

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effects of application of Prochaska's stages of change model in education of coronary artery bypass grafting patients on quality of life, lipid profile & some psychological complications of CABG, Shiraz 2012

Protocol summary

Summary

Objective: the effect of application of Prochaska's stages of change model in education of coronary artery bypass grafting patients on quality of life, lipid profile & some psychological complications of CABG. Design: randomised clinical trial. Inclusion criteria: Has only CABG surgery; Exclusion criteria: History of CABG surgery; Has severe and life-threatening diseases alongside with coronary artery disease such as CVA and cancer. Method: the study population: post CABG patients attending selected Shiraz hospitals. Sample size: 80. Intervention: after introducing the study and complete the consent form by patients researcher gather the basic information includes: laboratory test (lipid profile) and questionnaires (demographic data, quality of life, anxiety and depression and stages of change) then the patients are divided into two control and experimental group by randomization. Education based on stages of change model of Prochaska was done for experimental group for 8 weeks. The control group only received routine programs. Two months after intervention laboratory test, quality of life, anxiety and depression, and stages of change of all the patients re-assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307162621N13**
Registration date: **2014-01-17, 1392/10/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-17, 1392/10/27

Registrant information

Name

Marzieh Moattari

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4250

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moattarm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-11-20, 1392/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of application of Prochaska's stages of change model in education of coronary artery bypass grafting patients on quality of life, lipid profile & some psychological complications of CABG, Shiraz 2012

Public title

The effect of education on coronary artery bypass grafting patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Has only CABG surgery; Residence in shiraz city or province; Access to telephone follow-up program by the researcher; Ability to read and write; Ability to understand the content based on the researcher,s judgment; Willing to participate in the study; Exclusion criteria: History of CABG surgery; Family members have expertise in medical sciences field; Have severe and life-threatening diseases alongside with coronary artery disease such as CVA and cancer; Have hearing problems; Have psychiatric or cognitive disorders.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science,Zand st.

City

Shiraz

Postal code

Approval date

2013-01-26, 1391/11/07

Ethics committee reference number

6428

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

Z95.1

ICD-10 code description

presence of aortocoronary bypass graft

Primary outcomes

1

Description

Quality of life

Timepoint

Before and 2 months after intervention

Method of measurement

Mac New questionnaire

2

Description

Anxiety and Depression

Timepoint

pre test and post test (2 months after intervention)

Method of measurement

Hospital Anxiety and Depression Scale

3

Description

Triglyceride

Timepoint

Before and 2 months after intervention

Method of measurement

mg\dl

4

Description

Stages of change of patients

Timepoint

Before and 2 months after intervention

Method of measurement

Stages of change allgoritm

5

Description

Cholesterol

Timepoint

Before and 2 months after intervention

Method of measurement

mg\dl

6

Description

Cholesterol / High Density Lipoprotein (HDL)

Timepoint

Before and 2 months after intervention

Method of measurement

7

Description

Low Density Lipoprotein (LDL) / High Density Lipoprotein (HDL)
Timepoint
Before and 2 months after intervention
Method of measurement

8

Description
Body Mass Index (BMI)
Timepoint
Before and 2 months after intervention
Method of measurement
Weight / (Height)²

9

Description
Smoking
Timepoint
Before and 2 months after intervention
Method of measurement
Demografic Form

Secondary outcomes

empty

Intervention groups

1

Description
Education based on stages of change model of Prochaska for intervention group took 8 weeks. These educations started immediately after discharge and continued in 2,4,6,8 weeks.
Category
Behavior

2

Description
Control group took routine educations.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Dr. Masih Shafa
Street address
Cardiac Surgery ICU, Namazi hospital, Namazi Square
City
Shiraz

2

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Dr. Masih Shafa
Street address
Cardiac Surgery ICU, Shahid Faghihi hospital, Zand street
City
Shiraz

3

Recruitment center
Name of recruitment center
Alzahra heart center
Full name of responsible person
Dr. Masih Shafa
Street address
Cardiac Surgery ICU, Alzahra heart center, Astaneh street
City
Shiraz

4

Recruitment center
Name of recruitment center
MRI hospital
Full name of responsible person
Dr. Masih Shafa
Street address
Cardiac Surgery ICU, MRI hospital, Chamran Blv.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Shiraz University of Medical Sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Marzieh Moattari
Position
PHD in Nursing, Faculty Member, Shiraz University of Medical Sciences
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty