Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of applying virtual reality technology with two approaches of distraction and patient education on preoperative anxiety and postoperative pain in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison of the two approaches using virtual reality distraction and patient education on the level of preoperative anxiety and postoperative pain in surgical patients undergoing laparoscopic cholecystectomy

Design
Clinical trials involving 165 patients with two intervention groups and one control group, with parallel groups, patients will be randomly divided into blocked methods by stata software.

Settings and conduct
This study will be performed in the surgical department of Mashhad educational hospitals. After obtaining informed consent, patients' anxiety will be assessed using the Spielberger Anxiety Questionnaire before surgery and after preoperative intervention. The severity of the pain after the operation will be measured before each pair of glasses and after insertion through the visual acuity scale (VAS) and the McGill Pain Questionnaire. Due to the type of research, it is not possible to blind the people under study and the researcher, but the statistical analyst and the allocator of the research units to the three groups will be unfavorable.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Uncomplicated cholelithiasis , Cholecystitis Exclusion conditions: History of gastrointestinal surgery over the past two weeks History of vestibulocochlear abnormalities History of seizures and epilepsy

Intervention groups
Intervention group 1 using virtual reality with a patient training approach before preoperative surgery a film about the operating room, after surgery: a pain with content controlling pain In intervention group 2, use virtual reality to distract thoughts with the content of pleasant images in the two stages before and after the operation. In the control group, the usual training is performed

Main outcome variables
Anxiety of patients before surgery, The severity of the pain after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200623047901N1**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**

Registration date
2020-07-06, 1399/04/16

Registrant information

Name
Fateme Abbasnia

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
2020-07-10, 1399/04/20

Expected recruitment end date
2020-09-10, 1399/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of applying virtual reality technology with two approaches of distraction and patient education on preoperative anxiety and postoperative pain in patients undergoing laparoscopic cholecystectomy

Public title
The effect of virtual reality on anxiety and pain in patients undergoing laparoscopic cholecystectomy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Uncomplicated cholelithiasis , Cholecystitis Lack of diagnosed mental disorder, lack of cognitive impairment, difficulty understanding the scale of pain No addiction to opioids or strong painkillers Lack of severe pain due to the nature of the disease (cancer) Fluency in Persian
Exclusion criteria:
History of gastrointestinal surgery over the past two weeks History of vestibulocochlear abnormalities History of seizures and epilepsy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sequencing using stata software and block method. Blocks of sizes 6, 9, and 12 will be used to increase unpredictability. The group will be packed in an envelope and the envelopes will be sorted and numbered according to the generated sequence. After obtaining the informed consent, the first available envelope will be opened for each client and his group will be identified.
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 Mashhad University of Medical Sciences
Street address
Ibn Sina Ave, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2020-04-28, 1399/02/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.019

Health conditions studied

1

Description of health condition studied
Laparoscopic cholecystectomy patients with Cholelithiasis
ICD-10 code
K80
ICD-10 code description
Cholelithiasis

2

Description of health condition studied
Laparoscopic cholecystectomy patients with Cholecystitis
ICD-10 code
K81
ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Postoperative pain scores measured in the McGill Pain Questionnaire and the Visual Analogue Scale
Timepoint
Measuring the amount of pain 4 hours after surgery (pre-intervention) and 15 minutes after intervention, every 4 hours to 24 hours after surgery
Method of measurement
McGill Pain Questionnaire, Visual Pain Measurement Scale

2

Description
Anxiety score before surgery Spielberger questionnaire
Timepoint

Measure the amount of anxiety before surgery (before the intervention), 15 minutes after the intervention

Method of measurement

Through Spielberger's Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: First Intervention Group (Patients of Virtual Reality Technology Group with Patient Training Approach): Before Surgery: (After admission of the patient in the surgical ward) glasses are placed for the patient. Containing animated content for 5 minutes that simulates the operating room environment, anesthesia, surgery, and wakefulness. After surgery: 4 hours after the operation, the glasses are placed on the patient, which contains animated content, simulating deep breathing, how to get out of bed, effective cough, and changing position for 5 minutes. Wear glasses to control pain at least twice before bedtime

Category

Other

2

Description

Intervention group: The intervention group 2 (for groups of virtual reality technology with the approach of distraction)Before surgery: Glasses containing a film with music and soothing images will be played for 5 minutes via a virtual reality headset.After surgery: 4 hours after surgery at least twice before bedtime, if the patient interferes with sleep after sleep, the same images will be played and executed for the patient by the glasses.

Category

Other

3

Description

Control group: No specific action will be taken by the researcher, and the same hospital training, including educational pamphlets and face-to-face training, will be provided by the ward nurses for all patients.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Abbasnia Fateme

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Ahmad Abad Ave

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Aghebati Nahid

Street address

Ibn Sina Ave ،School of Nursing and Midwifery

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Abbasnia Fateme

Position

Nursing Graduate Student - Surgical

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Aghebati Nahid

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Abbasnia Fateme

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after people have not been identified

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

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Health centers

From where data/document is obtainable

Mashhad School of Nursing and Midwifery

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

Immediately by visiting the library of Mashhad School of Nursing and Midwifery in person or online

Comments