Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of nursing consultation on anxiety and depression among elderly patients undergoing open heart surgery

Protocol summary

Study aim
This study is done to determine the effect of nursing counseling on the level of anxiety and depression in elderly patients undergoing cardiac surgery.This study will be conducted on 60 elderly patients undergoing coronary artery bypass graft surgery.

Design
Controlled clinical trial, simple randomized coin throwing method; samples include 60 patients that aged over sixty years old.

Settings and conduct
Nursing counseling in six sessions on elderly people aged over 60 years undergoing coronary artery bypass surgery in Karaj Rajaee Hospital.

Participants/Inclusion and exclusion criteria
Participants, elderly patients are candidates for coronary artery bypass surgery at Shahid Rajaee Hospital in Karaj. Entry conditions include: age 60 years old and older; having the first heart surgery; having non-emergency cardiac surgery; only coronary artery bypass surgery; lack of alcohol and drug addiction; hearing impairment; cognitive abnormalities; absence of psychological or anxiety disorders and Pre-defined depression; ability to speak in Persian.

Intervention groups
The intervention includes nursing counseling aimed at reducing anxiety and depression in older people who perform coronary artery bypass surgery.The samples, which include the elderly over 60 years old, are divided into two groups of intervention and control.The control group only receives the usual care in the hospital.The nursing counseling intervention is conducted in six sessions of 30 to 60 minutes.

Main outcome variables
Use of nursing counseling as an effective nursing intervention in the elderly under open heart surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190226042853N1**
Registration date: **2019-05-24, 1398/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-24, 1398/03/03**
Update count: **0**

Registration date
2019-05-24, 1398/03/03

Registrant information

Name
Morassa Savadishafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 26 3443 4229

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of nursing consultation on anxiety and depression among elderly patients undergoing open heart surgery

Public title
The effect of nursing consultation on anxiety and depression among elderly patients undergoing open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having aged 60 and over The first open heart surgery experience Non-emergency surgery. Only coronary artery bypass surgery is performed Absence of previous anxiety and depression Lack of alcohol and drug addiction Lack of hearing and cognitive impairment Ability to Speak Farsi The lack of psychological problems
Exclusion criteria:
Patient death Unwillingness to continue cooperation
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple coincidence by throwing coins
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The division of samples into two groups of intervention and control, which does not involve any intervention in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Pharmacy,Nursing and Midwifery
Street address
Valiasr Ave,Niayesh Intersection
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-06-22, 1396/04/01
Ethics committee reference number
IR.SBMU.PHNM.1396.791

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

2

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Anxiety and depression levels in the elderly according to the HADS questionnaire
Timepoint
Measure anxiety and depression before interaction and at the time of discharge
Method of measurement
Hospital Anxiety and Depression scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention in this study includes a nursing counseling program for 30 aged patients undergoing coronary artery bypass graft surgery.The intervention consists of six sessions ranging from 30 to 60 minutes, which will continue From the time of the nomination to the practice until the discharge expires.Consultation includes training sessions on the whole process of action, and everything that the patient needs, patient problems, interviews, free Q & A, problem design, and a solution with the patient's own collaboration.Consultation is also available individually.
Category

Prevention

2

Description
Control group: In this group of elderly people (30), only routine hospital care will be provided and no additional programs will be received.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaee Hospital
Full name of responsible person
Fatemeh Rahimi
Street address
Rajaee Ave., Shahid beheshti Blvd., Hesarak Town, Karaj
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Alborz
Postal code
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Phone
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+98 26 3455 4484
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rajaie@abzums.ac.ir
Web page address
Https://rajaie.abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Mahrokh Dolatian
Street address
Valiasr Ave., Niayesh intersection
City
Tehran
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1985717443
Phone
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Fax
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Email
sbnmf@sbmu.ac.ir
Web page address
http://nm.sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Morasa savadi shafi
Position
Master student of Geriatric nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Valiasr Ave, Niayesh intersection,School of Nursing and Midwifery of Shahid Beheshti
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Morasa Savadi Shafi
Position
Master student of geriatric nursing
Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Morasa Savadi Shafi

Position

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Other areas of specialty/work

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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