

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effect of Psychoeducational on mental health and quality of life in patients with coronary heart disease

#### Protocol summary

##### Summary

Aim of study is determine the effect of psychological education on mental health and quality of life in patients with coronary heart disease. This is a clinical trial study. Sample size is 70 patients with coronary heart disease that selected by sequence Sampling. In according to researchers selected eligible hospitalized patients with coronary artery disease who are admitted to the Emergency and CCU wards. Inclusion criteria of study are patients with: 1- Aged 21 to 65 years old; 2- Able to respond to inquiries and attending meetings; 3- No history of angioplasty and CABG (Coronary Artery Bypass Graft Surgery); 4- Any known problems including Alzheimer's brain, a stroke-transient cerebral attack. Exclusion criteria of study are patients with: 1- Acute and emergency medical and psychological conditions; 2- Unwillingness to continue participation in the intervention; 3- Migration of the patients. After explaining the objectives of study and informed consent data were collected using demographic information, Goldberg mental health (28 questions) and Mac New quality of life questionnaire. Then eligible patients randomized to intervention and control groups. For intervention group will be applied Psycho-educational intervention in 8 sessions, twice a week, ach section lasts 45 to 60 minutes. Control group will be received routing cares without psychological interventions. Sessions topics of Psycho-educational intervention were include: "How to coping anxiety with an emphasis on life skills, teaching of anger management, problem solving and communication skills, coping skills to depression and relaxation training". Outcomes: management of anger, anxiety, depression and establish proper communication behaviors in patients with coronary heart disease. After of intervention and one month groups will fill out questionnaires again.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060114086N4**  
Registration date: **2014-07-18, 1393/04/27**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-18, 1393/04/27

##### Registrant information

##### Name

Mohammad Aghajani

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 2001

##### Email address

aghajani\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2014-07-23, 1393/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of Psychoeducational on mental health and quality of life in patients with coronary heart disease

## Public title

Effect of Psychoeducational in patients with coronary heart disease

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: 1 - age between 21-65 years old. 2 - Patient is able to respond to inquiries and attending meetings. 3- No history of angioplasty and CABG (Coronary artery bypass graft). 4 - Having brain problems identified include Alzheimer's disease, stroke, and transient ischemic attack. 5 - Have writing and reading ability. Exclusion criteria: 1 - The existence of critical and emergency medical and psychological conditions. 2 - No desire to continue to participate in the intervention. 3 - Died or migrated patients.

## Age

From **21 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **70**

## 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

Kashan University of medical Science

##### Street address

Ghotbe Ravadi, Kashan

##### City

Kashan

##### Postal code

#### Approval date

2014-05-06, 1393/02/16

#### Ethics committee reference number

9327

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F53.0

#### ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

### 2

#### Description of health condition studied

Anxiety

#### ICD-10 code

F40

#### ICD-10 code description

Phobic anxiety disorders

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

One month later

#### Method of measurement

Health Questionnaire

### 2

#### Description

Anxiety

#### Timepoint

One month later

#### Method of measurement

Health Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: routine care of patients with coronary artery disease who are receiving.

#### Category

N/A

### 2

#### Description

Intervention group: psycho-educational intervention in a group of 8 sessions, 45 to 60 minutes, 2 times a week for two days of fall. Training sessions with at least 7 to 8 persons also are formed with repeated training sessions

in the days and hours of participation in all patients at the meetings is provided. Sessions include training on psychological problems such skills to deal with anxiety, with an emphasis on lifestyle skills anger management training, problem solving skills, coping skills, depression, relaxation training are

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Martyr Beheshti Hospital

**Full name of responsible person**

Bashiri Zahra

**Street address**

School of Nursing and Midwifery, Km 3 pole  
Ravandi,Kashan

**City**

Kashan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Gholam Ali Hamidi

**Street address**

Ghotbe Ravandi, Kashan

**City**

Kashan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Muhammad Aqhajani

**Position**

Masters

**Other areas of specialty/work****Street address**

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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*