Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 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

Province

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
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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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alishamsy@gmail.com
Web page address
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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

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Position
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Person responsible for updating data

Contact
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Position
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Fax
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Email
mazakeri@rums.ac.ir

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