Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Zahra Rostami
Position
Nursing Student
Latest degree
Master
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Person responsible for updating data

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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