

# 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**

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r.shoushi@gmail.com

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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Vida SHafipour

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Phd.Educational Nursing

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v.shafipour@mazuma.ac.ir

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## Person responsible for updating data

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**Full name of responsible person**

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**Other areas of specialty/work****Street address**

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## 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*