Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparative evaluation of discharge planning based on continuous care model and routine cardiac rehabilitation on the health related outcomes of patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim
Comparison of the efficacy of discharge planning based on continuous care model and cardiac rehabilitation on health related outcomes of patients after coronary artery bypass graft surgery

Design
This study is conducted as a combined embedded study. The quantitative part of the study of the clinical trial type and 88 patients undergoing coronary artery bypass graft surgery were assigned in two groups (intervention and control) by random block method.

Settings and conduct
This study will be carried out in Farshchian Cardiac center, affiliated to the Hamadan University of Medical Sciences in Hamadan.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients after coronary artery bypass grafting; desire to participate in the study; Proportion to one member of family to patient. Exclusion Criteria: Heart Failure class III and IV; Positive exercise test; Severe musculoskeletal problems; did not have access to a smartphone; on medication for psychiatric disorders.

Intervention groups
Intervention group: Patients will receive a continuous care program for four months alongside a cardiac rehab program. control group: patients will receive cardiac rehabilitation according to the routine program rehabilitation center. Patients will participate 3 sessions a week for one hour during one month in a supervised rehab program.

Main outcome variables
Quality of life; Functional capacity; re-hospitalization; Depression, Anxiety and Stress

General information

Reason for update
During the study, it was necessary to add items in the exclusion criteria that were added to the protocol. The sample size was corrected and the primary and secondary outcomes were edited.

Acronym

IRCT registration information
IRCT registration number: **IRCT20130211012439N3**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**
Update count: **2**

Registration date
2019-01-16, 1397/10/26

Registrant information

Name
Fatemeh Pakrad

Name of organization / entity
Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of discharge planning based on continuous care model and routine cardiac rehabilitation on the health related outcomes of patients undergoing coronary artery bypass graft surgery

Public title
Comparative evaluation of discharge planning and cardiac rehabilitation on the health outcomes of patients undergoing coronary artery bypass graft surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients after coronary artery bypass graft surgery The family and patient's willingness to participate in educational programs based on a continuous care model Close relationship of family member with patient

Exclusion criteria:
Heart Failure class III and IV Severe musculoskeletal problems Positive exercise test did not have access to a smart phone on medication for psychiatric disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
First of all, from patients with coronary artery bypass graft surgery and having inclusion criteria, a sample is selected according to the sampling method and based on balance block randomization method will be placed in cardiac rehabilitation group with education based on continuous care model (intervention) and the cardiac rehabilitation group (control). For this purpose, four sheets of paper are provided by the researcher, writing on two sheets “1” for “first” and on two “2” for second”. The paper sheets will be pooled, placed in a container, and randomly will be drawn one at a time for each patient without replacement until all four sheets are drawn. Then, the four paper sheets will be placed back into the container and this action will be repeated until the sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The cardiac rehabilitation nurse performed the assessments at each time point; she was blinded to random allocation.

Placebo
Not used

Assignment
Parallel

Other design features
This study will take place in two phases of quantitative and qualitative. In the quantitative phase, a clinical trial is conducted and in a qualitative phase, the nested mixed method is conducted through directed content analysis. Patients in the intervention group will be interviewed during the study and the data will be analysed through thematic analysis.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat Modares University

Street address
Nasr (Ghisha) Bridge, Jalale Al-Ahmad Great way

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14115-333

Approval date
2019-01-05, 1397/10/15

Ethics committee reference number
IR.MODARES.REC.1397.183

Health conditions studied

1

Description of health condition studied
Patients undergoing coronary artery bypass graft surgery

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Quality of life score in the short form questionnaire 36 questions

Timepoint
Before, immediately after and 3 months after the end of the intervention

Method of measurement
Short form questionnaire of quality of life

2

Description

Measure functional capacity

Timepoint

Before, immediately after and 3 months after the end of the intervention

Method of measurement

Using a treadmill according to a modified Bruce protocol.

Secondary outcomes

1

Description

re-hospitalization

Timepoint

Immediately after and 3 months after the end of the intervention

Method of measurement

through checking the computer system and directly querying patients (for potential hospitalizations elsewhere).

2

Description

Depression score in depression, anxiety and stress questionnaire

Timepoint

Before, immediately after and 3 months after the end of the intervention

Method of measurement

Depression Anxiety and Stress Scale

3

Description

Anxiety score in depression, anxiety and stress questionnaire

Timepoint

Before, immediately after and 3 months after the end of the intervention

Method of measurement

Depression Anxiety and Stress Scale

4

Description

Stress score in depression, anxiety and stress questionnaire

Timepoint

Before, immediately after and 3 months after the end of the intervention

Method of measurement

Depression Anxiety and Stress Scale

Intervention groups

1

Description

Intervention group: after introduction of the study and statement of the purposes, the patients will provide informed consents and complete the demographics form, quality of life questionnaire and Depression, anxiety and stress scale. Also, an exercise test will be done with a treadmill. Then, the Continuous Care Model will be presented to the participants along with cardiac rehabilitation program for four months. The Continuous Care Model consists of four stages: (1) orientation, (2) sensitization, (3) control, and (4) evaluation. At the end of one and four months, quality of life questionnaire and Depression, anxiety, and stress scale will be completed and an exercise test will be done.

Category

Rehabilitation

2

Description

Intervention control: In this group, patients will receive cardiac rehabilitation according to the routine program rehabilitation center. Patients will participate 3 sessions a week for one hour during one month in a supervised rehab program.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian cardiac center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Faculty of Medical Sciences, Tarbiat Modares University

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
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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
I must provide all information for the sponsoring institution.

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