Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 selfefficacy of family caregivers of patients after coronary artery bypass graft surgery

Design
A randomized open-label parallels 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

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Iran (Islamic Republic of)

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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
125/1
ICD-10 code description
بیماری تصلب شرایین قلب، کرونری(شریان)، آتروم، آترواسکلروزیس، 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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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

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Person responsible for scientific inquiries

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Full name of responsible person
Dr. Seyed Mousa Mahdizadeh Taraghdar
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Academic member - Assistant Professor
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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