

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

"The effect of spiritual care intervention on anxiety and self-efficacy of family caregivers of patients after coronary artery bypass graft surgery"

Protocol summary

Study aim

The effect of spiritual care intervention on anxiety and self-efficacy of family caregivers of patients after coronary artery bypass graft surgery

Design

A randomized open-label parallel control group clinical trial on 70 individuals. The SPSS random number table was used for randomization.

Settings and conduct

The qualified participants are divided into two groups of control and test based on the one-week time block. The control group receives only routine training and the test group receives spiritual care educational intervention in 6 sessions for 45-60 minutes daily.

Participants/Inclusion and exclusion criteria

Family caregivers of patients undergoing coronary artery bypass graft surgery; Inclusion criteria include: Be the first family members, At least have a primary education, Be 18 years old, Understand and speak Persian language, Have Interest and desire to participate in the study; And exclusion criteria such as: Have a history of use psychotropic drugs in the past 2 months, Having a history of stress-related accidents in the last 6 months, Taking care of another person at the same time, Having visual and hearing problems, Activity in medical professions, History of receiving training in the field of anxiety and self-efficacy

Intervention groups

Intervention group: Implementing a spiritual care education package and providing an educational booklet to caregivers; Control group: Routine training

Main outcome variables

"Anxiety" and "Self-efficacy" score based on "Beck Anxiety" and "General self-efficacy" questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211026052881N1**

Registration date: **2022-02-13, 1400/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-13, 1400/11/24**

Update count: **0**

Registration date

2022-02-13, 1400/11/24

Registrant information

Name

Sahar Fakhraei azad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4723 9452

Email address

fakhraeias961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"The effect of spiritual care intervention on anxiety and self-efficacy of family caregivers of patients after coronary artery bypass graft surgery"

Public title

"The effect of spiritual care intervention on anxiety and self-efficacy of family caregivers of patients after coronary artery bypass graft surgery"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

"Be the first family members" "At least have a primary education" "Be 18 years old" "Understand and speak Persian language" "Have Interest and desire to participate in the study "

Exclusion criteria:

"Have a history of use psychotropic drugs in the past 2 months" "Having a history of stress-related accidents in the last 6 months " "Taking care of another person at the same time " "Having visual and hearing problems " "Activity in medical professions " "History of receiving training in the field of anxiety and self-efficacy"

Age

From **18 years** old

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

Block randomization is performed with equal ratio (1: 1) in the intervention and control groups (A and B) using 4-member block sizes. The sequence within each block will be randomized using Excel software and rand() function. Eligible candidates will be assigned to one of the intervention or control groups based on a random chain formed after entering the study.

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 Mashhad University of Medical Sciences

Street address

Central Building of Razavi Khorasan University of

Medical Sciences, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-12-18, 1400/09/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.072

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

Prevention, treatment and rehabilitation of cardiovascular diseases

ICD-10 code

I25/1

ICD-10 code description

بیماری تصلب شرایین قلب، کرونری(شریان)، آنروم، آنرواسکلروزیس، بیماری اسکلروزیس

Primary outcomes**1****Description**

Anxiety score in Beck questionnaire

Timepoint

Measurement of anxiety at the beginning of the study (before the intervention), immediately and 4 weeks after the intervention

Method of measurement

Beck Anxiety Inventory

2**Description**

Self-efficacy score on the general self-efficacy scale

Timepoint

Measurement of self-efficacy at the beginning of the study (before the start of the study), immediately and 4 weeks after the intervention

Method of measurement

General Self-Efficacy Scale

Secondary outcomes

empty

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

Intervention group: The intervention includes a spiritual care training program based on the spiritual strategies of Richards and Bergin, which will be theoretically and practically implemented for family caregivers of patients

undergoing coronary artery bypass graft surgery. This training program will be done in 6 face-to-face sessions for 60-45 minutes daily. The first session will explain the objectives of the research and the importance of the curriculum and spiritual care. The second session explains the spirituality and mission of the chosen people and its impact on the quality of life. In the third session, explanations will be given about communication with God through worship, communication with nature, strengthening a positive attitude towards oneself. In the fourth session, you will learn about accepting your weaknesses and getting rid of negative intellectual and behavioral traits and trying to replace positive traits with negative traits, learning and spiritual belief, and deciding on spiritual growth. The fifth session will be about mental and environmental space for spiritual growth, and the last session will be about empowerment to solve the problems of oneself and others, continuous self-evaluation under the supervision of a spiritual individual, and finally a summary will be made. In-person training sessions with lectures, PowerPoint presentations, questions and answers, expression of experiences related to the topic of the meeting will be between the researcher and the patient caregivers. At the end, a training booklet containing the topics presented will be given to the research units.

Category

Rehabilitation

2

Description

Control group: No special intervention will be done and the program will be done routinely and commonly in the wards. At the end of the research, the necessary information and educational program will be given to this group and their families in the form of an educational pamphlet.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mahmoud Mohammadzadeh Shabestari

Street address

Ibn Sina Ave, Imam Reza hospital, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

fakhraeias961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarehan

Street address

Central Building of Razavi Khorasan University of Medical Science, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

fakhraeias961@mums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sahar Fakhraei Azad Titkanlo

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Mashhad School of Nursing and Midwifery, Ibn Sina

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

fakhraeias961@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Seyed Mousa Mahdizadeh Taraghdar

Position

Academic member - Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Mashhad School of Nursing and Midwifery, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

mahdizadehm@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Sahar Fakhraei Azad Titkanlo

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Mashhad School of Nursing and Midwifery, Ibn Sina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

fakhraeias961@mums.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