Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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(demografic 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 recieved 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
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Iran (Islamic Republic of)
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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

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Marzieh Moattari

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Full name of responsible person

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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