

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of spiritual care versus control group on anxiety level, blood pressure, and spiritual health of patients hospitalized in the cardiac care unit: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of spiritual care versus control group on anxiety level, blood pressure, and spiritual health of patients hospitalized in the cardiac care unit

##### Design

This is a randomized clinical trial with control group, phase III, in which eligible patients hospitalized in the cardiac care unit will be randomly assigned through the block randomization to the intervention and control groups. Blinding is not possible in this study.

##### Settings and conduct

This study will be performed in the Farshchian Heart Hospital in Hamadan city on 80 eligible patients hospitalized in the cardiac care unit. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Hospitalization of the patient in the cardiac intensive care unit Being a Muslim Being literate Exclusion criteria: Mental or cognitive disorder Visual or hearing impairment

##### Intervention groups

Intervention group: Routine treatment of the coronary care unit plus spiritual care daily for 45 to 60 minutes for 4 sessions Control group: Routine treatment of the coronary care unit

##### Main outcome variables

Primary outcome: The level of anxiety Secondary outcome: Blood pressure, spiritual health

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N470**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

##### Registration date

2023-04-17, 1402/01/28

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-10-22, 1402/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of spiritual care versus control group on anxiety level, blood pressure, and spiritual health of patients

hospitalized in the cardiac care unit: a randomized clinical trial

#### Public title

Effect of spiritual care versus control group on anxiety level, blood pressure, and spiritual health of patients hospitalized in the cardiac care unit

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 18 to 70 years Hospitalization of the patient in the cardiac intensive care unit Being a Muslim Being literate

##### Exclusion criteria:

Mental or cognitive disorder Visual or hearing impairment

#### 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

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

#### 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 Hamadan University of Medical Sciences

###### Street address

Vice-chancellor for Research and Technology,

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2023-01-21, 1401/11/01

#### Ethics committee reference number

IR.UMSHA.REC.1401.898

### Health conditions studied

#### 1

##### 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

The level of anxiety

##### Timepoint

Before the intervention and immediately after the end of the intervention

##### Method of measurement

Using the Spielberger questionnaire

### Secondary outcomes

#### 1

##### Description

Systolic and diastolic blood pressure

##### Timepoint

Before the intervention and immediately after the intervention

##### Method of measurement

Using a sphygmomanometer

#### 2

##### Description

Spiritual health

##### Timepoint

Before the intervention and one month after the intervention

##### Method of measurement

Using Paloutzian and Ellison Spiritual Health questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Routine treatment of the coronary care unit plus spiritual care daily for 45 to 60 minutes for 4 sessions (including history and discovery of the patient's spiritual needs such as prayer, asking for help, expressing frustration, silence, crying and staying away from others, reading Qur'an, discussion about the role of prayer in individual relaxation, using relaxation techniques such as praying, encouraging patients to seek help from God, meeting the basic needs of patients such as reducing pain, nutrition, sleep, breathing, avoiding and controlling pain, strengthening positive thinking in the patient, listening to the pain of the patient's heart, strengthening and increasing the patient's adaptation)

#### Category

Other

### 2

#### Description

Control group: Routine treatment of the coronary care unit

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshchian Heart Hospital in Hamadan city

##### Full name of responsible person

Zahra Rostami

##### Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 1740

##### Email

zahrarostami13771377@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Reza Shokoohi

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Zahra Rostami

##### Position

Nursing Student

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

zahrarostami13771377@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Azim Azizi

**Position**

PhD in Nursery

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

a.azizi@umsha.ac.ir

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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

**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology