

# 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)

##### Phone

+98 21 6612 2038

##### Email address

s\_sadeghpour@modares.ac.ir

##### 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

**City**

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.

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1379613541

##### **Phone**

+98 21 6400 5677

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##### **Email**

s\_sadeghpour@modares.ac.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Trabiat Modares University

##### **Full name of responsible person**

Yaghoub Fatollahi

##### **Street address**

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

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Tehran

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##### **Postal code**

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##### **Phone**

+98 21 8288 4546

##### **Email**

s\_sadeghpour@modares.ac.ir

#### **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 scientific inquiries

### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

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Assistant professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### 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**

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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**