

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

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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