

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-centered care model on health literacy level and sleep quality in patients after coronary artery bypass grafting

Protocol summary

Study aim

Determining the effect of family centered care on health literacy and sleep quality in patients after CABG

Design

This study is a randomized clinical trial with intervention and control group.

Settings and conduct

This study will be done in alzahra cardiovascular hospital on 100 post CABG patients. Since intervention are supportive-educational and must be done by the researcher, therefore there is no possibility for blindness.

Participants/Inclusion and exclusion criteria

Participants in this study are patients after CABG surgery. inclusion criteria are reading and writing literacy, non-emergency CABG, no history of CABG and being able to make phone calls.

Intervention groups

Intervention group: Family centered care will execute for patients and the family member responsive for care of the patient in 3 educational 30-40 minutes sessions. First session will be done 24-48 h before surgery and general topics about the disease, the reason for the need for CABG and preparations needed before surgery will be presented. In the second session, 48 hours after surgery, group discussion in 4-6 person groups will be used. topics of this session will be presented at five parts: diet, drug regimen, activity plan, complications of surgery and cares needed after surgery. In the third session, which is 4th day after surgery, wound care methods, physical exercises, how to use varicose socks and sternum protector will be educated. After this session, participants follow up for one month, two times a week, with phone calls, and the process of implanting of presented care plan will be evaluated. forth session is one month after patient discharge, and in this session participants will complete study questionnaires again. Control group: Control group will receive only routine cares and the researcher will not do any intervention for them.

Main outcome variables

Sleep quality Health literacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130212012452N7**

Registration date: **2018-05-05, 1397/02/15**

Registration timing: **retrospective**

Last update: **2018-05-05, 1397/02/15**

Update count: **0**

Registration date

2018-05-05, 1397/02/15

Registrant information

Name

Shahram Etemadifar

Name of organization / entity

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered care model on health literacy level and sleep quality in patients after coronary artery bypass grafting

Public title

The effect of family-centered care model in patients after coronary artery bypass grafting

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Non-emergency surgery Reading and writing literacy Being able to make phone calls

Exclusion criteria:

history of coronary artery bypass graft surgery patients with chronic underlying disease such as chronic renal failure, CVA and COPD

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants to this study allocate to intervention and control group by picking up a draw. In order to do this job, the researcher made 100 card, which on 50 of them is written "1", and on 50 of the is written "2", and asks each participant to pick up one of these cards. If the patients pick up the card which is written "1", he or she allocates to the control group, and if the participant pick up the "2" card, he or she allocates to the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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Approval date

2017-12-02, 1396/09/11

Ethics committee reference number

IR.SJUMS.REC.1396.179

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

Coronary artery bypass graft

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sleep quality score on Pittsburgh index

Timepoint

Before and one month after interventions

Method of measurement

Pittsburgh sleep quality index

2**Description**

Health literacy score in Health literacy for adult questionnaire

Timepoint

Before and one month after interventions

Method of measurement

Health literacy for adult questionnaire

Secondary outcomes

empty

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

Intervention group: Intervention group: for intervention group, family centered care will execute for patients and the family member responsive for care of the patient in

the form of 3 educational 30-40 minutes sessions. first session is 24-48 hours before surgery. In this session, general topics about the disease, the reason for the need for CABG and preparations needed before surgery will be presented. In the second session, 48 hours after surgery, group discussion in 4-6 person groups (2-3 patients with one family member for each) will be used. topics of this session will be presented at five parts: diet, drug regimen, activity plan, complications of surgery and cares needed after surgery. In the third session, which is 4th day after surgery, wound care methods, physical exercises, how to use varicose socks and sternum protector will be educated. After this session, participants follow up for one month, two times a week, with phone calls, and the process of implanting of presented care plan will be evaluated. forth session is one month after patient discharge, and in this session participants will complete study questionnaires again.

Category

Other

2

Description

Control group: Control group will receive only routine cares and the researcher will not do any intervention for them. To comply with the ethics of research, after the end of interventions and collecting post test data, all the educational topics used for intervention group, will be offered to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra cardiovascular hospital

Full name of responsible person

Zahra Abbasi

Street address

Alzahra cardiovascular hospital, Khatoon square, Sibouye Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Kamal Solati

Street address

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Shahram Eatamadifar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address

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

There are no more information

Study Protocol

No - There is not 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

No - There is not 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

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Zahra Abbasi

Position

Nursing Graduate Student