

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Reviews of the effectiveness of the learning-based mobile application (mobile app) to improve physical function of patients with osteoarthritis of the knee ladies

Protocol summary

Study aim

Reviews of the effectiveness of the learning-based mobile application (mobile app) to improve physical function of patients with osteoarthritis of the knee ladies

Design

Due to the importance of homogenization of the two groups of control and intervention, a randomized randomization method is used in which elimination of possible heterogeneity by classification is performed on the variables of the disease grade prior to random allocation. A clinical trial Blind two-way, calculation of sample size based on the formula and by conducting pilot studies.

Settings and conduct

Initial and pre-test measurements in the physiotherapy center of Imam Ali Hospital in Bojnourd, provide training and advice on how to conduct resistance exercises correctly through the application within 2 months randomly and without knowledge of the participants and evaluators. Patients will be treated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to do research. Radiological signs of knee osteoarthritis with the approval of a physician. Age 40-70 years. The patient and patient accompanying the smartphone should be available. Have the ability to use the mobile app. Exclusion criteria: Patients who have to undergo a knee surgery during the study. Use intra-articular intravenous medications during the study. During the study, they will develop mental illness. Underlying illness (such as diabetes, ...). They are reluctant to continue to participate in the study

Intervention groups

Intervention group: Patients with knee osteoarthritis who receive the application will receive training and advice for the correct performance of the exercise through the app within 2 months. Control group: Patients with knee

osteoarthritis who, according to the routine, are trained and advised to improve their quality of life.

Main outcome variables

Knee pain in women with knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161208031300N2**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**

Update count: **1**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Reza Ganji

Name of organization / entity

North Khorasan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Reviews of the effectiveness of the learning-based mobile application (mobile app) to improve physical function of patients with osteoarthritis of the knee ladies

Public title

Reviews of the effectiveness of the learning-based mobile application (mobile app) to improve physical function of patients with osteoarthritis of the knee ladies

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to do research Radiological symptoms of knee osteoarthritis with the approval of a physician The age range is between 40-70 years The smartphone itself is the patient or companion patient that is always available to the patient Ability to use the mobile app

Exclusion criteria:

Patients who undergo surgery on their knees. use intra-articular injectable drugs they will develop mental illness Underlying illness (such as diabetes, ...) Failure to follow up

AgeFrom **40 years** old to **70 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

A random assignment sequence has been created, each row of sequences placed inside a pre-waxed envelope, and then the envelopes are arranged in the box, and the patients removed one of the envelopes and then opened the envelope scholar. And doing the study according to the group in which the person is located.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind, a researcher who collects information about the performance and quality of life of patients, is not aware of the presence of any patient in the intervention group or group comparison. Also, in order to prevent the patients from moving between groups, after the patients were randomly assigned to the intervention and intervention group, they will be asked to request intervention from the patients in the couple's days and

the patients in the comparison group on the following days. The clinic is to prevent patients from speaking in groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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Bojnourd - Shahriar Avenue - above Imam Ali Hospital (AS) - Faculty of Medicine - Deputy of Research and Technology University

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Bojnurd

Province

North Khorasan

Postal code

9417696786

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

ir.nkums.rec.1397.085

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes**1****Description**

Knee pain

Timepoint

24 hours before the intervention and 24 hours after the intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

1

Description

improving the quality of life

Timepoint

24 hours before the intervention and 24 hours after the intervention

Method of measurement

Health Assessment Questionnaire

Intervention groups

1

Description

Intervention group: Patients with knee osteoarthritis who receive the application will receive training and advice for the correct performance of the exercise through the app within 2 months.

Category

Treatment - Devices

2

Description

Control group: Patients with knee osteoarthritis who, according to the routine, are trained and advised to improve their quality of life.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Specialized Clinic

Full name of responsible person

Reza Ganji

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Shahriar Avenue - next to Imam Ali Hospital

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Sponsors / Funding sources

1

Sponsor

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

seyed sajad arfaei chitgar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific

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Position

Assistant Professor, Faculty Member of North
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Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome of this study will be
shared through the article.

When the data will become available and for how long

The start of the access period will be 6 month after the
results are printed.

To whom data/document is available

For researchers working in academic and scientific
institutions and those engaged in the industry, they can
apply for them.

Under which criteria data/document could be used

Terms of use of data or documentation: 1. Failure to
remove or modify the original address of the authors of
scientific articles 2. Present actual research results 3.
Having specialized knowledge and academic competence
in the research subject 4. Observe the interests of
stakeholders at all stages 5. No publication of the results
of the plan without coordination and obtaining a license

From where data/document is obtainable

1. dr reza ganji r.ganji@nkums.ac.ir 2. dr hamid reza
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saadati Hasansaadati1391@gmail.com

What processes are involved for a request to access data/document

Applicants will be examined for their evidence and
confirmation of their academic and scientific evidence,
and will provide the files to them.

Comments