards inside the box. After the researcher shuffles the cards, the patients are asked to randomly pick a card from the box. If card A is taken in the intervention group, card B is taken in the control group (the selected cards do not return to the box after selection). This process continues until the sample size is completed.
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 Babol University of Medical Sciences
Street address
No. 7, 4 Golbahar Ave , 4 Golestan Ave , 6 Azadegan Blvd , Emam Reza street , Amol Town
City
Amol
Province
Mazandaran
Postal code
4613658389
Approval date
2025-01-20, 1403/11/01
Ethics committee reference number
IR.MUBABOL.REC.1403.115

Health conditions studied

1

Description of health condition studied
Patients undergoing knee replacement surgery
ICD-10 code
Z44
ICD-10 code description
Encounter for fitting and adjustment of external prosthetic device

Primary outcomes

1

Description
anxiety
Timepoint
Before performing the intervention and on the morning of the surgery, before performing the surgery.
Method of measurement
Spielberger questionnaire

2

Description
pain
Timepoint
before intervention and on the second, third and fourteenth day after surgery
Method of measurement
McGill questionnaire

Secondary outcomes

1

Description
sleep quality
Timepoint
before intervention and on the second, third and fourteenth day after surgery
Method of measurement
Pittsburgh Questionnaire

Intervention groups

1

Description
Intervention group: Four mindfulness techniques, which include: focus on breathing - body scan - visualization - mental stretching, are taught to the intervention group, and the control group receives training and routine care. In the technique of focusing on breathing, the participants are asked to close their eyes, and at the same time as a motivational text was read to them, they are taught to focus on their breathing and consciously from the nasal passage. Intermittent deep breathing for 10 minutes. In the body scanning technique, the participants are taught to focus on their breathing for 10 minutes and at the same time focus on their abdomen and then gradually shift their focus and awareness to another organ. In the visualization technique, we encourage the participants to do deep abdominal and diaphragmatic breathing and then muscle relaxation, and to imagine scenes such as the forest, the seashore, and the place of pilgrimage for 5 minutes, and show attention to the surrounding sounds and smells. In the mental stretching technique, participants are asked to perform stretching movements for 5 minutes by taking deep breaths and focusing on positive thoughts.
Category
Other

2

Description
Control group: routine care before knee replacement surgery, which includes blood reservation - ICU reservation - preparation of knee prosthesis - control of vital signs - control and check of hemoglobin - performing BS, urea, na, k, pt, ptt, Esr, Crp tests - Performs ECG - Receives internal and cardiac and anesthesia service consultation.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hefdah Shahrivar Hospital
Full name of responsible person
Doctor framarz Akbari
Street address
next to Red Crescent , Red Crescent St. , Mazandaran
City
Amol
Province
Mazandaran
Postal code
4613658389
Phone
+98 11 4422 4001
Email
amol17shahrivarhospital@gmail.com
Web page address
https://h-17shahrivar.mazums.ac.ir/

2

Recruitment center
Name of recruitment center
Emam Khomini Hospital
Full name of responsible person
Doctor Abdolahe Mohamadi
Street address
next to the Shomal Univercity , the entry of emamzade Abdolah City , Haraz Road , Amol , Mazandaran
City
Amol
Province
Mazandaran
Postal code
84595-46161
Phone
+98 11 4420 4491
Fax
+98 11 4420 4401
Email
ma.soleimani@mubabol.ac.ir
Web page address
https://h-eamol.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Doctor Ghadimi
Street address
Ganj Afroz Street , Babol , Mazandaran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 9592

Fax
+98 11 3219 0181
Email
info@mubabol.ac.ir
Web page address
https://www.mubabol.ac.ir/post/?id=20234
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Maede Soleymani
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No7 , 4 Golbahar Ave , 4 Golstan Ave , Azadegan Blvd , Emam Reza Street , Amol , Mazandaran
City
Amol
Province
Mazandaran
Postal code
4613658389
Phone
+98 11 4326 1686
Email
ma.soleimani@mubabol.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Maede Soleymani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No7 , Golbahar4 , Golestan4 , Azadegan 6 , Amol, Mazandaran
City
Amol
Province
Mazandaran
Postal code
4613658389
Phone
+98 11 4326 1686
Email
ma.soleimani@mubabol.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Maede Solimani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Emam Reza Street,Azadegan6,Golestan4,Golbahar4,Number7
City
Amol
Province
Mazandaran
Postal code
4613658389
Phone
+98 11 4326 1686
Fax
Email
ma.sileimani@mubabol.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available