

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of family centered and patient centered education on Chronic heart failure patient's self care behaviors

Protocol summary

Summary

The aim of this randomized clinical trial is to evaluate the effect of family-centered and patient-centered education on self-care behaviors in patients with chronic heart failure. The study population of 120 patients with chronic heart failure hospitalized in Rajai Heart Center and active member that have inclusion criteria, which are randomly divided into three groups of patient-centered, family-centered and control. At the beginning of the study a demographic questionnaire and a questionnaire measuring self-care behaviors of patients with chronic heart failure will be completed. The family-centered that includes patients and active member will be asked to participate in three sessions about self-care education will be presented by the researcher in the hospital. In the patient-centered group, only patients participate in the same training session. In the control group, common training will be provided. After 2 months of the intervention, the researcher will be coordinate with patients to complete this questionnaire again. The self-care behaviors and baseline groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071823159N3**

Registration date: **2015-09-27, 1394/07/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-27, 1394/07/05

Registrant information

Name

Alice Khachian

Name of organization / entity

School of Nursing and Midwifery, Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research funding of Iran University of medical sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of family centered and patient centered education on Chronic heart failure patient's self care behaviors

Public title

The effect of education on on Chronic heart failure patient's self care behaviors

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; Confirmed diagnosis of heart failure by the doctors (in their medical records); Patients with heart failure with ejection fraction of 35% or less ;Non acute conditions The absence of disabilities - cognitive impairment of vision, hearing and

communication; People's willingness to participate in this study; Having caregivers (family members) that have inclusion criteria. Family caregivers criteria for inclusion: family caregivers have a minimum education (reading and writing); willingness to participate in the study; patient care should be at least three months and those who have assumed responsibility for patient care. Exclusion criteria: absence of more than one of the training sessions for groups ; wanting to stay in the study for both groups; Fatal; worsening of the patient's condition; transfer to another ward; prolonged hospital stay (more than 1 month); People who score high on self-care questionnaires were received before the intervention; Participating in the same study

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University Of Medical science

Street address

Iran University of Medical Sciences -Hemat Highway

City

Tehran

Postal code

Approval date

2015-05-03, 1394/02/13

Ethics committee reference number

105/632 / ۵/۱۳۹۴.۹۴

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50.0

ICD-10 code description

Heart failure

Primary outcomes

1

Description

The self-care behaviors

Timepoint

Before and 2 Month after intervention

Method of measurement

self care behavior of patient with heart failure questioner

Secondary outcomes

empty

Intervention groups

1

Description

Family-centered group that, including the patient and his active member of family will be asked in the three educational sessions on topics related to self care, including the introduction of disease, chronic heart failure, risk factors, symptoms, diet, exercise appropriate medical treatment and proper care and management of the disease that the researcher will participate in the hospital. Each session lasted 45 minutes and will be scheduled according to the needs of patients and their family members may continue for up to 60 minutes. The teaching methods and, if possible, as a group with a maximum number of 10 participants will be accompanied by questions and answers and images.

Category

Lifestyle

2

Description

In patient-centered group that only patients participate in the training session educational content will be the. Educational content will be the same in both groups, the content includes the introduction of chronic heart failure, risk factors, symptoms, diet, proper exercise, proper medication and self-care and management of the disease.

Category

Lifestyle

3

Description

The control patients will receive training in common hospital care

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaei Cardiovascular, Medical & Research Center
Full name of responsible person
Nasim Naderi
Street address
next to Mellat Park, Vali Asr st, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
Room #503, 5th floor, Central building of Iran University of Medical Sciences, between Chamran and Hemmat Expways, Hemmat Expway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
School of Nursing and Midwifery, Iran University of Medical Sciences
Full name of responsible person
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Position

Nursing Msc Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty