

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial comparing the effectiveness of empowerment program on the perception of risk and health dimensions in two groups of patients with coronary heart disease

Protocol summary

Study aim

the investigate effect of empowerment program on perception of risk and health dimensions in patients with coronary heart disease

Design

clinical trial, randomized, available sample and Block Balanced Randomization (BBR) method

Settings and conduct

The present study is carried out in the Post CCU offices of Tehran Heart Center. Assignment of patients in two groups of test and control was done by Block Balanced Randomization method. The Randomization Sequence was generated with using the free web site at <http://www.randomization.com>. By obtaining a written consent indicating voluntary participation and prior to commencement of intervention, demographic and disease questionnaire and perception of risk and health dimensions questionnaire is completed by two groups. Intervention contains 3 workshop sessions in three consecutive days based on a 5-step MAGIC empowerment program is developed. Then, eight weekly telephone contacts in the 8 weeks to follow up are performed after the patient discharge of hospital. Control group receives routine cares of the ward. Then, at the end of intervention, the perception of risk and health dimensions questionnaire is completed by the patient in two groups. MAGIC empowerment program contains five steps: Motivating patient self-awareness, Assessing the causes of problems, Goal setting, Individual self-care plan development, and Checking whether the goal was reached.

Participants/Inclusion and exclusion criteria

Patients with age of 18 to 65 years and ability of read and write can participate in study and they are omitted from the study upon appearance the acute phase of illness and patient death.

Intervention groups

patients with coronary heart disease

Main outcome variables

empowerment program

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201607254443N22**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **prospective**

Last update: **2018-01-01, 1396/10/11**

Update count: **1**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 2160

Email address

zakerimo@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputyof Tehran University of Medical Science

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effectiveness of empowerment program on the perception of risk and health dimensions in two groups of patients with coronary heart disease

Public title

Effect of empowerment program on the perception of risk and health dimensions in patients with coronary heart disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

adult 18-65 years; least ability to read and write; diagnosis of ischemic heart disease through diagnostic tests and physician; Ability to communicate; being in stable condition.

Exclusion criteria:

psychological problems; participate in the empowerment of similar.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in two groups of test and control was done by Block Balanced Randomization (BBR) method. The Randomization Sequence was generated with using the free web site at <http://www.randomization.com>.

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**

Tehran University of Medical Sciences

Street address

Ghods street, Keshvarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-06-19, 1396/03/29

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2691

Health conditions studied**1****Description of health condition studied**

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes**1****Description**

perception of risk

Timepoint

Before the the intervention, immediately after ending the intervention

Method of measurement

the perception of risk of heart disease scale(PRHDS)

2**Description**

physical health

Timepoint

Before the the intervention, immediately after ending the intervention

Method of measurement

Seattle Angina Questionnaire(SAQ)

3**Description**

life satisfaction

Timepoint

Before the the intervention, immediately after ending the intervention

Method of measurement

Life Engagement Test(LET)

4

Description

life orientation

Timepoint

Before the the intervention, immediately after ending the intervention

Method of measurement

Revised Life Orientation Test(LOT-R)

5

Description

optimism

Timepoint

Before the the intervention, immediately after ending the intervention

Method of measurement

Revised Life Orientation Test(LOT-R)

Secondary outcomes

empty

Intervention groups

1

Description

In control group no intervention is conducted by researcher and patients receive routine cares of the ward.

Category

Other

2

Description

In test group, intervention contains 3 workshop sessions in three consecutive days based on a 5-step MAGIC empowerment program is developed. Then, eight weekly telephone contacts in the 8 weeks to follow up are performed after the patient discharge of hospital. MAGIC empowerment program contains five steps: Motivating patient self-awareness, Assessing the causes of problems, Goal setting, Individual self-care plan development, and Checking whether the goal was reached.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tehran Heart Center hospital

Full name of responsible person

Zakerimoghdam masoumeh

Street address

North Kargar Street, Tehran Province, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Email

mzakerimo@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research of Tehran university of medical sciences

Full name of responsible person

Zakerimoghdam Masoumeh

Street address

Eastern Nosrat street, Tohid square

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1417653761

Phone

+98 21 8163 3698

Email

mzakerimo@gmail.com

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 of Tehran university of medical sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Nursing midwifery faculty of Tehran university of medical sciences

Full name of responsible person

Zakerimoghdam Masoumeh

Position

Nursing education PHD, Faculty member

Latest degree

Ph.D.

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

Eastern Nosrat street, Tohid square

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Tehran

Province

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Postal code

1419733171

Phone

+98 21 6692 7171

Fax**Email**

zakerimo@sina.tums.ac.ir

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

Nursing midwifery faculty of Tehran university of medical Sciences

Full name of responsible person

Zakerimoghdam Masoumeh

Position

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available