

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of spiritual care based on healthy Sound Heart Model on post traumatic stress disorder and anxiety of family caregivers of patients with myocardial infarction.

Protocol summary

Study aim

The effect of spiritual care based on a healthy heart pattern on post-traumatic stress disorder and anxiety of family caregivers with myocardial infarction.

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 80 patients. Blocking method and Randomization.com online software were used for randomization.

Settings and conduct

In this study, 80 companions of patients with acute myocardial infarction hospitalized in Arak hospitals will be included in the study. After randomization, post-traumatic stress and anxiety of patients' companions will be evaluated and in the intervention group will be under spiritual care for 4 days and the control group will be under routine hospital care. The patients' companions will then be re-evaluated after one month. Blinding is not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First-degree relatives of patients with acute myocardial infarction, aged 18 to 70 years.

Exclusion criteria: suffering from psychiatric illnesses, suffering from chronic and debilitating illnesses.

Intervention groups

Family caregivers of the intervention group receive face-to-face and individual spiritual care of the healthy heart face-to-face and individually by the trained researcher in all sessions on all days of hospitalization for 8 sessions for 10 to 20 minutes. . In the control group, patients receive routine hospital care. For example, when they have questions, their questions will be answered and an educational pamphlet will be provided to them.

Main outcome variables

Post traumatic stress disorder, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044255N5**

Registration date: **2022-04-20, 1401/01/31**

Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**

Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Ali Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3276 7500

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care based on healthy Sound Heart Model on post traumatic stress disorder and anxiety of family caregivers of patients with myocardial infarction.

Public title

The effect of spiritual care on post-traumatic stress

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

First-degree relatives of the patient who was with the patient during the first 6 hours of the heart attack Age 18 to 70 years

Exclusion criteria:

Having psychiatric illnesses Chronic and debilitating diseases

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 patients with inclusion criteria will be divided into two groups of intervention and control using block randomization method in 10 blocks of 8 using online blocking software Randomization.com. Concealment in this study will be sealed using the envelope method. In this way, a number of envelopes with aluminum wrappers are prepared and each of the random sequences created is registered on a card and the cards are placed inside the envelopes. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, one of the envelopes of the letter is opened in order and the assigned group of that participant is revealed.

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.ARAKMU.REC.1400.351

Health conditions studied

1

Description of health condition studied

Post Traumatic Stress Disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Depression Anxiety Stress Scale

2

Description

Post traumatic Stress Disorder

Timepoint

Before the intervention and one month after the intervention

Method of measurement

The Post traumatic Stress Disorder Checklist for Diagnostic and Statistical Manual of Mental Disorders-5

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 40 patient's companions receive routine hospital care as a control group. For example, when they have questions, their questions will be answered and educational pamphlets will be provided to them.

Category

Behavior

2

Description

Intervention group: 40 patients as an intervention group on all days of hospitalization and during 8 sessions for 10 to 20 minutes and during 4 days (two sessions per day, one morning session and one evening session), receive spiritual care based on the healthy Sound Heart model, face to face and individually, by a trained researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Rezvan Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Rezvan Mirzaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

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Arak

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