Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effect of the caregiver burden reduction program on the outcomes of family caregivers of patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

1. Determination and comparison of the mean score of caregiver burden in family caregivers before and after the implementation of the program in the intervention and control group 2. Comparison of the mean score of caregiver burden in family caregivers before and after the implementation of the program between the two intervention and control groups

Design

A single-blind randomized clinical trial. Random allocation will done through block-of-four. The study will conducted on 60 family caregivers.

Settings and conduct

This research will be conducted in hospitals affiliated to Shiraz University of Medical Sciences. After obtaining informed consent, five days after discharge, the research questionnaires will be completed by caregivers and then divided into two intervention and control groups through random allocation. Single blinding will be done. For this purpose, general information about the research method will be given to the research samples, but none of the them will know which group they are in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: main caregiver of coronary artery bypass graft surgery, ability to read and write, having a smart phone equipped with virtual networks Exclusion criteria: working as a medical staff, having a diagnosed chronic physical or mental illness, and unwillingness to continue participating in the study.

Intervention groups

A program will be implemented to reduce the care burden of caregivers. For this purpose, the content of the program will be sent to the caregivers of the intervention group through electronic modules through virtual networks. Also, telephone follow-ups and individual consultations will be carried out by the researcher for these people. In the control group, only phone calls will be made to ensure medical follow-ups and doctor visits.

Main outcome variables

Caregiver burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240624062232N1**
Registration date: **2024-06-29, 1403/04/09**
Registration timing: **prospective**

Last update: **2024-06-29, 1403/04/09**
Update count: **0**

Registration date

2024-06-29, 1403/04/09

Registrant information

Name

Fatemeh Beheshtaeen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 4254

Email address

fabehesht67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of the caregiver burden reduction program on the outcomes of family caregivers of patients undergoing coronary artery bypass graft surgery

Public title
Investigation the effect of the caregiver burden reduction interventions on family caregivers of heart surgery patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be the primary caregiver of the patient Over 18 years of age Ability to read and write Ability to understand and speak Persian and express feelings and experiences Having no prior history of caring for patients undergoing coronary artery bypass graft surgery Caring for the patient that is candidate for coronary artery bypass graft surgery Having smart-phone equipped with a virtual social network and the ability to use it Willing to participate in research
Exclusion criteria:
Incurable and chronic disease in caregiver Caring for other chronic physical and mental patients in family A history of diagnosed mental illness or cognitive problems Employment as a medical staff Withdrawal from participation during the study Death of the patient during the study
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Caregivers are assigned to groups based on the randomization sequence that will be generated in advance, which is unpredictable and does not have a clear pattern. To assign samples to 2 groups, a block randomization method with a block size of 4 will be used using the software to generate random numbers in the block method.
Blinding (investigator's opinion)
Single blinded
Blinding description
The general introduction of the studied groups will be done, but participants will be unaware of the allocation of study groups.
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 street, Namazi Sq. Nursing and midwifery college
City
Shiraz
Province
Fars
Postal code
7193613119
Approval date
2022-12-17, 1401/09/26
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1401.110

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft surgery
ICD-10 code
I25.7
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s)

Primary outcomes

1

Description
Care burden
Timepoint
Five day after discharge (before intervention) and six weeks after discharge (after intervention)
Method of measurement
Novak Caregiver Burden Inventory

2

Description
General health
Timepoint
Five day after discharge (before intervention) and six weeks after discharge (after intervention)
Method of measurement

Goldberg General Health Questionnairre

Secondary outcomes

1

Description
Carer quality of life
Timepoint
Five day after discharge (before intervention) and six weeks after discharge (after intervention)
Method of measurement
Adult Carer Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group: The electronic content will be provided to the family caregivers from the 5th day after the discharge of the patients, gradually within a period of 1 week. This content includes training in the form of patient care manuals after coronary artery bypass surgery, common post-operative medications, stress management, time management, strategies to improve sleep, caregiver-patient communication skills, caregiver-family communication skills, The use of spirituality and a number of audio and video clips will reduce stress and improve sleep. Also, weekly follow-ups and psychological and educational counseling will be implemented for people if needed. This will continue from the 5th day after discharge to 6 weeks after discharge. Research questionnaires will be completed before and after the implementation of the intervention.
Category
Behavior

2

Description
Control group: Two calls will be made by the researcher to the caregivers during the period of time (5 days after discharge to 6 weeks after discharge) to remind them about treatment follow-ups and doctor's visits. Before and after that, research questionnaires will be completed.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Amir reza Dehghanian
Street address
Zand St, Shiraz Town
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Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Email
FaghihiHsp@Sums.ac.ir

2

Recruitment center
Name of recruitment center
Alzahra Heart Center
Full name of responsible person
Hojatollah Roosta
Street address
Astana St, Siboyeh Blvd, Shiraz Town
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Postal code
5493771649
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info@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad hashem Hashem pour
Street address
Zand St, Shiraz Town
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Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
vcrdep@sums.ac.ir
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
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
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Molazem
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Ph.D candidate
Latest degree
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
Ph.D candidate
Latest degree
Master
Other areas of specialty/work
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fbeheshtaeen@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Only some parts of the data including primary and secondary outcomes can be shared.
When the data will become available and for how long
The access period starts 4 months after the results are published
To whom data/document is available
Researchers working in medical and academic centers
Under which criteria data/document could be used
These data will be used only for research and treatment purposes
From where data/document is obtainable
To receive the data, they can send a message to the following email address and submit their request: fbeheshtaeen@yahoo.com
What processes are involved for a request to access

data/document

After sending the request email, the applicant must present his documents to the researcher (educational and research purposes). After confirmation by the researcher, the data will be available to them within a week.

Comments