

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of educational support on caregiving burden and anxiety among caregivers of patients undergoing coronary artery bypass graft surgery (CABG)

Protocol summary

Summary

This randomized clinical trials with Control group -just pretest, evaluate the effect of educational support on anxiety and burden of family caregivers caring for patients undergoing coronary artery bypass grafting. The samples were randomly allocated block 4 modes in caregivers of patients undergoing coronary artery bypass intervention (educational support programs) and control group (no intervention educational support) will be done. The sample size is 80,40 patients in the intervention group and 40 patients in the control group. Demographic and disease questionnaire, Spielberger anxiety questionnaire and caregiver burden inventory, by the subjects in the two groups before the intervention (at the first of entrance) as baseline data will be completed. At the day before discharge of participants will be asked to fill questionnaires. Family caregivers in the intervention group in four sessions on an individual basis in the patient's room and staff break room (at the first of entrance to the study, at the day before surgery, the second day after surgery and before discharge from the hospital) 45 to 60 minute, they will train, 6 weeks after surgery, both groups will be completed questionnaires. Then Data will be analyzed using descriptive and inferential statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030526900N1**
Registration date: **2016-07-24, 1395/05/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-24, 1395/05/03

Registrant information

Name

Helen Daliri Rad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

International Branch, Iran University of Medical Sciences

Expected recruitment start date

2016-04-18, 1395/01/30

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational support on caregiving burden and anxiety among caregivers of patients undergoing coronary artery bypass graft surgery (CABG)

Public title

Designing and implementation of educational support program based on family caregivers needs of patients undergoing coronary artery bypass surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: a member of the family, alone, that has the primary role in patient care; hold at least 2 months of patient care as care-givers and family members; not having physical illness and psychological that disable the person in care; not having previous history of cardiac surgery in caregiver; not having previous history of caring of patient undergoing cardiac surgery; no care at the same time, another person with physical and mental diseases; caregiver is not member of the healthcare team; surgery is not emergency; having at least literate to read and write; caregiver be able to communicate in Persian. Exclusion criteria: lack of participating in one of the training sessions; death of the patient or caregiver.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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**

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences - Corner of Milad Hospital - Hemmat Expy - Tehran

City

Tehran

Postal code**Approval date**

2016-05-10, 1395/02/21

Ethics committee reference number

IR.IUMS.REC 1395.9313677002

Health conditions studied**1****Description of health condition studied**

Coronary artery bypass graft surgery

ICD-10 code

Diseases o

ICD-10 code description

125.1

Primary outcomes**1****Description**

Caregiving burden

Timepoint

The first entrance, before discharge and 6 weeks after discharge

Method of measurement

Caregiver Burden Inventory(CBI)

Secondary outcomes**1****Description**

Anxiety

Timepoint

The first entrance, before discharge and 6 weeks after discharge

Method of measurement

Spielberger anxiety inventory

Intervention groups**1****Description**

This study is a randomized clinical trial that family caregivers in the intervention group in four sessions on an individual basis in a patient's room and staff break room (at the first of entrance to the study, before surgery, the second day after surgery and before discharge from the hospital) will train 45 to 60 minutes.

Category

Prevention

2**Description**

Caregivers in the control group will receive hospital care and training routine.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Inpatient wards of the educational, medical and research center in Tehran Shahid Rajai hospital

Full name of responsible person

Helen Daliri

Street address

Corner of niayesh - Next to Mellat Park - Vali Asr Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Branch, Iran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sadegh Ghasemi

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Iran University of Medical Sciences - Corner of Milad Hospita - Hemmat Expressway - Tehran

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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

International Branch, Iran 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

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Helen Daliri

Position

Master Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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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