

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effectiveness of rehabilitation through the home visit and telephone follow up on self-efficacy in coronary artery bypass graft patients and their family caregivers' burden.

Protocol summary

Study aim

Comparison of the effectiveness of rehabilitation through home visit and telephone follow up of patients with coronary artery bypass graft surgery and their family caregivers' burden

Design

Patients with coronary artery bypass surgery and their caregivers, control group, home visit and follow-up, randomized blocking, and placement in blocks, sample size of each group 40 with a probability of 10% dropping 44 in each group during discharge

Settings and conduct

Before and after clinical trials, patients with coronary artery bypass graft surgery, Khorramabad Heart Center, and their families, after satisfaction completed questionnaires, visit group, 1 weekly visit, 2 times weekly follow up Four weeks, at the end, questionnaires were completed in the last visit, in the other two groups completed the questionnaire by visiting the home

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients: 70 to 30 years The absence of mental or psychomotor disorder caregiver: Have a reading and writing literacy Exit criteria Patients: Having known psychomotor disorder caregiver: Aged 18 and over

Intervention groups

The intervention group 1: Home visit: completion of a questionnaire during discharge, delivery of booklet, one day after discharge, then weekly visit at home four weeks, completing the questionnaires Intervention group 2: Telephone follow up, completion of a questionnaire during discharge, delivery of booklet, one day after discharge, then two times weekly telephone training, referral to home in last session of fourth week, completion of questionnaires Control group: completion of questionnaire during discharge, provision of routine to the patient, referral to home during last session of fourth

week, completion of questionnaires

Main outcome variables

Self-efficacy of patients; family burden caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100609004129N2**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name

Shirin Hasanvand

Name of organization / entity

Lorestan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-27, 1397/04/06

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of rehabilitation through the home visit and telephone follow up on self-efficacy in coronary artery bypass graft patients and their family caregivers' burden.

Public title
The effect of rehabilitation on the effectiveness of coronary artery bypass graft surgery patients and their caregivers' burden.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing coronary artery bypass graft surgery
Familiarity with Persian language, Laki and accent Lori
The absence of mental or psychomotor disorder
The absence of hearing impairment, vision, speech, The absence of chronic disease disability
Access to fixed telephony
Having a caregiver available during admission
Aged 18 and over (caregiver)
Have a reading and writing literacy (caregiver)

Exclusion criteria:

previous record of participation in cardiac rehabilitation programs
The incidence of the disease Systemic
The incidence hemodynamic disorder
Literacy is not read and write (caregiver)
Having known psychomotor disorder (caregiver)

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
The studied units (patient and caregiver) will be assigned to the three groups according to the criteria for inclusion in the study and available on the basis of randomized blocking. The entry of individuals to each of the groups will be done in the order of the number of selected blocks and will be done using the layout inside the block.

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 Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaie Square, Moaalem St

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Khorrarnabad

Province

Lorestan

Postal code

6819833895

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.LUMS.REC.1397.027

Health conditions studied

1

Description of health condition studied

self-efficacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

patient Self-efficacy

Timepoint

During discharge from the hospital one month after the discharge

Method of measurement

Joker Questionnaire

Secondary outcomes

1

Description

Caregivers burden, family Caregivers

Timepoint

During the discharge of the hospital and completion of the intervention up to 4 weeks after discharge

Method of measurement

Novak and Gest Questionnaire

Intervention groups

1

Description

Intervention group 1: Visit at home with the presence of a nurse in coordination with the patient's home and assess and train her for 4 weeks, weekly 1 time (4 sessions each), and each time for about an hour, from the first day after discharge. Complete the patient's questionnaire and care and delivery of the Educational booklet, patient counseling and family about the lifestyle modification including risk management, assessment of sleep status, nutrition, appetite and excretion, drug use and drug complications, mood and mental state of the patient, stopping use Smoking, wound care, referral to doctor, personal hygiene, bathing, sex work, traveling, driving, prayer Dan, climbing stairs, pressure, and blood sugar control is carried out, at the end of the rehabilitation program, during the last visit, this will be questionnaires completed by patients and caregivers.

Category

Rehabilitation

2

Description

Intervention group2 : Telephone follow up, telephone training and counseling based on the 2 weekly rehabilitation program for 4 weeks (totaling 8 telephone calls) and each call approximately 30 minutes from the first day after discharge by completing the patient and caregiver questionnaire and delivering the educational booklet. , And counseling and training, such as a home visit group, and completing questionnaires on the last day of the 4th week with the researcher's visit to the home.

Category

Rehabilitation

3

Description

Control group: From the first day of discharge after the discharge, by completing the patient and caregiver questionnaire, according to the routine of the treatment center during the discharge of the patient from the hospital, the training was provided by providing the hospital training package and completed the questionnaire on the last day of the 4th week The researcher will go home.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Shirin Hasanvand

Street address

Shaheed Madani Hospital, Imam Hossein Square, Kheirabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Morvat Taheri Kalani

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Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaie Square, Moaaalem Street

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr Shirin Hasanwand

Position

Ph.D. in Nursing, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Forouzan Gohari

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Student

Latest degree

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

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