Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluation of the effectiveness of supportive-educational program based on Cope care model on resilience, care burden and quality of life of family caregivers of patients with heart failure

Protocol summary

Study aim
Determining the effectiveness of supportive-educational program based on Koop care model on resilience, care burden and quality of life of family caregivers of patients with heart failure

Design
Clinical trial with experimental and control group, single blind, randomized, in three stages on 90 caregivers of patients with heart failure. For randomization, the available method (card method) is used.

Settings and conduct
1- The study site will be in inpatient wards heart failure patients from Shahid Chamran Teaching-Research and Treatment Hospital in Isfahan. 2- The study is performed on 90 caregivers of patients with heart failure. 3- Blinding is for patients and their clinical caregivers, so that until the end of the study, only the facilitator and the student will be aware of the caregiver groups and the caregivers and patients themselves won't be aware of their group at all. Only members of the test group will receive additional content and coordination for the sessions through WhatsApp groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The age of the caregiver is over 18 years old and under 65 years old; Being able to read and write in Persian; Not participating in another similar study at the same time; not providing care for another chronic illness at the same time. Non-inclusion criteria: Reluctance of the caregiver to participate in the study; Caregiver be a member of the health team.

Intervention groups
Intervention group: In this study, a six-session program is performed during a month. In these sessions, a booklet is given to the caregivers. During these sessions, the three main problems of the caregivers are used by using the coupe and booklet model to reduce and eliminate it. Control group: A training booklet is given to caregivers, and no intervention is performed in this group.

Main outcome variables
Resilience; Care burden; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211128053202N1**
Registration date: **2022-02-20, 1400/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-20, 1400/12/01**
Update count: **0**

Registration date
2022-02-20, 1400/12/01

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
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of supportive-educational program based on Cope care model on resilience, care burden and quality of life of family caregivers of patients with heart failure

Public title
The effect of supportive-educational program based on Cope care model on resilience, care burden and quality of life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The age of the caregiver is over 18 years and less than 65 years. Not participating in another similar study at the same time. Not taking care of another person with a chronic disease at the same time. The person declares that the psychiatric disorder is not known The person should be appointed from the patient as the main caregiver The person under his care must be a patient with heart failure and have already referred to the center for treatment. Ability to use virtual networks. Being able to read and write in Persian.
Exclusion criteria:
The unwillingness of the person to participate in the study Caregiver be a member of the health team.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Ninty caregivers of patients with heart failure who were eligible for the study are randomly assigned (by card method) to the experimental and control groups, so that 45 cards with number one and 45 cards Number two will be placed in a package in an envelope. And on the day of random division of research units, caregivers will be asked to choose a card. People who belong to number one are in the test group. And the people assigned to number two will be in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The people in the intervention and control groups do not get to know each other before, during and after the intervention and do not meet until the end of the study so that they do not know which group the caregiver is in.Rather, only by the end of the study do the facilitator and the student know which caregivers are in which group. Only those in the intervention group in the WhatsApp groups will be given the necessary additional information and coordination to hold meetings, while these materials and coordination will not be notified to the control group. The booklet provided at the time of sampling to individuals in both intervention and control groups has the same content.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
School of Nursing and Midwifery; Isfahan University of Medical Sciences; Hezar Jerib Street
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Isfahan
Province
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Postal code
81746-73461
Approval date
2021-12-25, 1400/10/04
Ethics committee reference number
IR.MUI.NUREMA.REC.1400.196

Health conditions studied

1

Description of health condition studied
Cope model, Family caregivers of patients with heart failure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Caregiver burden based on Zariat questionnaire
Timepoint
Before intervention, after intervention and three months after intervention
Method of measurement
Zariat questionnaire

2

Description
Quality of life score based on SF-36 questionnaire
Timepoint
Before intervention, after intervention and three months after intervention
Method of measurement
Quality of Life Questionnaire SF-36

3

Description
Caregiver resilience score based on Conner and Davidson questionnaire
Timepoint
Before intervention, after intervention and three months after intervention
Method of measurement
Conner and Davidson Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Selection of three major common problems among caregivers during the care of a patient with heart failure, then during the sessions, all three problems of individuals based on the coupe model are addressed. In this way, the booklet (which is based on the common problems of caregivers) is given to them in the introductory session. 1. Based on the priority of problems in each session, the coupe model is used(Apply the problem-solving process based on the coup model to each problem(According to the components of the model, this model is implemented, which includes: In the creative component: Since it is an intellectual and motivational activity, in this regard, the caregiver is encouraged to be able to see different aspects of the problem and by using his abilities and characteristics, he can come up with new and appropriate ideas and solutions for the problems and gaps. Compile with difficulty.In the optimism component: take care to have a positive yet realistic attitude and flexibility in relation to the guided problem solving process, which, In addition to accepting himself and recognizing his value, he can be encouraged to control his thoughts and feelings and maintain a sense of competence and efficiency. Caregivers are also encouraged to establish an intimate and optimistic relationship with the patient and to gain trust and show their understanding and hope in this regard. In addition, he encourages the patient to take care of himself with empathy. In the planning component: in order to solve problems, the caregiver is guided to follow a regular and accurate approach to identify, solve problems, review and follow the specified program. In the specialized information component: the caregiver seeks to receive information from health professionals in order to understand different aspects of the disease, situations, problems and care needs for the patient, as well as to increase information, understand emotions and how to deal with it, as a caregiver. Follows)). Be sure to copy the caregivers before, during and after the sessions to encourage the use of the booklet in accordance with the problem under consideration in each session to complete the implementation of the model.
Category
Other

2

Description
Control group: Coupe model booklet and informed consent questionnaire, demographic information form and questionnaires of other variables were given to them in the first meeting with caregivers (before the intervention for the experimental group) and after three months (three months after the intervention) will be completed by the caregivers.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
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Isfahan, Salman Farsi St., after the city bridge, Dr. Chamran Martyr Heart Hospital
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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
Esfahan 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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Person responsible for updating data

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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