

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effects of home-based cardiac rehabilitation and routine care on patients' quality of life after coronary artery bypass graft surgery

Protocol summary

Study aim

Comparison the effects of home-based cardiac rehabilitation and routine care on patients' quality of life after coronary artery bypass graft surgery

Design

In this research, 104 eligible patients underwent coronary artery bypass graft surgery in cardiac surgery units of Ahvaz Golestan and Emam Ghomaii hospitals will be chosen. Patients will be allocated to two equal groups of intervention and control according to table of random numbers.

Settings and conduct

This study will be conducted on cardiac surgery units of Ahvaz Golestan and Emam Ghomaii hospitals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having 30-70 years old; having ejection fraction more than 40%; having systolic blood pressure less than 160 mmHg and diastolic blood pressure less than 105 mmHg; having normal sinus rhythm; having full conciseness; being able to read and write. Exclusion criteria: having history of stroke, end stage renal diseases, liver diseases, anemia, mental and nervous disorders, peripheral nervous system disorders, and uncontrolled diabetes; having delirium and dementia.

Intervention groups

In intervention group firstly patients will be divided to group of 2-3 individuals, and for each group in companion with their family members four educational sessions about home-based cardiac rehabilitation program with one hour duration and one day interval will be implemented by researcher in the recruitment hospitals. In the next stage, follow-up will be done at home and education will be presented again two times in each month for three months. In control group, patients will receive only routine care with no specific education. However, education will be presented to all patients in control group at the end of the study.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171114037468N1**

Registration date: **2017-12-28, 1396/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-28, 1396/10/07**

Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

kobra limooei

Name of organization / entity

ahvaz jundishapur university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 916 303 6731

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of home-based cardiac rehabilitation and routine care on patients' quality of life after coronary artery bypass graft surgery

Public title

The effects of home-based cardiac rehabilitation on patients' quality of life after coronary artery bypass graft surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having 30-70 years old Having ejection fraction more than 40% Having systolic blood pressure less than 160 mmHg and diastolic blood pressure less than 105 mmHg Having normal sinus rhythm Having full conciseness Being able to read and write

Exclusion criteria:

Having history of stroke, end stage renal diseases, liver diseases, anemia, mental and nervous disorders, peripheral nervous system disorders, and uncontrolled diabetes Having delirium and dementia

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: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated to two equal groups of intervention and control according to table of random numbers.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,

Golestan road, Ahvaz, Khozestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.AJUMS.REC.1396.548

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft surgery

ICD-10 code

T82.218D

ICD-10 code description

Other mechanical complication of coronary artery bypass graft, subsequent encounter

2

Description of health condition studied

Quality of life after cardiac surgery

ICD-10 code

I97.110

ICD-10 code description

Postprocedural cardiac insufficiency following cardiac surgery

Primary outcomes

1

Description

Quality of life

Timepoint

Before education, 6 weeks and 12 weeks after education

Method of measurement

Macnew quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group firstly patients will be divided to groups of 2-3 individuals, and for each groups in companion with their family members four educational sessions about home-based cardiac rehabilitation program with one hour duration and one day interval will be implemented by researcher in the recruitment hospitals. In the next stage, follow-up will be done at home and education will be presented again two

times in each month for three months.

Category

Rehabilitation

2

Description

Control group: In control group, patients will receive only routine care with no specific education. However, education will be presented to all patients in control groups at the end of the study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Kobra Limooei

Street address

Golestan hospital, Golestan road, Ahvaz, Khozestan

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2

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeyni hospital

Full name of responsible person

Kobra Limooei

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Imam Khomeyni hospital, Azadegan road, Ahvaz, Khozestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Behzad Sharif Makhmalzadeh

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

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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

Vice chancellor for research of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kobra Limooei

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Midwifery and Nursing, Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Shahram Baraz Pordjanjani

Position

Assistant Professor

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Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of patients demographical data and main outcomes will be shared.

When the data will become available and for how long

Six months after data publishing

To whom data/document is available

Data will be available only for researchers working on academic and university associations.

Under which criteria data/document could be used

Mention of study name and authors name

From where data/document is obtainable

Kobra Limooei: School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

What processes are involved for a request to access data/document

At last one month after request

Comments