

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of training on Anxiety, stress, pain management and some postoperative complications in abdominal surgery patients referring to Ali ibn Abitaleb Hospital in Rafsanjan in 2019

Protocol summary

Study aim

Effect of training on anxiety, stress, pain management and some postoperative complications in abdominal surgery patients

Design

The patients were Random block divided into 4 groups (1 control group and 3 intervention groups). Implementing educational interventions and evaluating the results.

Settings and conduct

A study at Ali ibn Abitaleb Hospital in Rafsanjan will be performed by class division and the intervention will be administered to patients in 48 hours before surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age of 18-75 years old, elective surgery in the abdominal area, up to 46 hours after the operation in the hospital, the ability to understand and speak in Farsi, mental illness recorded, Lack of addiction to narcotics, lack of history of chronic pain Exit criteria: Unwillingness of patients to continue the study, return to the operating room, confusion during the postoperative period, admission to the RCT, any factor that causes the patient to get out of reach 48 hours.

Intervention groups

Individual training 48 hours before surgery (intervention 1: by physician, intervention 2: by nurse and intervention 3: delivering educational pamphlet). The content of training in this section is related to the type of operation, the definition of pain, the types of pain, how Pain relief, pain relief and pain medication, such as music therapy, methods of deviation, reading, relaxation breathing exercises, undesirable effects of postoperative pain in the physical, emotional, economic, and early stages of life. Outdoors activities will last for 30 minutes Children. And in the control group, the usual care of abdominal surgery patients will be used. The control group will receive the usual care of abdominal surgery patients.

Main outcome variables

Anxiety, stress, pain management, postoperative complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040630N1**

Registration date: **2019-02-18, 1397/11/29**

Registration timing: **prospective**

Last update: **2019-02-18, 1397/11/29**

Update count: **0**

Registration date

2019-02-18, 1397/11/29

Registrant information

Name

Mohammad Ali Zakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3429 2316

Email address

mazakeri@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of training on Anxiety, stress, pain management and some postoperative complications in abdominal surgery patients referring to Ali ibn Abitaleb Hospital in Rafsanjan in 2019

Public title
Effect of training on Anxiety, stress, pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Criteria for entering the study: Age between 18 and 75 years Patient with criteria for performing elective surgery in the abdomen To be hospitalized for up to 46 hours after surgery. Ability to understand and speak Persian Interested in participating in the study The absence of mental illness recorded in the case Able to communicate and understand the questionnaire Non-drug addiction and other narcotic drugs No history of chronic pain
Exclusion criteria:
Exit criteria: Unwillingness of patients to continue reading There is no problem as long as the patient is unable to continue studying Return to the operating room Confusion during the postoperative period Admission to the Intensive Care Unit Participate in another clinical trial at the same time Any factor that causes the patient to get out of reach 48 hours (lack of cooperation, early clearance, and personal satisfaction).

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Random block Patients will be divided into 4 blocks and in randomized layers with a level of education. Levels of classification based on the level of education in three levels (Illiterate, less than diploma and more than diploma).

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 Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd, Rafsanjan

City

Rafsanjan

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Kerman

Postal code

7717933777

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.RUMS.REC.1397.186

Health conditions studied

1

Description of health condition studied

Abdominal pain

ICD-10 code

R10

ICD-10 code description

Abdominal and pelvic pain

2

Description of health condition studied

anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

3

Description of health condition studied

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes

1

Description

pain management

Timepoint

After the intervention

Method of measurement

Revised American Pain Society Patient Outcome Questionnaire

2

Description

anxiety

Timepoint

Before and after intervention

Method of measurement

state-trait anxiety inventory

3

Description

emotional preoperative stress

Timepoint

Before intervention

Method of measurement

brief measure of emotional preoperative stress

Secondary outcomes

1

Description

postoperative complications

Timepoint

after intervention

Method of measurement

Report the type of postoperative complications

Intervention groups

1

Description

Intervention group: Training by a doctor (Training by physician Individually, one session will be performed for 30 minutes 48 hours before surgery. Training includes providing comprehensive information about the type of surgery, the definition of pain, types of pain, the explanation of the causes of postoperative pain and emotion, the importance of pain control, pain management, how to reduce pain by pharmacological and non-pharmacological methods, and actions taken by The patient can be used to relieve pain).

Category

Treatment - Other

2

Description

Intervention group: Training by a nurse (Training by nurse Individually, one session will be performed for 30 minutes 48 hours before surgery. Training includes providing comprehensive information about the type of surgery, the definition of pain, types of pain, the explanation of the causes of postoperative pain and emotion, the importance of pain control, pain management, how to reduce pain by pharmacological

and non-pharmacological methods, and actions taken by The patient can be used to relieve pain).

Category

Treatment - Other

3

Description

Intervention group: Training with pamphlets (Training Patients will be given a pamphlet within 48 hours before the surgery. Trainings include providing comprehensive information about the type of surgery, the definition of pain, types of pain, the explanation of the causes of postoperative pain and emotion, the importance of pain control, pain management, how to reduce pain by pharmacological and non-pharmacological methods, and actions taken by The patient can be used to relieve pain).

Category

Treatment - Other

4

Description

Control group: No training (In the control group the training will not be given).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ibn abitaleb hospital , Rafsanjan, Iran

Full name of responsible person

Gholamreza Bazmandeghan

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shmsizadeh

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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

Rafsanjan 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**

Rafsanjan University of Medical Sciences

Full name of responsible person

Mohammad Ali Zakeri

Position

Nurse

Latest degree

Master

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

Mohammad Ali Zakeri

Position

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Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

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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