

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of family supportive program through telenursing care on caregivers burden in family with Congestive Heart failure in Bojnurd in 2019

Protocol summary

Study aim

1- Determination of caregiver burden score in family caregivers of patients with heart failure, before and one month after intervention in intervention group 2- Determination of caregiver burden score in family caregivers of patients with heart failure, before and one month after intervention in control group 3- Comparison of caregiver burden score in family caregivers of patients with heart failure, before and one month after intervention in the intervention and control groups

Design

66 patient caregivers will be enrolled admitted. At the first a list of all heart failure patients admitted to Hospital will be prepared during the last few years and then using random number table in groups of standard discharge plan and telenursing and standard discharge plan will be placed.

Settings and conduct

Pre-intervention caregiver pressure will be measured in two groups before intervention. The intervention program will be conducted in the intervention group and both groups will have regular telephone contact and counseling. In addition to standard care, the intervention group's family caregivers will load the relevant data into the data transfer software and send to cardiologist. Caregiver burden will be measured in the two groups at the end of one month of intervention.

Participants/Inclusion and exclusion criteria

Inpatient Criteria: At least six months have passed since the diagnosis of heart failure. The patient has a family. The patient has a family caregiver who has the highest share of patient care. Outpatient Criteria: Not able to communicate with telemedicine care for 2 weeks.

Intervention groups

Both groups will be given discharged time training. Contact and telephone counseling will be conducted with both study groups. Training will be given to the

intervention group on telenursing equipment and how to upload data into the data transfer software.

Main outcome variables

Caregiver Burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161018030366N3**

Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name

Mohammad Ghaderi

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family supportive program through telenursing care on caregivers burden in family with Congestive Heart failure in Bojnurd in 2019

Public title

The effect telenursing care on caregivers burden in family with Chronic Heart failure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

At least six months have passed since the diagnosis of heart failure. The patient has a family. The patient has a family caregiver who has the highest share of patient care. Have a caregiver over 18 years of age. Lack of family caregivers with mental disorder and chronic diseases Ability to read and respond to the Farsi questionnaire.

Exclusion criteria:

Not be able to provide appropriate telemedicine care after receiving trained nursing education Not able to communicate with telemedicine for 2 weeks. If the patient also has a private nurse and the patient's caregiver uses other educational programs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a list of all chronic heart failure patients admitted to Imam Hassan Hospital in Bojnourd during the past year will be compiled and the samples will be randomly divided into tele-nursing group and standard care group by random number table. Based on this, the researcher will go to the cardiology department and the sample will be selected based on which group the patient was previously in. To blind patients, sampling will be done at discharge so that other patients are not aware of the study method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both groups of participants will be contacted by

telephone and counseled, and neither participant will be aware of the actual intervention. In this study, the researchers will try not to be aware of the intervention group. for blinding the data analyzer, the study groups would be coded and thus the analyst would not know the nature of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of North Khorasan University of Medical Sciences

Street address

Shahryar Street, School of Nursing

City

Bojnurd

Province

North Khorasan

Postal code

96786-94176

Approval date

2019-10-27, 1398/08/05

Ethics committee reference number

IR.NKUMS.REC.1398.073

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**

Family Caregiver burden

Timepoint

Pre- intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention in the tele-nursing group will consist of three parts: 1- Discharge training to family caregivers at discharge 2- Manage scheduled contacts 3- Remote monitoring of vital signs and weight of the patient at home. The discharge plan will be taught by a research nurse who is not a member of the patient treatment team. Through Booklet, he will teach family caregivers training on heart failure, medication, salt avoidance, fluid monitoring, exercise training, daily weight control and foot swelling, and limb time. Discharge planning training, training on how to measure vital signs, and working with tele-nursing equipment individually and face-to-face will be given to the patient's family caregiver prior to discharge. These tutorials will include how to use tele-nursing, how to measure physiological parameters and their importance. The patient contact plan will be conducted by one patient call coach. Patients will be given a heart failure educational booklet, a 7-day, one-month checklist and informed consent form. Patients in the intervention group should have an Internet-enabled smartphone and an approved information exchange software such as Whats App, Telegram or Soroush and a blood pressure monitor to measure blood pressure. Patient caregivers will be taught how to measure blood pressure, pulse rate, respiration and weighting to measure the physiological parameters of the patient on a daily basis and to upload the software. The call coach will teach caregivers about the pathophysiology of the disease, the symptoms, the treatment regimen and the fluid restriction. The call coach will provide caregivers a weekly counseling and pharmacy program. The phone caller will record and monitor patient vital information and weight information daily and provide feedback to caregivers. Will provide a patient visit if necessary.

Category

Rehabilitation

2

Description

Control group, Standard care: Common discharge plans for the standard care group will include a heart failure training booklet for family caregivers of patients to examine symptoms and symptoms, teach health care skills, and assist in understanding illness and facilities, and if they have problems call to call coach. The call coach should contact the family caregiver of the patients, actively and weekly after discharge, to inform them of the patient's condition and to provide counseling if needed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hassan Mojtaba Hospital

Full name of responsible person

Dr Haghighi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Seyed Kaveh Hojjat

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Emam Ali Blv, Shahriyar Street.

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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

Bojnourd 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

m.ghaderi@nkums.ac.ir

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Ghaderi

Position

Instructore

Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

For greater security of participants' data

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