

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Designing , implementation and evaluation of educational intervention program using mobile application regarding caring behavior on postoperative in patients undergoing lumbar disc herniation surgery

Protocol summary

Study aim

Determining the effect of educational intervention program via a mobile application on the caring behavior of patients after lumbar disc herniation surgery in Fayyaz Bakhsh Hospital, Tehran

Design

Clinical trial with control group, with parallel groups, randomized, non-blind, continuous disease on 30 patients. Blocking method was used for randomization.

Settings and conduct

After obtaining the code of ethics, the researcher provides the mobile application to the intervention group (patients admitted for lumbar disc herniation surgery in Fayyaz Bakhsh Hospital in Tehran) by continuous randomization method.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Patients undergoing lumbar disc herniation surgery 2. Having a smartphone and knowing how to use it 3- Non-received training before the intervention Exclusion Criteria Death of participated patients

Intervention groups

Intervention group: Patients undergoing lumbar disc herniation receiving postoperative care behaviors training through smart mobile application software
Control group: Patients undergoing lumbar disc herniation surgery without receiving postoperative care behaviors training through smart mobile application software

Main outcome variables

Knowledge about care behaviors after lumbar disc surgery; Attitudes about caring behaviors after lumbar disc surgery; Performance on care behaviors after lumbar disc surgery.

General information

Reason for update

Acronym

LDH

IRCT registration information

IRCT registration number: **IRCT20210117050059N1**

Registration date: **2021-03-06, 1399/12/16**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **0**

Registration date

2021-03-06, 1399/12/16

Registrant information

Name

Soheila Sadeghpourezbarami

Name of organization / entity

The University OF Tarbiat Modares

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing , implementation and evaluation of educational intervention program using mobile application regarding caring behavior on postoperative in patients undergoing lumbar disc herniation surgery

Public title

educational intervention program using mobile application regarding caring behavior on postoperative in patients undergoing lumbar disc herniation surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients are candidates for lumbar disc herniation surgery Having a smartphone and knowing how to use it Has not received training before the intervention literate

Exclusion criteria:

Patients with mental disorders. Patients with learning disabilities.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the block randomization method is used. Thus, the researcher identified the people eligible to participate in the study by visiting the hospital. Then, the identified individuals who volunteered to participate in the study were randomly assigned to the experimental and control groups using a quadratic blocking method. The letter A was considered for the intervention group and the letter B for the control group. Then all the permutation compounds of the letters AA and BB, which are 6 different compounds, were written (AABB for combination 1, ABBA for combination 2, ...) and from combinations 1 to 6, one combination was randomly selected. For example, if combination 1 was selected, it meant that the first and second people were in the experimental group and the next two people were in the control group, and this process continued continuously until the sample size was reached.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Educational intervention in the field of care behaviors

after lumbar disc herniation is provided to patients through smart mobile application software.

Secondary Ids

empty

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

Trabiat Modares University

Street address

Jalal Al-Ahmad St., Nasr Bridge, Tarbiat Modares University, School of Medicine

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Tehran

Province

Tehran

Postal code

111-14115

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.MODARES.REC.1399.209

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

Lumbar Disc Herniation

ICD-10 code

M51.26

ICD-10 code description

Other intervertebral disc displacement, lumbar region

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

knowledge about caring behaviors after lumbar disc herniation surgery

Timepoint

Immediately after the educational intervention, one month after the educational intervention

Method of measurement

Through a researcher-made questionnaire of LUMbar Caring Tool (LUCAT)

2**Description**

Improving attitudes about caring behaviors after lumbar disc herniation surgery

Timepoint

Immediately after the educational intervention, one month after the educational intervention

Method of measurement

Through a researcher-made questionnaire made by LUCAT

3

Description

performance on care behaviors after lumbar disc herniation surgery

Timepoint

Immediately after the educational intervention, one month after the educational intervention

Method of measurement

Through a researcher-made questionnaire made by LUCAT

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes three phases: pre-test, content training, and post-test. Pre-test in both intervention and control groups is sent to their mobile phone as an online questionnaire. The application is designed to be installed on the smartphones of the intervention group, ie patients undergoing disc herniation surgery, and how to use it is explained to people. Educational content about caring behaviors after lumbar disc herniation surgery in the intervention group will be activated immediately after completing the pre-test form. Patients have access to educational content for 4 weeks at any time and place. At the end of 4 weeks, access to the educational content is automatically disabled. And the link to receive the post-test is sent by the researcher immediately, one month later, and three months after the educational intervention to both intervention and control groups. The questions are the same in both the pre-test and post-test stages.

Category

Other

2

Description

Control group: The intervention includes three phases: pre-test, content training and post-test. Pre-tests in both intervention and control groups are sent as an online questionnaire to their mobile phones. This group does not receive any training on caring behavior with the help of smart mobile application software. Post-test questionnaire is sent to the control group mobile phone immediately, one and three months after the educational intervention by the researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fayyaz Bakhsh Hospital

Full name of responsible person

Soheila Sadeghpourezbarami

Street address

Shahid Fayyaz Bakhsh Hospital, Persian Gulf Blvd, 7 km of Karaj Old Road, Fatah Highway.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Trabiat Modares University

Full name of responsible person

Yaghub Fatollahi

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al-Ahmad St.

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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

Trabiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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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

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

Title and more details about the data/document

Part of the data on the main consequences can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Repeated measurement analysis to evaluate the duration of training 6 months after the last intervention

From where data/document is obtainable

By sending an email to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir

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

One week after sending the email by the applicant to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir will be answered.

Comments