

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of cognitive behavioral intervention on mental health situation in Myocardial Infarction patients.

Protocol summary

Summary

This clinical trial will be done on thirty Myocardial Infarction patient referring Darrehshahr Hospital. They will be divided in two control and intervention groups with pretest and post test. Eligible participants randomly divided in two groups: intervention group (n=15) and control one (n=15). At the beginning of study after getting written consent for each person the demographic characteristics and GHQ questionnaire will be completed. After random allocation, for the intervention group eight cognitive behavioral intervention session hold by the researcher. The first session one month after Myocardial Infarction, and next sessions once a week consisting 60 minutes in hospitals clinic. There is no intervention in control group. One week after finishing the sessions, GHQ questionnaire will be completed by both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111913568N2**

Registration date: **2014-02-23, 1392/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-23, 1392/12/04

Registrant information

Name

Rostam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3724 6613

Email address

rjalali@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-02-04, 1392/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive behavioral intervention on mental health situation in Myocardial Infarction patients.

Public title

The effect of cognitive behavioral intervention on mental health in Myocardial Infarction patients.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having an experience of an myocardial infarction; and age range between 35-65 years; education high school or higher degrees; completing written informed consent. Exclusion criteria: not interesting for continuing; having a remarkable mental disorder; patients death.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

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

Kermanshah University of Medical Science

Street address

Shahid Beheshti Blvd

City

kermanshah

Postal code

Approval date

2013-11-09, 1392/08/18

Ethics committee reference number

33917

Health conditions studied

1

Description of health condition studied

Myocardial Infarction Disease

ICD-10 code

I21

ICD-10 code description

Acute Myocardial Infarction

Primary outcomes

1

Description

Mental Health

Timepoint

Before and one month after intervention.

Method of measurement

GHQ-28 questionnaire.

Secondary outcomes

1

Description

Physical Health

Timepoint

Before and one month after intervention.

Method of measurement

GHQ-28 questionnaire.

2

Description

Anxiety

Timepoint

Before and one month after intervention.

Method of measurement

GHQ-28 Questionnaire.

3

Description

Depression

Timepoint

Before and one month after intervention.

Method of measurement

GHQ-28 Questionnaire.

Intervention groups

1

Description

There is no intervention in control group but they received ordinary treatment.

Category

Rehabilitation

2

Description

In this study, the researcher hold eight cognitive behavioral intervention session(once a week lasting 60 minutes)for the intervention group. The first session once a month after Myocardial Infarction and the next sessions are held once a week in a 7 weeks duration.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Assr Hospital, Darrehshahr, Ilam

Full name of responsible person

Fateme Ghiasi

Street address

Opposite Vali Assr Hospital, Shahid Jafari street, Darrehshahr, Ilam

City

Darrehshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr farid najafi

Street address

Vice Research and Technology Affair, No 2 Building,
Shahid Beheshti Blvd,

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Nurse

Other areas of specialty/work

Street address

Opposite Vali Assr Hospital, Shahid Jafari Street,
Darrehshahr, Ilam

City

Darrehshahr

Postal code

69641-54565

Phone

+98 84 2546 3259

Fax

Email

ghiasifateme@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Nurse

Other areas of specialty/work

Street address

Opposite Vali Assr Hospital, Shahid Jafari Street,
Darrehshahr, Ilam

City

Darrehshahr

Postal code

69641-54565

Phone

+98 84 2546 3259

Fax

Email

ghiasifateme@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Nurse

Other areas of specialty/work

Street address

Opposite Vali Assr Hospital, Shahid Jafari Street,
Darrehshahr, Ilam

City

Darrehshahr

Postal code

6964154565

Phone

+98 84 2546 3259

Fax

Email

ghiasifateme@ymail.com

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