

# 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

m.savadi63@sbmu.ac.ir

##### 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

##### City

Karaj

##### Province

Alborz

##### Postal code

3197635141

##### Phone

+98 26 3455 2001

##### Fax

+98 26 3455 4484

##### Email

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

##### Province

Tehran

##### Postal code

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##### Phone

+98 21 8865 5366

##### Fax

+98 21 8865 5363

##### 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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m.savadi63@sbmu.ac.ir

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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  
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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  
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Master student of geriatric nursing  
**Latest degree**  
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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