Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

ali محمدآبادی

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
Age
From **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

Shortened Beck Depression Inventory

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
Street address
Dr. Gharib Street, End of Keshavar Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2756
Email
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
Street address
Dr Mirkhani Street (Eastern Nusrat), Tohid Square, Tehran
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Tehran
Postal code
1419733171
Phone
+98 21 6694 1669
Email
tums_edu@tums.ac.ir
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
Street address
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