# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

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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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https://vc-research.kums.ac.ir/fa/tamas

**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**
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Narges Sadeghi
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Student
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## Person responsible for updating data

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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