Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the Effect of Multimedia Education on Anxiety and Pain in Patients Undergoing Laparoscopic Cholecystectomy

Protocol summary

Study aim

The aim of the present study is to determine the effect of multimedia education on anxiety and pain in patients undergoing laparoscopic cholecystectomy.

Design

In this study, 80 candidates for laparoscopic cholecystectomy are selected with convenience sampling method and randomly divided into four groups (two intervention groups and two control groups). For randomization, 80 numbers generated by statistical software are written on 80 cards, and to conceal the random allocation, cards will be placed in sealed opaque envelopes.

Settings and conduct

This study will be conducted in the surgical wards of Imam Reza Hospital, Kermanshah. Solomon four-group design will be used. The day before the surgery, multimedia education will be done in the intervention groups. In general, anxiety and hemodynamic parameters will be measured before receiving the intervention, before entering the operating room and 24 hours after the surgery, and the pain level will be measured 24 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study; patients at the age of 18-65 years old; being able to communicate; having no severe vision and hearing problems; being able to read and write; no history of abdominal surgery. Exclusion criteria: drug addiction; use of sedative medications; having psychological disorders; having respiratory diseases such as asthma and chronic obstructive pulmonary disease.

Intervention groups

There are two intervention groups, in both groups, multimedia education will be done in the form of videos, photos and pamphlets for 30 minutes (one group with a pre-test and the other without a pre-test). Also, in this study, there are two control groups (one group with a pre-test and the other group without a pre-test) in which no intervention will be done and they will receive routine care.

Main outcome variables

Anxiety; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013568N7**
Registration date: **2023-02-13, 1401/11/24**
Registration timing: **prospective**

Last update: **2023-02-13, 1401/11/24**
Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Rostam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Multimedia Education on Anxiety and Pain in Patients Undergoing Laparoscopic Cholecystectomy

Public title
The Effect of Multimedia Education on Anxiety and Pain in Patients Undergoing Laparoscopic Gallbladder Removal
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Patients at the age of 18-65 years old Being able to communicate Having no severe vision and hearing problems Being able to read and write No history of abdominal surgery
Exclusion criteria:
Drug addiction Use of sedative medications Having psychological disorders Having respiratory diseases such as asthma and chronic obstructive pulmonary disease
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be used and the random sequence generation tool will be statistical software. Patients are randomly assigned to four groups (two intervention groups (one group with a pre-test and another without a pre-test) (20 patients in each intervention group) and two control groups (one group with a pre-test and another without a pre-test) (20 patients in each control group)). For this purpose, the 80 numbers generated by the software are written on 80 cards, and in order to conceal the allocation, the cards will be placed in sealed opaque envelopes. Odd numbers will be considered for the intervention groups and even numbers for the control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In the present study, Solomon four-group design will be used. In this way, patients are randomly assigned to four groups (two intervention groups (which will receive multimedia education) and two control groups (which will receive routine care)). In one of the intervention groups, before the intervention, a pre-test (measurement of state and trait anxiety) will be performed, but in the other intervention group, the pre-test will not be performed (anxiety level will not be measured before receiving the intervention). Regarding the control groups, it will be done in the same way; in one of the control groups a pre-test will be done, but not in the other group. The post-test (measurement of anxiety on the day of surgery (before entering the operating room) and also 24 hours after surgery will be performed in all four groups. In addition, hemodynamic parameters will be measured the day before surgery, the day of surgery (before entering the operating room) and 24 hours after surgery in the four groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Deputy of Research and Technology, No. 2 Building, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah
City
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Province
Kermanshah
Postal code
6714673159
Approval date
2023-01-24, 1401/11/04
Ethics committee reference number
IR.KUMS.REC.1401.503

Health conditions studied

1

Description of health condition studied
Cholelithiasis
ICD-10 code
K80
ICD-10 code description
Cholelithiasis

2

Description of health condition studied
Cholecystitis
ICD-10 code
K81

ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
State anxiety score in Spielberger State-Trait Anxiety Inventory scale
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in two of the four groups (one of the intervention groups and one of the control groups), the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Spielberger State-Trait Anxiety Inventory scale

2

Description
Trait anxiety score in Spielberger State-Trait Anxiety Inventory scale
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in two of the four groups (one of the intervention groups and one of the control groups), the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Spielberger State-Trait Anxiety Inventory scale

3

Description
Pain intensity in Visual Analogue Scale
Timepoint
24 hours after surgery in all four groups
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Hemodynamic parameters (heart rate)
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in the four groups, the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Using a pulse oximeter

2

Description
Hemodynamic parameters (systolic blood pressure)
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in the four groups, the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Using a blood pressure device

3

Description
Hemodynamic parameters (diastolic blood pressure)
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in the four groups, the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Using a blood pressure device

4

Description
Hemodynamic parameters (Arterial blood oxygen saturation level)
Timepoint
At the beginning of the study (before the intervention, the day before surgery) in the four groups, the day of surgery before entering the operating room in all four groups and 24 hours after surgery in all four groups
Method of measurement
Using a pulse oximeter

Intervention groups

1

Description
Intervention group: In the intervention groups (intervention group with pre-test and intervention group without pre-test) the day before the surgery, multimedia education will be done for 30 minutes. In the group with pre-test, first, the patient's anxiety level is measured using Spielberger State-Trait Anxiety Inventory scale, as well as hemodynamic parameters, and then the intervention is performed. In the other intervention group, the pre-test will not be performed before receiving the intervention, but hemodynamic parameters will be measured. Intervention: explanations about the function of gallbladder, cholelithiasis and cholecystitis, risk factors and pathophysiology of these diseases, the benefits of laparoscopic cholecystectomy compared to open surgery is presented to patients in the form of a video, and pamphlets related to the mentioned items are provided to them, and operating room and recovery room pictures will be shown. Then explanations about general anesthesia, drugs used for this purpose and complications of general anesthesia are presented to them, followed by the injection of anesthetic drugs by an anesthesiologist, as well as how intubation is done and tools used in this procedure, including laryngoscope and tracheal tube, in the form of a video, and the pictures of

these tools will be shown to them. The surgical team, including the surgeon, assistant surgeon, scrub nurse, circulator nurse and anesthesia expert, and their duties are explained to the patient, and a video about preparing the surgical instruments, the surgical bed, and disinfecting the surgical site is shown to the patient. Information about the surgery, including creating three holes in the abdomen, blowing carbon dioxide gas, and then performing sutures and placing a hemovac drain, and the duration of the surgery is provided to the patients in a video, and the pictures related to the location of the sutures are shown to them. Postoperative complications and the care provided in the ward until discharge including drugs, drain, dressings, the duration of not receiving anything by mouth (the duration of being NPO (nothing by mouth)) and not leaving the bed and the length of stay in the hospital is presented to the patients in the form of a video and pamphlets related to these items are provided to them. Then, the method of doing breathing exercises to reduce the patient's pain is explained in a video and a pamphlet containing this information is provided to them. The intervention groups will also receive usual care. In order to assess the content validity of the prepared educational package, the educational content will be provided to 12 experts. To display videos and photos, smartphone will be used.

Category

Treatment - Other

2

Description

Control group: There will be no intervention in the control groups (control group with pre-test and control group without pre-test). In the control group with pre-test, the day before surgery, the patient's anxiety level will be measured using Spielberger State-Trait Anxiety Inventory scale, as well as hemodynamic parameters, but in the other group, only hemodynamic parameters will be measured the day before surgery. These two groups only receive routine care, including heart consultation, anesthesia consultation, informed consent, which includes information such as the advantages of the proposed method, alternative methods, disadvantages of the proposed method, comparison of the proposed and alternative methods in terms of advantages and disadvantages, and the risk level of the proposed method, necessary laboratory tests, shaving and marking the surgical site and not receiving anything by mouth (being NPO (nothing by mouth)) before the surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Narges Sadeghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
For keeping anonymous
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available