

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

Phone

+98 26 3443 4229

Email address

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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

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Rajaee Ave., Shahid beheshti Blvd., Hesarak Town, Karaj

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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

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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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