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

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.

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.

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.

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.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210306050602N1**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **retrospective**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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 berequested 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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7413717969
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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 Highway, Mazandaran University of Medical Sciences
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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

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Full name of responsible person
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Position
Senior student in the operating room of Mazandaran University of Medical Sciences

Latest degree
Bachelor

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Person responsible for updating data

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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