Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of a healthy lifestyle empowerment program on improving health-related quality of life and adherence to health-promoting behaviors in two intervention and control groups of patients undergoing coronary artery bypass graft

Protocol summary

Study aim

Determination of the impact of a healthy lifestyle empowerment program on health-related quality of life and adherence to health-promoting behaviors in coronary artery bypass graft patients

Design

This randomized controlled trial was conducted on 97 undergoing CABG (49 in control group and 48 in intervention group) selected by classified block randomization

Settings and conduct

This study was conducted in Shahid Rajaie. The healthy lifestyle empowerment program (HELP) was implemented in four 45-60-minute training sessions held by the first researcher. The sessions were held in groups of three to five in the education office of male and female surgical wards and included face-to-face training with the the contents of the dimensions of health promoting behaviours including health responsibility, physical activity, nutrition, spiritual growth, interpersonal relations, and stress management. The post-discharge telephonic follow-ups were performed in the fourth and eighth weeks after discharge to repeated educational content and to answer participants` questions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- aged 45-65 years, 2-undergoing first-time CABG 3-full hearing and speech ability 4- lack of diagnosed mental illness as documented in the case file 5- willingness to participate in the study and giving written informed consent, and no sign of drug abuse
Exclusion criteria: 1- failure to participate in at least half of the training sessions 2- not completing questionnaires 3- death during the HELP or the data collection process 4- postoperative complication and readmission

Intervention groups

Patients undergoing coronary artery bypass graft

Main outcome variables

health-related quality of life adherence to health-promoting behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171213037860N1**
Registration date: **2020-03-01, 1398/12/11**
Registration timing: **retrospective**

Last update: **2020-03-01, 1398/12/11**
Update count: **0**

Registration date

2020-03-01, 1398/12/11

Registrant information

Name

Parvaneh Vasli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date
2019-01-21, 1397/11/01
Actual recruitment end date
2019-05-21, 1398/02/31
Trial completion date
2019-05-21, 1398/02/31

Scientific title
Comparison of the Effectiveness of a healthy lifestyle empowerment program on improving health-related quality of life and adherence to health-promoting behaviors in two intervention and control groups of patients undergoing coronary artery bypass graft

Public title
Effectiveness of a healthy lifestyle empowerment program on health-related quality of life and adherence to health-promoting behaviors in patients undergoing coronary artery bypass graft
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
aged 45-65 years, undergoing first-time CABG, full hearing and speech ability, lack of diagnosed mental illness as documented in the case file, willingness to participate in the study, giving written informed consent, no sign of drug abuse.
Exclusion criteria:
failure to participate in at least half of the training sessions not completing questionnaires death during the program or the data collection process, and postoperative complication and readmission. postoperative complication and readmission
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **86**
Actual sample size reached: **97**
Randomization (investigator's opinion)
Randomized
Randomization description
classified block randomization using coin toss
Blinding (investigator's opinion)
Single blinded
Blinding description
The study is a single-blind study. This means that the study participants were not aware of which study groups they were in.
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
ValiAsr Street
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Postal code
1985717443
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.SBMU.PHNM.1396.1008

Health conditions studied

1

Description of health condition studied
Atherosclerotic heart disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
health-related quality of life - adherence to health-promoting behaviors
Timepoint
Befor and 3 months after healthy lifestyle empowerment program
Method of measurement
Information about Health-related quality of life (HRQoL) was collected by the 12-item Short-Form Health Survey (SF-12) and information about adherence to HPBs was collected by the Persian version of Health-Promoting Lifestyle Profile II (HPLP-II)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients undergoing coronary artery bypass graft. The intervention for this group was the healthy lifestyle empowerment program (HELP). HELP as an intervention was implemented in four 45-60-minute training sessions held by the first researcher. The sessions were held in groups of three to five in the education office of male and female surgical wards and included face-to-face training and sharing of experiences among patients. The contents of the HELP gram were chosen based on the latest scientific literature, with the cooperation of cardiologists, psychologists, and nutrition and religious experts, and covered different dimensions of health promoting behaviors including health responsibility, physical activity, nutrition, spiritual growth, interpersonal relations, and stress management. The chosen contents were compiled into an educational booklet and a pamphlet. To reinforce the effect of the HELP, post-discharge telephonic follow-ups were performed in the fourth and eighth weeks after discharge. In these follow-ups, the contents of the HELP were briefly repeated and questions of the patients were answered.

Category

Lifestyle

2

Description

Control group: patients undergoing coronary artery bypass graft. The Participants of control group received routine discharge training, which recommends a low salt diet, 30-minute daily walk, and adherence to the medication regime prescribed by the physician.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular Hospital

Full name of responsible person

Parvaneh vasli

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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

Thesis grant

Grant code / Reference number

-

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvaneh vasli

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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
No - There is not a plan to make this available
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments
-