

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of supportive nursing program on depression anxiety and stress of family member of patient during coronary artery bypass surgery

Protocol summary

Summary

This study is performed to evaluate the effect of supportive nursing program for patient's family members under depression, anxiety and stress during coronary artery bypass graft surgery (CABG). This semi-experimental study is conducted on 52 patient's family members in different groups considering the inclusion criteria. Inclusion Criteria includes having main role in supporting patient, Be at least 18 years of age, have no study in medical science and Ability to understand Persian conversation. Exclusion Criteria includes Lack of family member of patient cooperation in data collection and patient's surgery take longer than usual like sever bleeding, unexpected problem or patient death. The experimental group members will be provided with supportive nursing program including informational and emotional support. The members of the control group also will be received routine intervention. Data will be collected by demographic and modified Depression Anxiety and Stress (DASS) questionnaires. The questionnaires will be given to the family member at the the beginning and end of surgery and level of depression, anxiety and stress will be compared in control and intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404034443N10**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 2160

Email address

zakerimo@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive nursing program on depression anxiety and stress of family member of patient during coronary artery bypass surgery

Public title

The effect of supportive nursing program on depression anxiety and stress of family member of patient during coronary artery bypass surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria : have main role in supporting patient;
Be at least 18 years of age; have no study in medical

science; Ability to understand Persian conversation; The absence of mental illness. Exclusion Criteria: Lack of family member of patient cooperation in data collection; patient's surgery take longer than usual (like sever bleeding, unexpected problem or patient death).

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: **104**

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

Tehran University of Medical Sciences

Street address

Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd

City

Tehran

Postal code

1419733171

Approval date

2014-03-15, 1392/12/24

Ethics committee reference number

130/3020/92/3

Health conditions studied

1

Description of health condition studied

family member during coronary artery by pass graft

ICD-10 code

Z63.8

ICD-10 code description

سایر مشکلات ویژه مربوط به گروه مراقبت اولیه

Primary outcomes

1

Description

depression anxiety and stress

Timepoint

before surgery and after surgery

Method of measurement

Depression Anxiety Stress Scales (DASS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The intervention in this study is supportive nursing program for patient's family members. This Program will be started in the beginning of surgery and continue until the end of surgery. The first part is about informational support that includes talk to patient's family and adequately informed about patient's condition and process of surgery, answer to questions of family and report patient situation every thirty minutes, in emotional support the family member encourage to talking about concerns and fears , expression of feeling, assurance that the best possible care is provided to their patient and in the third part for personal support private place for communication with family will be provided.

Category

Other

2

Description

Control group: Will receive routine intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac Research, Educational and Treatment Center of Shahd Rajaei

Full name of responsible person

Pegah Salahshoor

Street address

end of Niayesh Highway, Vali-asr Ave.,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

research assistant of university Dr.Footoohi

Street address

tehran-keshavarz bolvare-ghods street-central
Building

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

Senior expertise/Scientific Panel member

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

Tehran-tohid Square-Eastern nosrat-School of Nursing
and Midwifery

City

Tehran

Postal code**Phone**

+98 21 6692 7171

Fax**Email**

zakerimo@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

Senior expertise/Scientific panel member

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

Tehran-tohid Square-Eastern nosrat-School of Nursing
and Midwifery

City

Tehran

Postal code**Phone**

+98 21 6692 7171

Fax**Email**

zakerimo@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

Position

senior expertise/Scientific panel member

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

Tehran-tohid square-eastern nosrat-school of nursing
and midwifery

City

Tehran

Postal code**Phone**

+98 21 6692 7171

Fax**Email**

zakerimo@sina.tums.ac.ir

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