

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of designed educational video on the level of anxiety and quality of wound care in patients undergoing spinal surgery

Protocol summary

Registration timing: **retrospective**

Study aim

Determining the mean score of anxiety in patients who are candidates for spine surgery before and after the training video and the control group.

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Design

The parallel clinical trial with control and intervention groups. Single-blind with a random assignment performed on 90 patients (45 people in each group). The permuted block method is used for randomization.

Registrant information

Name

zohre Khodadadi jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5422 8202

Email address

khodadadist1393@gmail.com

Settings and conduct

Patients who are candidates for spine surgery (including CD insertion, discectomy and stenosis) referred to Peymaniyeh hospital in Jahrom. The control and intervention groups have one week different in terms of sampling.

Participants/Inclusion and exclusion criteria

fully conscious, ability to communicate and speak, with informed consent to participate in the study, no vision problems, no history of mental illness or severe stressors in the last 6 months, no illness Background such as skin disease and diabetes. Exclusion criteria: dissatisfaction to participate in the study or death of the patient.

Recruitment status

Recruitment complete

Funding source

Intervention groups

In the control group, we will teach through videos the night before the operation. We will not have a training for the control group and only routine trainings will be explained by the nurse.

Expected recruitment start date

2021-04-13, 1400/01/24

Expected recruitment end date

2021-05-04, 1400/02/14

Actual recruitment start date

2021-04-12, 1400/01/23

Actual recruitment end date

2021-06-19, 1400/03/29

Trial completion date

2021-06-19, 1400/03/29

Main outcome variables

The effect of educational video on the level of knowledge, quality of wound care of patients, surgical anxiety

Scientific title

The effect of designed educational video on the level of anxiety and quality of wound care in patients undergoing spinal surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210306050602N1**

Registration date: **2021-07-18, 1400/04/27**

Public title

The effect of designed educational video on the level of anxiety and quality of wound care in patients undergoing

spinal surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should be fully conscious. Be able to communicate and speak. Have informed consent to participate in the study. Do not have vision problems. Have no history of mental illness or severe stressors in the past 6 months. No underlying diseases such as skin diseases and diabetes

Exclusion criteria:

Dissatisfaction with participating in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign the samples to the intervention and control group, using the Block Randomization method, we make four blocks from the letters A and C, which determine the six AACC-ACCA-CCAA-CAAC-CACA-ACAC blocks from 1 to 6, and Randomly using the table of random numbers to determine 88 patients, the names of the groups are determined, but its list is determined, and according to the continuous referral of patients based on the determined list, which is kept in the hands of the main executor. By preparing 88 envelopes, the patient's reference number is specified on the envelope and the type of intervention or control inside the envelope, and after each patient's visit, the type of intervention or control is determined by opening the envelope and the necessary action is taken for each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Health care providers, such as nurses, will not be informed about the content and method of training and will be requested to provide all routine trainings to all patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Sari, Joibar intersection, at the beginning of Vali-e-Asr Highway, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.MAZUMS.REC.1400.023

Health conditions studied

1

Description of health condition studied

Candidates for spine surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

The night before surgery and in the morning of surgery

Method of measurement

Using the Spielberger Anxiety Inventory

2

Description

Awareness

Timepoint

Before and after the training video

Method of measurement

Using a researcher-made questionnaire

3

Description

Quality of surgical wound care

Timepoint

48 hours and two weeks after surgery

Method of measurement

Using the checklist and view

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, we will train the night before the surgery and fill in the anxiety questionnaire the night before the operation. In the morning of the operation, the questionnaire will be filled in again. In 48 and two weeks after the operation, we will examine the quality of wound care. We will check the level of awareness before and after the training.

Category

Other

2

Description

Control group: We will not intervene for the control group, we will only fill in the anxiety and awareness questionnaire and check the quality of wound care in 48 hours and two weeks after the operation.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahrom Peymanieh Hospital

Full name of responsible person

Zohre Khodadadi Jahromi

Street address

Red Crescent Street Alley 24

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Fars

Postal code

7413717969

Phone

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Email

khodadadist1393@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saidi

Street address

Sari, Joibar intersection, at the beginning of Vali-e-Asr

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Web page address

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

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

Mazandaran University of Medical Sciences

Full name of responsible person

Zohre Kodadadi Jahromi

Position

Senior student in the operating room of Mazandaran University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zohre Khodadadi Jahromi

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohre Khodadadi Jahromi

Position

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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