Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Supportive Training Program on Depression and Anxiety and Satisfaction of Families of Patients with Acute Coronary Syndrome Admitted to the Cardiac Care Unit

Protocol summary

Study aim
Determining the effect of supportive educational program on depression, anxiety and satisfaction of families of Patients with acute coronary syndrome admitted to the cardiac care unit

Design
Clinical trial with community based and pragmatic control group, with parallel group, without blindness, Randomized by SPSS software

Settings and conduct
families of patients with acute coronary syndrome admitted to the cardiac care unit of Imam Reza and Ghaem Hospital who are eligible for the study will be included in the study and will be randomly selected and assigned to the intervention and control groups according to the sequences that generated by SPSS software. In the intervention group a supportive educational program is implemented.The intervention is performed from the day of admission and lasts up to 3 days in the cardiology ward.In the control group, patients family will receive routine treatment.anxiety,depression will be checked before and after the intervention with DASS questionnaire. and also satisfaction questionnaire will be completed after the intervention in both groups

Participants/Inclusion and exclusion criteria
Patient including criteria: Definitive Diagnosis of Acute Coronary Syndrome Patient's family including criteria:Being first-degree members of the family, Fluency in Persian, having no history mental disorders, having at least primary education, not having health care jobs, not taking care of another person at the same time, having no history of admission to the cardiac care unit, and having no audible and visual problems.

Intervention groups
In the intervention group, a Supportive Training Program will be performed for 72 hours for the family of patients with acute coronary syndrome admitted to the cardiac care unit. In the control group, patients family will receive routine manner.

Main outcome variables
Level of Depression, anxiety and satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181101041524N1**
Registration date: **2019-07-08, 1398/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-08, 1398/04/17**
Update count: **0**

Registration date
2019-07-08, 1398/04/17

Registrant information

Name
Fateme Faroujizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3859 1511

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-15, 1398/03/25

Expected recruitment end date
2019-09-16, 1398/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Supportive Training Program on Depression and Anxiety and Satisfaction of Families of Patients with Acute Coronary Syndrome Admitted to the Cardiac Care Unit

Public title

The Effect of Supportive Training Program on Depression and Anxiety and Satisfaction of Families of Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Including criteria for patient:Diagnosis of acute coronary heart disease by clinical signs, ECG and enzyme tests approved by the cardiologist Including criteria for patient family:First-class members of the family of patients admitted to the cardiac care unit according to the patient's choice Primary education Fluency in Persian

Exclusion criteria:

History of hospitalization in ccu ward Having health care jobs Having a visual and audio problem Take care of another person at the same time Having a history of illness and mental disorders based on the patient's history and self-declaration

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units according to the sequences that generated by SPSS software before the start of the study were randomly divided into intervention and control groups. In order to prevent the dissemination of information between the two group,until the patients selected for the first group are not discharged from the ward, sampling for the second group will not take place.

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Opposite University Street 18-University Street

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Razavi Khorasan

Postal code

9137654511

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.007

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

depression

Timepoint

At the time of admission and 72 hours after admission

Method of measurement

Depression, Anxiety and stress Scales(DASS)

2

Description

the amount of anxiety

Timepoint

At the time of admission and 72 hours after admission

Method of measurement

Depression, Anxiety and stress Scales(DASS)

3

Description

Satisfaction of family members of hospitalized patients

Timepoint

72 hours after admission

Method of measurement
Family Satisfaction in the Intensive Care Unit FS-ICU (34)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The educational and supportive program will be implemented, which will include the educational, support and counseling needs of the patient's family in this program.The intervention will be implemented from the patient's Hospitalization day in the CCU ward and will continue for up to 3 days in the cardiology ward.The supportive program includes information support and emotional support.In this way, in the emotional support from the time of admission, the researcher will be with family members and while performing psychological support from them, she describes the patient's condition and listens to their words and she Reassures them about the patient's care and answer questions, concerns and express their feelings and It also considers a scheduled visit to the patient's family; this is the case during the period of admission to the cardiac care unit, after the patient is in a stable position, the patient's companion can meet his patient once a day.Meetings will be scheduled according to need of companion and patient.The family will be taught to control their feelings and use promising and hopeful words to calm the patient.In support of information the patient family will be informed about the patient's condition and vital signs daily and during this time the researcher will answer the patient's family questions and concerns.In the training program, the CCU ward, equipment, patient connections, the nature of the disease and the treatment process will be explained.These trainings will be face-to-face and educational pamphlets will be given to the family.When treatment is required, a description of the treatment options will be provided about the benefits and complications of each treatment.These trainings take place in a room and in a quiet environment for 40 minutes in coordination with the head nurse to determine the training room.Finally, on the third day of hospitalization in the cardiology ward, post-discharge care, such as proper diet, proper physical activity, and regular use of medications, will be trained for a maximum of 45 minutes plus pamphlets.The number of training sessions during the hospital stay is scheduled according to the need for attendance, in which at least two training sessions are held during these three days of intervention.

Category
N/A

2

Description
Control group: control group will receive the usual care, so that at the beginning of the patient's stay, a welcome pamphlet is given to the family, which includes information on the rules and environment of the ward, telephone number and hours of the visit.Information is also given to the patient's family upon request from the family regarding the patient's condition.At the discharge time, information is provided to the patient about the diet, medications and physical activity, along with educational pamphlets.Routine training in hospitals is general and does not need to be performed based on the needs of the patient's family.There is no advice on the types of treatments and only information about the ACS disease care and cardiac care unit is provided to all patients in the form of a pre-prepared training pamphlet

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Quaem hospital
Full name of responsible person
Fateme Hajiabadi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fateme Faroujizadeh

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available