Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of care application on pain and motor rehabilitation of patients after knee arthroplasty Surgery

Protocol summary

Study aim
Designing and building a care application that is a candidate for knee replacement surgery to increase the level of awareness of patients.

Design
A clinical trial with the control group, one blind, randomized, sample size 100, a random selection of individuals in this study will be such that using random number generator software

Settings and conduct
All patients who are candidates for knee arthroplasty are admitted to the orthopedic ward of Baqiyatallah Hospital in Tehran. The researcher fills in the initial demographic form of the application, then all the information of the two groups is recorded in the application and the people in the target group receive the application and the people in the control group receive the routine training of the hospital. In this way, people do not know in which group of education they are.

Participants/Inclusion and exclusion criteria
Participants should be available if they meet the inclusion criteria, including having a smartphone, reading and writing literacy, age over 18, normal body mass index, first-time complete knee arthroplasty, and a non-traumatic patient.

Intervention groups
The intervention is performed on the test group or groups and in the control group, the placebo intervention or no intervention is performed. Finally, the results of the groups are compared. In this study, an application has been designed for the case group by Puzzle Software Company, which has educational content in the form of text, images, and audio, and its educational content includes postoperative knee arthroplasty care, nutrition, and physiotherapy movements. The control group will have routine hospital care.

Main outcome variables
Motor Rehabilitation, Pain, Age, Gender, Normal Body Mass Index, Care Application, Education Level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210724051973N1**
Registration date: **2022-04-29, 1401/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-29, 1401/02/09**
Update count: **0**

Registration date
2022-04-29, 1401/02/09

Registrant information

Name
reza salehinia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5553 4412

Email address
rezaotg@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-13, 1401/01/24

Expected recruitment end date
2022-06-15, 1401/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of care application on pain and motor rehabilitation of patients after knee arthroplasty Surgery

Public title
The effect of care application on pain and motor rehabilitation of patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Participants are available if they meet the inclusion criteria (including having a smartphone, reading and writing literacy, age over 18, normal body mass index (since body mass index affects the function and severity of lower body joint pain) Candidate for complete knee arthroplasty for the first time and non-traumatic patient
Exclusion criteria:
Exclusion criteria (including reluctance of the patient and her companions to enter the study, inability to read and write, lack of mobile phone, lack of normal body mass index) are
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The random selection of people in this study will be such that using random number generator software according to CONSORT 2010, someone outside the study enters the number of sample volumes in this software and its output includes one hundred irregular numbers, half of which The numbers are in the sample group and the other half are in the control group. Clinical self-examination is a study to evaluate the treatment and special care measures such as surgery, education or preventive methods. They are randomly assigned to the experimental and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this method, blinding is used to prevent bias caused by interventions. In general, blinding controls the confounding factors. In the one-way blind method, the sample or intervener is not aware of the intervention method. This study is one-sided so that all subjects in the case group or in the control group must first fill in the initial demographic form of the application via the researcher's mobile phone, then all the information of the two groups is recorded in the application and individuals Those in the case group receive the application, and those in the control group receive routine hospital training. Thus, people do not know in which group of training they are.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mazandaran University of Medical Sciences
Street address
Farahabad Street
City
Mazandaran
Province
Mazandaran
Postal code
4815733971
Approval date
2022-04-13, 1401/01/24
Ethics committee reference number
IR.MAZUMS.REC.1401.004

Health conditions studied

1

Description of health condition studied
Mobile application
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain and rehabilitation
Timepoint
A week
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: application-In this study, for the case group, an application with Android user interface has

been designed by Puzzle Software Company, which has educational contents in the form of text, images and audio, and its educational content includes: post-arthroplasty care of the knee (how Doing daily tasks such as sitting and getting up correctly, how to bathe and wash, how to get in and out of the car), nutrition (introduction of a set of nutrient-rich substances such as protein, iron, calcium And vitamins, fiber, water, omega-3s and zinc), physiotherapy movements (including movements that strengthen the muscles around the knee, such as quadriceps movement, heel slide movement, ankle movements such as squeezing the accelerator pedal, bending the knee, lifting exercises Foot) to collect these materials from the phd physiotherapist, physiotherapist and doctor of sports nutrition and use valid articles and finally approved by an orthopedic specialist

Category

Rehabilitation

2

Description

Control group: Routine hospital care-The control group performed routine hospital care on a face-to-face basis performed by ward nurses, which included training on how to perform routine chores at home (bathing and toilet, how to sit and stand, etc.), how to wash the surgical site. , Will receive the correct use of walkers and mobility aids.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Reza Salehinia

Street address

Mollasadra Street

City

Tehran

Province

Tehran

Postal code

141556437

Phone

+98 21 81261

Email

rezaotg@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Houshang Akbari

Street address

Farahabad

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4000

Email

ravabetomoomi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

50

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

Mazandaran University of Medical Sciences

Full name of responsible person

Reza Salehinia

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Surgery Room

Street address

Farahabad

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4000

Email

rezaotg@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Houshang Akbari

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Farahabad

City
sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3304 4000

Email
rezaotg@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Reza Salehinia

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Surgery Room

Street address
Farahabad

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3304 4000

Email
rezaotg@gmail.com

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