

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 least 18 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 least 18 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 discharge,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

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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