

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Cardiac Pain Management and Cardiopulmonary Resuscitation Trainings on Self-control, Depression and Anxiety in the Spouses of the Patients with Myocardial Infraction Admitted to the Hospitals Affiliated to Shiraz University of Medical Sciences

Protocol summary

Summary

Goal of the study: to investigate the effect of cardiac pain management and cardiopulmonary resuscitation trainings on self-control, depression, stress and anxiety in the spouses of the patients suffering from myocardial infraction who admitted to Coronary Care Units of the hospitals affiliated to Shiraz University of Medical Sciences. Design: This is an interventional study. Sampling methods: participants (N=84) were randomly assigned into case and control groups (two groups of 42 each). Setting and conduct: after obtaining informed consent, Depression, Anxiety and Stress Scale and Rotter's Internal-External Locus of Control Scale were completed by participants before the intervention. Inclusion criteria: included ability to understand the information presented (which is confirmed by researcher) and not participating in similar training programs simultaneously or since 6 months before the study. Exclusion criteria: included unwillingness to participate in the study and any debilitating psychiatric diseases such as psychosis. Intervention: the participants in the case group attended workshops including theoretical and cardiopulmonary resuscitation practical trainings. One month later, the researcher met the participants of the case group at their home, reviewed the trainings and answered all their questions regarding the trainings they received. The questionnaires were completed again by the participants of the case group immediately after and one month after the intervention; while the participants of the control group completed them only one month after the intervention. The study lasts for five months in both groups. Primary outcome measures included: self-control, depression, stress and anxiety in the spouses of the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310128124N2**

Registration date: **2014-07-03, 1393/04/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-03, 1393/04/12

Registrant information

Name

Zahra Molazem

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

molazem@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Cardiac Pain Management and Cardiopulmonary Resuscitation Trainings on Self-control, Depression and Anxiety in the Spouses of the Patients with Myocardial Infraction Admitted to the Hospitals Affiliated to Shiraz University of Medical Sciences

Public title
The Effect of Cardiac Pain Management and Cardiopulmonary Resuscitation Trainings on Self-control, Depression and Anxiety in the Spouses of the Patients with Myocardial Infraction Admitted to the Hospitals Affiliated to Shiraz University of Medical Sciences

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria included ability to understand the information presented (which is confirmed by researcher) and not participating in similar training programs simultaneously or since 6 months before the study.
Exclusion criteria included unwillingness to participate in the study and any debilitating psychiatric diseases such as psychosis

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

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
Ethics Committee of Shiraz University of Medical Sciences
Street address

Central building of Shiraz University of Medical Sciences Shiraz, Zand Blvd.

City
Shiraz

Postal code

Approval date
2013-08-19, 1392/05/28

Ethics committee reference number
CT-92-6680

Health conditions studied

1

Description of health condition studied

Decreased self-control

ICD-10 code

F60.3

ICD-10 code description

Emotionally unstable personality disorder

2

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

3

Description of health condition studied

Anxiety and Depression

ICD-10 code

F41.2

ICD-10 code description

Mixed anxiety and depressive disorder

Primary outcomes

1

Description

Stress

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

Depression, Anxiety and Stress Scale

2

Description

Anxiety

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

Depression, Anxiety and Stress Scale

3

Description

Depression

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

Depression, Anxiety and Stress Scale

4

Description

Self-control

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

Rotter's Internal-External Locus of Control Scale

Secondary outcomes

empty

Intervention groups

1

Description

The intervention included holding workshops comprising theoretical and individual cardiopulmonary resuscitation practical trainings for the participants of the case group, telephone follow-ups and visiting the patients at their home.

Category

Prevention

2

Description

Without any intervention on the control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Heart Hospital

Full name of responsible person

Azam Zare

Street address

Sibooyeh Blvd., Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Ms.Hosseini

Street address

Zand st., Shiraz

City

Shiraz

3

Recruitment center

Name of recruitment center

Nemazee Hospital

Full name of responsible person

Ms. Gholami

Street address

Nemazee Square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Full name of responsible person

Dr. Basir Hashemi

Street address

Central building of Shiraz University of Medical Sciences, Zand st.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Molazem

Position

Ph.D

Other areas of specialty/work

Street address

Fatemeh Collage of Nursing and Midwifery (P.B.U.H),
Nemazee square

City

Shiraz

Postal code

Phone

+98 71 1647 4254

Fax

Email

molazem@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Molazem

Position

Ph.D

Other areas of specialty/work

Street address

Fatemeh Collage of Nursing and Midwifery (P.B.U.H),
Nemazee square

City

Shiraz

Postal code

Phone

+98 71 1647 4254

Fax

Email

molazem@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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Zahra Molazem

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molazem@sums.ac.ir

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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