

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect Of Spiritual Care On Post Traumatic Stress Disorder Following Acute Myocardial Infarction

#### Protocol summary

##### Study aim

Determining the mean score of post traumatic stress in patients in the intervention group. Determining the mean score of post traumatic stress in patients in the control group. Comparison of mean score of post traumatic stress disorder in the control and intervention group.

##### Design

This is a clinical trial with control group in which 80 patients with acute myocardial infarction, who have inclusion criteria, will be selected, and they are divided into two groups by block method.

##### Settings and conduct

This study will be conducted in the coronary care unit of Amir Kabir Hospital in Arak. Spiritual care is provided by the nurses who have received adequate training in this regard.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient has an acute myocardial infarction; according to a cardiologist's diagnosis; Being alert; Speaking in Persian; Being Muslim; Have no known mental illness; Have no mental retardation. Exit criteria: Unwillingness to continue the study; Occurrence of a new heart attack; Occurrence of any severe complications of myocardial infarction (cardiogenic shock and severe heart failure); The necessity of using a pacemaker and implantable cardioverter defibrillator; ;Performing a coronary artery bypass graft surgery; Patient death; Displacement of the patient's place of residence.

##### Intervention groups

For patients in the intervention group, the spiritual care program includes three sessions. Each session is held for half an hour and three consecutive days. For patients in the control group, the usual care is performed.

##### Main outcome variables

The post traumatic stress disorder checklist is a commonly used tool for investigating the incidence of post traumatic stress disorder.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180903040935N1**

Registration date: **2018-11-25, 1397/09/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-25, 1397/09/04**

Update count: **0**

##### Registration date

2018-11-25, 1397/09/04

##### Registrant information

##### Name

Zohreh Ababaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3503

##### Email address

mozo16883@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-01-21, 1397/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect Of Spiritual Care On Post Traumatic Stress Disorder Following Acute Myocardial Infarction

#### Public title

The Effect Of Spiritual Care On Post Traumatic Stress Disorder

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The patient has an acute myocardial infarction, according to a cardiologist's diagnosis. Being alert. Speaking in Persian. Being Muslim. Have no known mental illness. Have no mental retardation.

##### Exclusion criteria:

Unwillingness to continue the study. Occurrence of a new heart attack. Occurrence of any severe complications of myocardial infarction (cardiogenic shock and severe heart failure). The necessity of using a pacemaker and implantable cardioverter defibrillator. Performing a coronary artery bypass graft surgery. Patient death. Displacement of the patient's place of residence.

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 80

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients will be selected according to inclusion and exclusion criteria and will be randomly divided into intervention and control groups by blocked randomization using computer software.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Factorial

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Vice-Chancellor for Research, Arak University of

Medical Sciences, Basij Square, Sardasht, Arak

#### City

Arak

#### Province

Markazi

#### Postal code

3819693345

#### Approval date

2018-09-23, 1397/07/01

#### Ethics committee reference number

1397.156

## Health conditions studied

### 1

#### Description of health condition studied

Acute Myocardial Infarction

#### ICD-10 code

I21

#### ICD-10 code description

I21.0, I21.1, I21.2, I21.3, I21.4, I21.9

## Primary outcomes

### 1

#### Description

Score of post traumatic stress disorder.

#### Timepoint

One month after the start of the study.

#### Method of measurement

Post Traumatic Stress Disorder Checklist.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The participants of the intervention group undergo spiritual need-based program. This program consisted of a 30 minute session per day for 3 consecutive days. The first session focuses on reducing concerns about the future by explaining Truth. In the second session, promotion of self-esteem is considered by explaining self-esteem and eliminating its conflicts. At the third session, emphasis is placed on reducing feelings of guilt and attaining calm. one month later, Post Traumatic Stress Disorder Checklist (PCL) will be completed by patients.

#### Category

Prevention

### 2

#### Description

Control group: Patients in the control group receive routine care. one month later, Post Traumatic Stress

Disorder Checklist (PCL) will be completed by patients.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Amirkabir hospital

**Full name of responsible person**

Zohreh Ababaei

**Street address**

Alamoll Huda Street

**City**

Arak

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**Postal code**

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**Email**

it@arakmu.ac.ir

**Web page address**

<https://amirkabirhos.arakmu.ac.ir/Portal/Home/Default.aspx>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Arjomandzadegan

**Street address**

Basij Square, Arak University of Medical Sciences

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**Province**

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6941738481

**Phone**

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**Email**

Research@arakmu.ac.ir

**Web page address**

<https://oldvcr.arakmu.ac.ir/Portal/home>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Zohreh Ababaei

**Position**

Master,s student critical care nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Nursing school, Payambar Azam Complex, Basij Square, Sardasht Arak

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**Email**

mozo16883@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Korosh Rezaei

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Zohreh Ababaei

**Position**

Bachelor of Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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mozo16883@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Demographic characteristics and post traumatic stress score.

**When the data will become available and for how long**

Start the access period 6 months after the publication of the results.

**To whom data/document is available**

All individuals can access the information.

**Under which criteria data/document could be used**

Nothing.

**From where data/document is obtainable**

Korosh Rezaei; k.rezaei@arakmu.ac.ir; Arak University of Medical Sciences; 00989183677622.

**What processes are involved for a request to access data/document**

Two weeks after the applicant's request.

**Comments**