Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of family support programs on depression, anxiety, stress and satisfaction of family caregiver`s in patients' open heart surgery.

Protocol summary

Summary

Objective: This study aimed to determine the effect of family support program on the anxiety, depression, stress, and satisfaction of the family caregivers of patients with open heart surgery. Samples: Ninety family caregivers of the patients undergoing open heart surgery in FATEMEH- ZAHRA Hospital, Sari, Iran recruited in the study. Inclusion criteria: Family member should have a key role in the patient's care, have the ability to read and understand Persian, be at least18 years old, not have a history of taking care of a cardiac surgical patient, not be a member of the healthcare team, and finally the patient shouldn't be the candidate of emergency surgery. Exclusion criteria: Occurrence of any postoperative complications such as bleeding, reoperation, etc.; the patient is extubated in the first 24 hours after surgery, the patient or her/his family members cannot participate in all instructional sessions. Intervention: In this experimental clinical trial, the participants will be divided into experimental and control groups. In the experimental group, family caregivers receive information support ,instructional sessions and booklets, phone calls along with emotional support. On the other hand the control group receives the routine hospital support. Anxiety, depression, and stress levels were measured by DASS21 questionnaire and Satisfaction measured with satisfaction of the family members of patients in Intensive Care Units questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051624342N2**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name
Vida Shafipour
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 7342
Email address
v.shafipour@mazuma.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology , Mazandaran University of Medical Sciences

Expected recruitment start date

2016-05-17, 1395/02/28

Expected recruitment end date

2016-09-18, 1395/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family support programs on depression, anxiety, stress and satisfaction of family caregiver`s in patients' open heart surgery.

Public title

The effect of family support programs on depression, anxiety, stress and satisfaction of family caregiver`s in

patients' open heart surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Family member should have a key role in the patient’s care, have the ability to read and understand Persian, be at least18 years old, not have a history of taking care of a cardiac surgical patient, not be a member of the healthcare team, and finally the patient shouldn’t be the candidate of emergency surgery. Exclusion criteria: Occurrence of any postoperative complications such as bleeding, reoperation, etc.; the patient is extubated in the first 24 hours after surgery, the patient or her/his family members cannot participate in all instructional sessions.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mazandaran University of Medical Sciences Ethics Committee

Street address

Moalem Square,

City

Sari,

Postal code

4816715793

Approval date

2016-05-14, 1395/02/25

Ethics committee reference number

IR.Mazums.REC.95-2118

Health conditions studied

1

Description of health condition studied

Family caregiver`s, patients candidate for open heart surgery

ICD-10 code

Z95

ICD-10 code description

Presence of cardiac and vascular implants and grafts

Primary outcomes

1

Description

Depression, Anxiety and Stress

Timepoint

One day before surgery ,24 hours before dischage,14 days after discharge

Method of measurement

Depression Anxiety Stress Scales (DASS)

Secondary outcomes

1

Description

Satisfaction with family caregiver`s

Timepoint

24 hours before discharge from hospital

Method of measurement

Satisfaction Questionnaire family members of adult patients hospitalized in intensive care

Intervention groups

1

Description

Intervention Group: The intervention mainly will be done based on two aspects: informational support including instructional sessions and booklets, and phone calls with caregivers. Another aspect called emotional support includes giving enough time to the family member to talk about her/his concerns, fears, and their feelings, making them sure about the provision of adequate care at the hospital, and encouraging the family caregivers to be hopeful and trust in God

Category

Other

2

Description

The control group: Receiving usual hospital routine

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital Of Heart
Full name of responsible person
Ahmad Ali Enayati
Street address
Artesh Street,
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor of Research and Technology, Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
Street address
Vice-Chancellor of Research and Technology, Mazandaran University of Medical Sciences
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor of Research and Technology, Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences,
Full name of responsible person
Fariba Shoushi
Position
Master Critical Care Nursing Student,
Other areas of specialty/work
Street address
Mazandaran University of Medical Sciences
City
Sari,
Postal code
Phone
+98 33795555
Fax
Email
r.shoushi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Vida SHafipour
Position
Phd.Educational Nursing
Other areas of specialty/work
Street address
Nasibeh School of Nursing and Midwifery, Vesal Shirazi Street
City
Sari,
Postal code
Phone
+98 11 3336 7342
Fax
Email
v.shafipour@mazuma.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Fariba SHoushi
Position
Master Critical Care Nursing Student
Other areas of specialty/work
Street address
Nasibeh School of Nursing and Midwifery, Vesal Shirazi Street
City
Sari,
Postal code
Phone
+98 33795555
Fax
Email
r.shoushi@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty