Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of self-management program 5A model based on the quality of life of patients with acute coronary syndrome

Protocol summary

Summary

Objective: To determine the effect self-management program on quality of life of elderly patients with acute coronary syndrome. Study design: Randomized. Study population: elderly patients with acute coronary syndrome. Inclusion criteria: Pleased to be working; Age over 60 years; Acute coronary syndrome is diagnosed by a doctor confirmed; Speak Farsi or Persian language to understand; Not cognitive disorders; Mental illness or severe depression that does not need to be hospitalized; There is no impairment or disability; Not blind and deaf; No event or stressful event in the past 6 months; Are living Bojnurd. Exclusion criteria: Acute diseases such as stroke during the study; Heart disease during the study or any other symptoms resulting to be hospitalized of the elderly ; To participate in the meetings; The desire to withdraw from the study; Death; Sudden stressful life events at any stage the study. Sample size: 54 patients (27 patients per group); Case study: self-management program for the intervention group; Includes five steps: Assess ;Advise; Agree; Assist; Arrange. For the first four steps are two sessions a week and to Arrange; At first phone calls daily, after two weeks, twice a week and after a month once a week until the end of the intervention period. Intervention time: 2 months; The primary outcome: the impact on quality of life.

General information

Acronym

5A- Assess ;Advise; Agree; Assist; Arrange

IRCT registration information

IRCT registration number: **IRCT2016090629728N1**
Registration date: **2016-11-26, 1395/09/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-26, 1395/09/06

Registrant information

Name

Zahra Javanvash

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3231 9839

Email address

info@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2016-10-16, 1395/07/25

Expected recruitment end date

2016-12-15, 1395/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management program 5A model based on the quality of life of patients with acute coronary syndrome

Public title

The effect of self-management program on quality of life of elderly patients with acute coronary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pleased to be working; Age over 60 years; Acute coronary syndrome is diagnosed by a doctor confirmed; Speak Farsi or Persian language to understand (or be accompanied who is fluent in Farsi); Not cognitive disorders such as Alzheimer's and amnesia; Mental illness or severe depression that does not need to be hospitalized; There is no impairment or disability; Not blind and deaf; Ability to read or write is (or his retinue are literate); No event or stressful event in the past 6 months; Patients who live with their families; Are living Bojnurd exclusion criteria: Acute diseases such as stroke during the study; Heart disease during the study or any other symptoms (such as physical illness or severe depression) resulting to be hospitalized of the elderly ; To participate in the meetings; The desire to withdraw from the study; Death; Sudden stressful life events at any stage the study (death of loved -Financial problems - fire, etc).

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized allocation blocking

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee OF Sabzevar University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, University of Medical Sciences, next to the police, Sabzevar, Khorasan Razavi, Iran

City

Sabzevar

Postal code

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.MEDSAB.REC.1395.79

Health conditions studied

1

Description of health condition studied

acut coronary syndrom

ICD-10 code

I20.9-121.

ICD-10 code description

Subsequent myocardial infarction of other sites- Acute transmural myocardial infarction of other sites--Angina pectoris, unspecified Angina: NOS cardiac Anginal syndrome Ischaemic chest pain

Primary outcomes

1

Description

Quality of Life

Timepoint

Before and two months after intervention

Method of measurement

Quality of Life Questionnaire lipid

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group : self-management programs implemented in five stages; Assess stage: In this phase, using assessment form, patient risk factors, history of the patient's deterioration, heart problems, drugs, sleep, nutrition , activities and information on the records will be investigated through interviews or phone; Advise stage: At this stage, according to the results of the previous stage, abnormalities diagnosed, the patient

information reaches and benefits of behavior change are emphasized, Agree stage: between patients and researchers about the function of the patient's written agreement comes the action. Thus, according to a problem has been detected for each patient, good behavior and agreed objectives determined for each of the objectives, action plan design. For each behavioral objectives measure between 0 to 10 specific the patient's degree of confidence in the program set; Assist stage: Education, such as taking blood pressure, Pulse control, Glucose control, face-to-face and the patient is asked to do these exercises daily and record their performance; Arrange stage: The stage performance will be followed patients for two months.

Category

Behavior

2

Description

Control group : only the medical care provided by specialists use.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maryam Mojdekanloo

Street address

Imam Reza Hospital, Street Sayed Jamaluddin Asadabadi, Bojnurd, North Khorasan, Iran

City

Bojnurd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of Medical Sciences

Full name of responsible person

Musa al-Reza Tadayonfar

Street address

School of Nursing and Midwifery, Sabzevar University of Medical Sciences

City

Sabzevar

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Javanvash

Position

Elderly Nursing Graduate Student

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

MostfaRad

Position

PhD

Other areas of specialty/work

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Person responsible for updating data

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Web page address

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