Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of First phase of cardiac Rehabilitation on Illnes Perception and Health Literacy of patients under coronary artery bypass graft of

Protocol summary

Study aim
The effect of phase I cardiac rehabilitation on perception of disease and health literacy of patients undergoing coronary artery bypass grafting was evaluated.

Design
This study is a pre-test and two-group clinical trial; the participants were 60 (30 in the control group and 30 in the intervention group). Randomization is done by block method

Settings and conduct
The first phase of cardiac rehabilitation was performed preoperatively, intraoperatively (two days postoperatively) and postoperatively (five days postoperatively) for patients undergoing coronary artery bypass grafting.Its effect onillness perception of health literacy in control and intervention groups was performed in Shahid Rajaee hospital of Alborzn cardiac surgery and internal coronary ward.

Participants/Inclusion and exclusion criteria
All patients undergo open heart surgery who only perform coronary artery bypass grafting.

Intervention groups
Implementation of the first phase of cardiac rehabilitation for intervention group and routine care for control group

Main outcome variables
illness perception;Health literacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190805044442N1**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

Registration date
2020-02-01, 1398/11/12

Registrant information

Name
fahimeh reyhani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-23, 1396/09/02

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2017-11-23, 1396/09/02

Actual recruitment end date
2018-02-20, 1396/12/01

Trial completion date
2018-03-11, 1396/12/20

Scientific title
The Effect of First phase of cardiac Rehabilitation on Illnes Perception and Health Literacy of patients under coronary artery bypass graft of

Public title
The effect of the first phase of cardiac rehabilitation in cardiac surgery patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients waiting for coronary artery bypass graft surgery; at least two days have passed since their angography. Consent to participate in the research No neurovascular diseases (according to the patient's own medical records) First time experience coronary artery bypass graft surgery Be vigilant (aware of location, time and person). Surgery in the operating room has undergone a routine procedure (coronary artery bypass grafting only) There are no postoperative complications such as extensive drainage, pneumothorax, tamponade, dangerous arrhythmia, and so on.

Exclusion criteria:

In case of death of sample During the study, the patient may experience acute complications from surgery. If the condition worsens (re-entry to the operating room) • In case of incomplete completion of the questionnaire of dissatisfaction with continuing to participate in the research at each stage

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random method was used to select the subjects in the control and intervention groups. According to the sample size, 30 patients were in the control group and 30 in the intervention group. Questionnaires were completed by people who were eligible for the study. Then they were randomly assigned into intervention and control groups. Sample allocation was performed in both groups randomly. And after the number of people in each block reached five. Sampling from another group was repeated. Up to 30 in each group. Six blocks of five were created in each group. A total of 68 patients were included in the study

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 for Research of University of Social Welfare and Rehabilitation Sciences

Street address

Evin, Student Boulevard, Koodakyar Dead End

City

tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۷۱

Approval date

2017-07-04, 1396/04/13

Ethics committee reference number

IR.USWR.REC.1396.138

Health conditions studied

1

Description of health condition studied

Cardiac rehabilitation

ICD-10 code

Z50.0

ICD-10 code description

Cardiac rehabilitation

Primary outcomes

1

Description

Comparison illness perception score between intervention and control groups

Timepoint

Measurement of illness perception score before intervention and one month after hospital discharge

Method of measurement

Illness Perception Questionnaire

2

Description

Measure health literacy score before intervention and one month after hospital discharge

Timepoint

Measure health literacy score before intervention and one month after hospital discharge

Method of measurement

Health Literacy for Iranian Adults questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first phase of cardiac rehabilitation was performed in 4 sessions of 30 minutes

in a multi-disciplinary form for patients in the intervention group .Including training by a rehabilitation nurse to help shape the patient's understanding of coronary artery bypass grafting, counseling by a nutrition expert, preoperative exercise training, and post-surgery coronary artery bypass graft physicians, as well as patient group education with family members After surgery, a rehab nurse was done.The health literacy and perception of the disease were analyzed in two steps before surgery and one month after the operation using SPSSv22 software, Chi-square, t-student and analysis of co variance and variance were analyzed.

Category

Rehabilitation

2

Description

Control group: Control group:The intervention in the control group only included routine hospital training .One month after the operation, they received a pamphlet of training that was provided by the intervention group in response to a questionnaire on illness and health literacy.Perceived status of disease and health literacy, in two stages before surgery and one month after operation by SPSSv22 software, using chi-square, independent and paired t-test and analysis of covariance and variance. Was analyzed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital

Full name of responsible person

Fahimeh Reyhani

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Sponsors / Funding sources

1

Sponsor

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Grant name

Not used.

Grant code / Reference number

استفاده نشده است

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source

20

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Fahimeh Reyhani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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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
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after unidentifiable people.
When the data will become available and for how long
"Start of access period 6 months after printing results"
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
I will decide whether to use the data or documentation provided by me in relation to the type of study and the conditions of its use.I will agree with the caller at the same time.
From where data/document is obtainable
Fahimeh Reihani Contact Number: 09125627510
Fahimeh Reihani Email Address: fahima.reyhani8888@gmail.com
What processes are involved for a request to access data/document
Applicants can receive the data after one month by phone or e-mail.
Comments