

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of spiritual care program on caring burden and fatigue in home caregivers of Cardiovascular patients

Protocol summary

Study aim

In this study, the caregivers of cardiovascular patients living in Yazd city will be considered as the research community in 1402 and 1403. Out of these, in addition to the conventional treatment method, the test group will be subjected to spiritual care intervention designed based on the spiritual model of Bergin & Richards, by the researchers. The questionnaires of this research include Novak and Ghassest's Care Burden Questionnaire (1989) and Smets' Multidimensional Fatigue Measurement Questionnaire (MFI) (1996),

Design

A community-based, practice-oriented clinical trial with an unblinded parallel group

Settings and conduct

Before the intervention, demographic information will be obtained by completing the researcher-made demographic questionnaire. Effect of educational intervention in the form of an educational clip that can be used on a mobile phone. The data collection will be done in two stages before the intervention and after the intervention

Participants/Inclusion and exclusion criteria

Entry criteria for caregivers 1. One person from each family and must be a first degree relative 2. Caring most hours of the day and most days of the week 5. Not suffering from mental disorders confirmed by a doctor 8. Not suffering from known vision and hearing diseases 9. Getting a score between 20-40 from the spiritual health questionnaire. Exclusion criteria of caregivers 2. Suffering from known vision and hearing diseases 3. Mental disorders confirmed by a doctor

Intervention groups

All participants will receive information on self-care for heart attack patients. In addition to these trainings, the test group will be subjected to spiritual care intervention by researchers. In this research, the educational booklet of spiritual care, which is designed based on the spiritual model of Bergins and Richard, will be used.

Main outcome variables

effect of spiritual care on caregiving burden ,fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240117060718N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3245 2321

Email address

maryas873@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-18, 1402/11/29

Expected recruitment end date

2025-02-17, 1403/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spiritual care program on caring burden and fatigue in home caregivers of Cardiovascular patients

Public title

the effect of spiritual care program on caring burden and fatigue

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1. One person from each family and must be a first degree relative. 2. Care most hours of the day and most days of the week (main caregiver). Having Islam and Shia religion . Physical and mental preparation of the patient to answer the questions Minimum reading and writing literacy Ability to speak Persian Getting a score between 20-40 from the spiritual health questionnaire

Exclusion criteria:

Suffering from debilitating diseases Suffering from known vision and hearing diseases 3. Mental disorders confirmed by a doctor

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by available sampling method. Each participant who enters the study will be given a code. People will be randomly assigned to test and control groups using random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

در این پژوهش جزوه آموزشی مراقبت معنوی که بر اساس الگوی معنوی برگینز و ریچارد طراحی شده است، مورد استفاده قرار خواهد گرفت

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

NO.8975111909. Sahebazzaman Avn .Mobarake village .Bafgh Town.YAZD

City

Bafgh

Province

Yazd

Postal code

8975111909

Approval date

2023-07-14, 1402/04/23

Ethics committee reference number

IR.SSU.REC.1402.028

Health conditions studied**1****Description of health condition studied**

The effect of caregiving on fatigue and caregiving burden

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fatigue and care burden

Timepoint

From February 2024 to February 2025

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Home caregivers of cardiac patients

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bafgh Valiasr hospital

Full name of responsible person

Tahereh Askari

Street address
Valiasr Avn Valiasr Hospital Bafgh Yazd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mostafa Javadi
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Web page address
http://ssu.ac.ir

Grant name

1402

Grant code / Reference number

1402

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

20

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

Yazd University of Medical Sciences
Full name of responsible person
Maryam KESHAVARZ
Position
Special care nursing master's student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Other areas of specialty/work

Anesthesiology

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying
individuals

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

The data is accessible to researchers working in
academic and scientific institutions and people working
in industry

Under which criteria data/document could be used

The use of data is allowed for all research, educational
and scientific work, and there is no restriction in terms of
data analysis

From where data/document is obtainable

Maryam Keshavarz, a master's student in intensive care
nursing 0098917172041255 maryas873@gmail.com

What processes are involved for a request to access data/document

Contact via email and contact number The response time
is 2 working days

Comments