Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effects of Spiritual and Religious Need-based Interventions on Spiritual Well-being and Anxiety in Elderly People Hospitalized in Cardiac Intensive Care Unit of Imam Reza hospital in Lar City

Protocol summary

Summary

This study is an interventional study with a pre-test and post-test control group design. Goal of the study: to determine the effects of spiritual and religious need-based interventions on spiritual well-being and anxiety in elderly people hospitalized in Cardiac Intensive Care Unit of Imam Reza hospital in Lar city. Sampling methods: Sample size is determined as 66 and participants are randomly assigned into case and control groups (two groups of 33 each). After obtaining informed consent, Spiritual Health and State-Trait Anxiety Inventories are completed by participants at the beginning of hospitalization and stabilizing the patients. Inclusion criteria included age over 60, confirmed diagnosis of any type of heart diseases, willingness to participate in the study, lack of cognitive or psychological disorders; while exclusion criteria included undergoing other interventions or complementary therapies (such as meditation and yoga) during hospitalization, consuming antidepressants and anti-anxiety medications during the study, deterioration of the patient's condition, repeated myocardial infarction, patients' severe psychological conflicts due to religious and spiritual interventions and hospital stay of less than three days. The older adults in the case group undergo spiritual and religious need-based interventions consisted of a 60-90 minute session per day for 3 consecutive days. The inventories are completed once again by the participants of the control group after discharge and those of the case group after the intervention. The study is lasted for a four- month period in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052615426N2**

Registration date: **2014-06-02, 1393/03/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-02, 1393/03/12

Registrant information

Name

Maryam Hazrati

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Expected recruitment start date

2014-05-26, 1393/03/05

Expected recruitment end date

2014-09-27, 1393/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Spiritual and Religious Need-based

Interventions on Spiritual Well-being and Anxiety in Elderly People Hospitalized in Cardiac Intensive Care Unit of Imam Reza hospital in Lar City

Public title
The Effects of Spiritual and Religious Need-based Interventions on Spiritual Well-being and Anxiety in Elderly People Hospitalized in Cardiac Intensive Care Unit of Imam Reza hospital in Lar City
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age over 60 years old; confirmed diagnosis of any type of heart diseases; willingness to participate in the study; lack of cognitive or psychological disorders. Exclusion criteria: undergoing other interventions or complementary therapies (such as meditation and yoga) during hospitalization; consuming antidepressants and anti-anxiety medications during the study; deterioration of the patient's condition; repeated myocardial infarction; patients' severe psychological conflicts due to religious and spiritual interventions and hospital stay of less than three days.
Age
From **60 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
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
Zand Blvd, Central building of Shiraz University of Medical Sciences
City
Shiraz
Postal code
Approval date
2014-05-25, 1393/03/04
Ethics committee reference number
CT-9373-7023

Health conditions studied

1

Description of health condition studied
Anxiey
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Reducing anxiety
Timepoint
At the time of hospitalization (after patient's stabilization) and at the time of discharge
Method of measurement
Spielberger's State-Trait Anxiety Inventory

2

Description
Increasing spiritual well-being
Timepoint
At the time of hospitalization (after patient's stabilization) and at the time of discharge
Method of measurement
Spiritual Health Inventory (Paloutizan & Ellison)

Secondary outcomes

empty

Intervention groups

1

Description
The participants of the case group undergo spiritual and religious need-based interventions consisted of a 60-90 minute session per day for 3 consecutive days. The interventions include attending to the patient with full consideration for 30 minutes, giving hope to the patient, talking with him/her about spiritual experiences, encouraging the sense of generosity, strengthening the relationships with family and important people in his/her life, providing opportunities for worship and prayer, giving the patient small booklets made by researcher including precious words of religious elders and world's scientists about hope, generosity and forgiveness, hanging pictures of natural and relaxing landscapes on the walls of the wards, giving the patient Holy Quran and

prayer books, providing Walkman for listening to fine music, prayers and Quran verses and facilitating the patient's visits with family members and friends.

Category

Prevention

2

Description

Without any intervention on the control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Lar City

Full name of responsible person

Maryam Mahmoudi Rad, Head Nurse of CICU

Street address

Dadman Highway, Imam Reza Hospital, Lar

City

Lar

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

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs, Zand Ave.

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

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

Full name of responsible person

Elham Hedayati

Position

MS candidate of Geriatric Nursing

Other areas of specialty/work

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Full name of responsible person

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Position

Candidate of PhD Institute of Gerontology UPM Universities of Putra Malaysia

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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