

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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 Cope 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 cope 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

Sima Babaee

Name of organization / entity

Country

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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

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School of Nursing and Midwifery; Isfahan University of Medical Sciences; Hezar Jerib Street

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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

Dr. Masoumeh Sadeghi

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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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Full name of responsible person

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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**

Esfahan University of Medical Sciences

Full name of responsible person

Sima Babaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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