

# 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**

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**Position**

Nurse

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Kermanshah University of Medical Sciences

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**Position**

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**Other areas of specialty/work**

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**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*