

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of showing surgery educational documentary film on the anxiety of patients candidate for lumbar disc surgery

Protocol summary

Study aim

Determine the effect of showing surgery educational documentary film on the anxiety of patients candidate for lumbar disc surgery

Design

Clinical trial with control group, non-randomized assignment to intervention and control groups, with parallel group, without blindness

Settings and conduct

The researcher will not be able to exchange information between a hospital in the control group and the hospital in the intervention group because of the patient's lack of interaction. And the researcher on consecutive days, referring to the special clinic of Al-Zahra and Ayatollah Kashani hospitals and in coordination with the honoring of these hospitals, the list of patients with a lumbar spine and included in their list of activities and have entry requirements They will identify and coordinate with them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have the ability to communicate voice and audio the desire to participate in the study Ability to read and write Not attending other training programs during the study No cognitive impairment, no known mental illness Previously, surgical procedures for vertebral discs have not been performed age 18-64 years
Exclusion criteria: Opt out of the study for any reason is Use of sedative or anxiolytic drugs during the study Coincident in another study

Intervention groups

Intervention group: First, measure the mean anxiety score before the intervention, then show a documentary film for lumbar disc surgery and then measure anxiety with the Spielberger questionnaire one day after the intervention Control group: Measurement of anxiety score before intervention and then measuring anxiety with the Spielberger questionnaire the next day without any intervention other than routine training

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180531039926N1**

Registration date: **2018-07-26, 1397/05/04**

Registration timing: **retrospective**

Last update: **2018-07-26, 1397/05/04**

Update count: **0**

Registration date

2018-07-26, 1397/05/04

Registrant information

Name

Mohammad reza Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 5665

Email address

mr.abdi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-07-22, 1397/04/31

Trial completion date

empty

Scientific title
Investigating the effect of showing surgery educational documentary film on the anxiety of patients candidate for lumbar disc surgery

Public title
the effect of showing surgery educational documentary film on the anxiety of patients candidate for lumbar disc surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Have the ability to communicate voice and audio the desire to participate in the study Ability to read and write Not attending other training programs during the study No cognitive impairment, no known mental illness Previously, surgical procedures for vertebral discs have not been performed age 18-64 years
Exclusion criteria:
Opt out of the study for any reason is Use of sedative or anxiolytic drugs during the study Coincident in another study

Age
From **18 years** old to **64 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Isfahan University of Medical Sciences

Street address

Isfaha University Of Medical Sciences Faculty Of

Nursing and Midwifery , Hezar Jereb avenue , Isfahan

City
Isfahan

Province
Isfahan

Postal code
81746-73461

Approval date
2018-01-15, 1396/10/25

Ethics committee reference number
IR.MUI.REC.1396.3.840

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

state anxiety

Timepoint

Before and one day after the intervention

Method of measurement

Spielberger state anxiety inventory

2

Description

trait anxiety

Timepoint

Before and one day after the intervention

Method of measurement

Spielberger trait anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, measure the mean anxiety score before the intervention, then show a documentary film for lumbar disc surgery for 20 minutes and then measure anxiety with the Spielberger questionnaire one day after the intervention

Category

Other

2

Description

Control group: Measurement of anxiety score before intervention and then measuring anxiety with the Spielberger questionnaire the next day without any intervention other than routine training

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

St-zahra educational hospital

Full name of responsible person

Mohammad reza Abdi

Street address

Isfahan University of Medical Sciences, Hezar jarib St, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

mr.abdi30@gmail.com

2

Recruitment center

Name of recruitment center

Kashani educational hospital

Full name of responsible person

Mohammad reza Abdi

Street address

Kashai street, Kashani hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3233 0091

Email

mr.abdi30@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Taleghani

Street address

خ هزار جریب، دانشگاه علوم پزشکی اصفهان، دانشکده پرستاری و مامایی

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7580

Email

zahra_ghazavi@nm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad reza Abdi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 30, Shahid Ebrahimi Coy, Mosque of Seyed Street

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Esfahan

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8136953861

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Email

mr.abdi30@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Ghazavi

Position

Academic Member/ Master of Science

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Psychiatric Nursing Dept. Nursing and Midwifery
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Jereb Avenue

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Email

mr.abdi30@gmail.com

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

Not applicable

Title and more details about the data/document

Tez

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

In order to influence the care and treatment

From where data/document is obtainable

email:mr.abdi30@gmail.com mohammad reza abdi

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

SMS or Email

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad reza Abdi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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City

Esfahan