Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of supportive educational program on self-care in patient with chronic heart failure and care burden in family caregiver: A parallel randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of supportive educational program on self-care in patient with chronic heart failure and care burden in family caregiver

Design

The study is a parallel clinical trial with a control group. Data are collected before and after the intervention. Sampling is a randomized block design with random allocation (data collector and data analyzer are blinded and will not know how individuals are assigned to groups)

Settings and conduct

supportive educational program for patients with heart failure referred to the heart clinic of Imam Hossein Hospital and their caregivers.The first session will consist of an overview of the training program for 20 to 30 minutes and two sessions as a group training (30 to 35 minutes) in groups of 6 to 8 people. Phone follow-up includes one call per week.

Participants/Inclusion and exclusion criteria

Age range 40 years and over Confirmation of the disease with a cardiologist Patients with appropriate physical conditions for intervention Patients in need of a specific treatment plan include of medication, diet and physical activity Patients of class II and above with a EF equal to or less than 45% Exclusion criteria: Known physical and mental illnesses that affect quality of life Participation in previous educational programs

Intervention groups

The supportive educational program consists of three training sessions including one face-to-face training session with each patient and caregiver and two group training sessions (over two weeks) and two follow-up phone sessions for the intervention group. The control group will use heart clinic training programs and at the end of the study, a educational booklet will be provided to patients.

Main outcome variables

1: Self-Care Heart Failure Index 2:Caregiver Burden Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046586N1**
Registration date: **2020-03-06, 1398/12/16**
Registration timing: **prospective**

Last update: **2020-03-06, 1398/12/16**
Update count: **0**

Registration date

2020-03-06, 1398/12/16

Registrant information

Name

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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

2020-04-02, 1399/01/14

Expected recruitment end date

2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of supportive educational program on self-care in patient with chronic heart failure and care burden in family caregiver: A parallel randomized clinical trial

Public title

The effect of educational-supportive program on self-care of patients with heart failure and caregiver burden

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

inclusion criteria of patient: - Age 40 years and over - Heart disease that will be diagnosed by a specialist cardiologist in the hospital. -Patients with heart failure are enrolled that are suitable physical condition to participate in the educational program and do not live alone and the patient has a family member to care . - Patients were enrolled in a study that, depending on the severity of the disease, required a specific treatment program following the pharmacological, dietary, and physical activity, ; It will focus on patients of Class II and above with EF less and equal 45 of NYHA criterion and criterion B and C of American Heart Association and American College of Cardiology. The latest clinical guideline for classification of patients with heart failure include of: Mild Heart Failure (Class II): LVEF 40-49% (mean 45%)، Moderate heart failure (grade III): LVEF rate of 30 to 39% (mean 35%) ،Severe heart failure (class IV): LVEF less than 30% Inclusion criteria of caregiver: - Family caregivers who devote the most time to participating in the care of the patient and helping him / her to adapt and adhere to the educational plan. -Have the opportunity to participate in educational sessions. - Have at least three months of patient care experience. - Ability to read and write. -Be able to communicate. - Have never attended any educational sessions before. - The caregiver should not care for another patient other than the patient with heart failure. -Have the first care experience of a patient with heart failure. - Do not suffer from psychological problems(based on the self-care statement). - Not a member of the medical team.

Exclusion criteria:

Exclusion criteria of patient: -Known physical and mental illnesses that affect quality of life, such as dialysis or other known psychological problems, such as depression and schizophrenia, which require a particular medication or diet. -Participation in previous educational programs

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence and list of blocks will be obtained by the software consultant with statistics. The https://www.sealedenvelope.com website is a useful site for generating random sequences for block type randomization. This site is designed so that there is no limit to the number of random allocation groups.The block method is used to generate random allocation sequences.Patients will be selected according to the criteria of the researcher by sequential sampling method and will be randomly divided into two groups intervention and control. Randomization will be done in secret; after obtaining informed consent, which group (intervention or control) will be randomly assigned to each patient according to the specified blocks, as the participatory education for the patient and caregiver will take place, each patient's caregiver code will also be included. The random assignment sequence is obtained by the software's statistical and statistical expert.Patients and caregivers who have the inclusion criteria are enrolled by the researcher. Participants will be assigned randomly via specified blocking to hide the random assignment of the group names in the random assignment sequence. Participants were coded in order of entry into the study and assigned to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the study and the fact that the researcher is conducting the educational intervention as well as the patient and caregiver are aware of the type of education they receive (routine clinic education or supportive educational program) it is not possible to blind the participants and the researcher. In this study, data collectors and data analysts are blinded and not aware of how individuals are assigned to groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahroud University of Medical Science

Street address

Shahroud, Seventh Tir Square, Shahroud University of Medical Sciences and Health Services, Vice Chancellor

for Research and Technology

City

shahroud

Province

Semnan

Postal code

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Approval date

2020-02-28, 1398/12/09

Ethics committee reference number

IR.SHMU.REC.1398.170

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

First outcome: Assessment of self-care score of heart failure patients through the Self-Care Heart Failure Index (SCHFI) Questionnaire containing 15 questions in 3 subscales. Higher scores indicate greater self-care, scores above 70 indicate appropriate self-care. Second outcome : Caregiver burden assessment is a caregiver who is assessed through the Bartel Caregiver Inventory (CBI). The scores on this questionnaire range from zero to 96 which, given the mean total care burden scores, higher score indicates higher care burden.

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after the intervention

Method of measurement

Self-Care Heart Failure Index (SCHFI) / Bartel Caregiver Inventory (CBI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes a group of patients with heart failure and caregivers who receive educational-supportive program in three sessions including one individual training session per patient and caregiver on the first day of referral to the heart clinic and two group sessions (within two weeks) and two phone fallow up plan. The first training session includes introducing the researcher to the patient and caregiver and outlining the educational program, the content and number of sessions, and the importance of the research topic for the patient and caregiver, explaining the importance of the role of self-care in the patient, and the beneficial effects of self-care explaining and emphasizing the importance. The role of caregivers and the importance of reducing the burden of care giving and its effects on caregivers and patients is between 20 and 30 minutes, with face-to-face information focused on questions and answers. The second and third sessions will consist of group training (30-35 minutes) with the presence of patients and caregivers in groups of 6 to 8 persons. Group teaching will be delivered with PowerPoint slides, group discussion and hands-on presentation.The content of the second session will include general descriptions of heart failure, signs and symptoms, an explanation of how to properly care for yourself and its dimensions, and an explanation of the importance of how to care for and manage the patient's signs and symptoms in emergency situations and conditions. The third session includes the familiarity with the drugs and the necessity of their use and possible side effects, the importance of precise drug use in exacerbating and preventing hospitalization, the importance and necessity of making lifestyle changes for the patient and caregiver, including adherence to appropriate dietary plans, including consumption restrictions. Sodium and fluids, exercise and permitted exercise, drug compliance, smoking cessation, weight control. According to the advocacy approach of the educational program, during the face-to-face training sessions, specific needs and follow-up questions of patients and caregivers in the field of medication, diet, and physiotherapy program will be identified. Depending on the type of need, guidance will be given on how to access the specialist to meet the needs, and during the follow-up sessions, the patient referral process and caregiver will be followed up.

Category

N/A

2

Description

Control group: Patients with heart failure and their caregivers are referred to the heart clinic and receive oral education and pamphlets related to the clinic.At the end of the study, an educational booklet will be provided to patients.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital affiliated to Shahroud University of Medical Sciences

Full name of responsible person

Esmail Shariati

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
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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
Undecided - It is not yet known if there will be 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
Part of the patient and caregiver demographic information is shared after unidentifiable individuals All information about self-care assessment in patients and caregiver burden is shared after unidentifiable individuals
When the data will become available and for how long
Access period starts from August 2020
To whom data/document is available
Researchers and students of academic and scientific institutions
Under which criteria data/document could be used
data for correlational studies
From where data/document is obtainable
esmail.shariat@yahoo.com
What processes are involved for a request to access data/document
Clear explanation of the reason for the need to access the data and submit the data after two weeks
Comments