

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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**

Sabzevar University of Medical Sciences, next to the police, Sabzevar, Razavi Khorasan , Iran

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+98 58 3231 9839

**Fax****Email**

javanvashZ93@medsab.ac.ir; javanvashz@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

MostfaRad

**Position**

PhD

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mostafarad633@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Zahra Javanvash

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Elderly Nursing Graduate Student

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**Fax****Email**

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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*