

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effect of education by nurses and peer through video on anxiety and depression in patients undergoing open heart surgery

Protocol summary

Study aim

A comparative study on the effect of nurse and peer educator on the anxiety and depression of patients undergoing open heart surgery.

Design

clinical trial randomized by permutation blocks method that consists of three parallel groups of control, first intervention and second intervention. For each group, 38 cases were calculated.

Settings and conduct

103 patients candidate for open heart surgery in Imam Khomeini Hospital in 2018 will be randomly assigned by permutation blocks method to three groups of control (routine training only), the first intervention (nurse video training) and the second intervention (peer video training). Spielberger's explicit anxiety Questionnaire will be complete by samples in three steps (beginning of the preoperative, preoperative and fourteenth post-operative) and shortened form of Beck Depression Questionnaire will be complete by samples in two steps (beginning of the study and the fourth one after the operation).

Participants/Inclusion and exclusion criteria

Entry requirements include: • No history of previous operation • Age between 25 and 75 years • Having reading and writing skills • Not having a history of depression or anxiety disease • Do not take any anxiolytic, antipyretic and antipyretic drugs • Not having chronic illness with the current problem Exit conditions include: • Unwillingness to continue cooperation • Prolonged clearance after 10 days • Patient's deterioration after surgery and relocation to the special department or operating room

Intervention groups

The control group will receive only routine training, including nurse and physician's explanations, and educational pamphlets available in the ward. The first intervention group will receive an educational video, Which was taught by the nurse. The second intervention

group will receive an educational video Which was taught by the peer.

Main outcome variables

depression; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042585N1**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **retrospective**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

محمدآبادی ali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 4516

Email address

alimohammadabadi1370@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

2018-08-05, 1397/05/14

Actual recruitment end date

2018-11-22, 1397/09/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

Comparison of the effect of education by nurses and peer through video on anxiety and depression in patients undergoing open heart surgery

Public title

Comparison of the effect of education by nurses and peer through video on anxiety and depression in patients undergoing open heart surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

No history of previous operation Have literacy at reading and writing levels Not having a history of depression or anxiety disease Do not use any anti-anxiety, psychoactive and anti-depressant drugs Not having chronic illness with the current problem

Exclusion criteria:

Unwillingness to continue cooperation Prolonged clearance after 10 days Patient's deterioration after surgery and relocation to the special department or operating room

AgeFrom **25 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **114**Actual sample size reached: **103****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization was done using permutation blocks method. three randomly assigned random blocks to one of six blocks. Thus, 114 samples were divided into three groups of 38, with 35 cases in control group and 35 in each group in the first and second intervention group, taking into account the loss of specimens.

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 Tehran University of Medical Sciences

Street address

6th floor, Central Organization of the University, Ghods St, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

9411698014

Health conditions studied**1****Description of health condition studied**

Anxiety Caused by Heart Surgery

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2**Description of health condition studied**

Depression Caused by Heart Surgery

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes**1****Description**

explicit anxiety

Timepoint

The beginning of the study, preoperative and four week after surgery

Method of measurement

Spillbugger's explicit Anxiety Inventory

2**Description**

Depression

Timepoint

At the beginning of the study and four weeks after the operation

Method of measurement

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Only receive routine training.

Category

Other

2**Description**

Intervention group: For this group, in addition to routine training, there was only one video presentation showing explanations about the admission process, the transfer to the operating room and the postoperative recovery process in which a nurse played the role of educator.

Category

Other

3**Description**

Intervention group: For this group, in addition to routine training, there was only one film presentation showing explanations about the process of admission, the transfer to the operating room and the postoperative recovery process in which a peer played a role of trainer.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Ali Mohammadabadi

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Dr. Gharib Street, End of Keshavar Blvd, Tehran

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Imamhospital@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Waseq Rahim Parvar

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Dr Mirkhani Street (Eastern Nusrat), Tohid Square, Tehran

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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**

Tehran University of Medical Sciences

Full name of responsible person

Ali Mohammadabadi

Position

Master of sciences student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No. 38, Block 7th Hekmat 27, Tohid Town, Sabzevar

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Person responsible for scientific inquiries

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Person responsible for updating data

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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