Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Psycho-Educational Interventions on Anxiety, Physiological Indicators and Pain after the Surgery in the Coronary Artery Bypass Graft Patients

Protocol summary

Study aim
Supportive -Psycho-Educational Care.

Design
Randomized controlled clinical trial will be performed in parallel groups of phase 2 with 56 patients. A number is assigned to people with inclusion criteria. Then, using random number software, we randomly select 56 people. Using the randomized permutation block method with block size 4, we divide them into two groups of 28.

Settings and conduct
Sampling will be done in cardiac surgery wards of Shiraz University of Medical Sciences. The interventions will perform in three sessions before surgery along with giving routine sedatives face to face. There is no intervention for the control group. Anxiety, pain and physiological parameters of patients will measure by completing the Spielberger questionnaire and McGill pain scale and vital signs record sheet in both experimental and control groups during admission and after coronary artery bypass graft surgery and the results are compared with each other.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: - Candidates for coronary artery bypass graft surgery - Age between 18 to 65 years - Willing to participate in the study - No history of heart surgery - Ability to read and write - Minimum level of mild anxiety in baseline test - No history of antidepressants use - No physical disability and no obvious mental illness - No history of participation in similar studies Exclusion Criteria: - Lack of willing to cooperate after the surgery - Postoperative fever or infection

Intervention groups
Psycho-educational interventions will perform in three sessions before surgery as well as giving routine sedatives individually and face to face. There is no intervention for the control group.

Main outcome variables
The effect of psycho-educational interventions on the level of pain, anxiety and physiological indicators will determine.

General information

Reason for update

Acronym
--

IRCT registration information
IRCT registration number: **IRCT20090908002432N8**
Registration date: **2021-09-17, 1400/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-17, 1400/06/26**
Update count: **0**

Registration date
2021-09-17, 1400/06/26

Registrant information

Name
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Psycho-Educational Interventions on Anxiety, Physiological Indicators and Pain after the Surgery in the Coronary Artery Bypass Graft Patients

Public title

The Effect of Psycho-Educational Interventions on Anxiety, Physiological Indicators and Pain after the Surgery in the Coronary Artery Bypass Graft Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patient candidates for coronary artery bypass graft surgery No history of heart surgery Having literacy of reading and writing Ages between 18 to 65 years Willing to participate in the study Participating in pre-test assessment and having a minimum level of mild anxiety No history of antidepressants use No physical disabilities and no mental illnesses No participation in similar studies

Exclusion criteria:

Lack of cooperation after the surgery Postoperative fever and infection Any problems during anesthesia and surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we will pick up the people who has the inclusion criteria based on their profiles and get a number to each one. Then, we will randomly select 56 of them with the random number software. We will use the randomized permutation block design with the size of 4 to allocate them into the two groups of intervention (n=28) and control (n=28).

Blinding (investigator's opinion)

Double blinded

Blinding description

Control and intervention group members should not be in the same room or close to each other so that the sound of training would not heard by the control group. We will ask the control group not to share the training with other patients.

Placebo

Not used

Assignment

Parallel

Other design features

The present study is performed on 56 patients volunteered for coronary artery bypass graft surgery who are eligible to enter the study. Samples were selected through target-based sampling method until reaching the desired sample size and then samples were divided into two groups of experimental and control by random allocation method using RA software. Psycho-educational interventions were placed in three training sessions in the morning or evening the day before surgery and routine sedatives were given individually and face to face. Brochures were given to patients for study. Educational interventions included (effective breathing exercises after heart surgery and the way to use spirometry, self-care training and nutritional care after surgery, giving information about the process of the disease and treatment, routine medications after surgery and their side effects, surgery site, stitches and chest tube care training). Psychological interventions included: five mindfulness exercises trainings (conscious breathing, conscious observation, conscious listening, conscious awareness, conscious appreciation). There is no intervention for the control group. Spielberger questionnaire and McGill inventory will completed by the patient after surgery and before discharge. Physiological parameters of the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

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Shiraz University of Medical Sciences, Zand Street, Shiraz.

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Approval date

2021-05-27, 1400/03/06

Ethics committee reference number

1400.175.IR.SUMS.REC

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Anxiety
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Physiological indexes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Level of anxiety
Timepoint
Before intervention, during admission and after intervention
Method of measurement
Spielberger state-trait anxiety questionnaire

Secondary outcomes

1

Description
Pain
Timepoint
Before intervention, during admission and after intervention
Method of measurement
McGill Scale

Intervention groups

1

Description
Intervention group: Psycho-educational interventions will perform in 3 sessions alongside prescribing routine sedatives face to face before surgery. An educational brochure will give to patients. Educational interventions are including effective breathing exercises after heart surgery, spirometer use techniques, self-care training, nutritional care after surgery, giving information about the course of disease and treatment, routine medications after surgery and their side effects, training to take care of the surgical site, stitches and chest tube. Mental interventions including conscious breathing, conscious observation, conscious listening, conscious mindfulness, conscious appreciation.
Category
Other

2

Description
Control group: There is no intervention for the control group. Spielberger questionnaire and McGill inventory will completed by the patient after surgery and before discharge. Physiological parameters of the patients will measure and record by the research assistant.
Category
Other

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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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
Shiraz 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

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Full name of responsible person
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Position
Master of Science In Nursing, Faculty member of School of Nursing and Midwifery, Shiraz University o

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is 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

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
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From where data/document is obtainable
-

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

Comments
-