Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of family-centered empowerment model on dignity of patients with heart failure

Protocol summary

Summary

This study is a randomized clinical trial which aims to determine the effect of family-centered empowerment model on dignity in patients with heart failure in patients admitted to intensive care and heart wards FatemeZahr hospital in Sari and ValiAsr in Ghaemshahr takes place in the year 1396.In this study 80 patients of the study population based on the criteria and sampling will be chosen and the application randomization patients will be grouped according to four blocks in the two groups 1 and 2.Randomly number 1 in the empowerment group and number 2 in the control group will be dedicated.After selecting any of the samples and then explain the purpose of the study and informed consent demographic,social status and inherent dignity for patients in both groups will be completed.In group 1 the family-centered empowerment model will be taught in four steps:understanding the threat,self efficacy,self esteem and evaluation.In group 2 will not be a special intervention and routine will be done for them.Before and after the intervention using data collected will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703223064N7**
Registration date: **2017-04-18, 1396/01/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-18, 1396/01/29

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research - Shahroud University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family-centered empowerment model on dignity of patients with heart failure

Public title

Effect of empowerment model on dignity of patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients older than 40 years; informed written consent; the absence of mental illness or drugs influencing the mental; ability to read and write; understand and speak Persian; passing at least one month of diagnosis of heart failure; the possibility to make phone calls with patient Exclusion criteria: the

reluctance of patients to continue treatment; failure patients to continue treatment due to disease progression or death

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Ethics Committee of Shahroud University of Medical Sciences

Street address
Shahroud University of Medical Sciences, Hafte-Tir Square

City
Shahroud

Postal code

Approval date
2017-03-07, 1395/12/17

Ethics committee reference number
ir.shmu.rec.1395.186

Health conditions studied

1

Description of health condition studied
heart failure

ICD-10 code
I50.9

ICD-10 code description
Heart failure, unspecified

Primary outcomes

1

Description
Patients dignity

Timepoint
Before intervention-A month after the intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the control group of 40 patients will be randomly selected they will be given training routine and before and one month after the intervention will evaluate patients dignity.

Category
Other

2

Description
In the study group,40 patients were randomly selected and family-centered empowerment model they will be taught in 4 stages:1-Understanding the threat:Treatment by raising the level of knowledge about the nature and risk of complications from the disease in group discussion is presented.The contents of the meeting includes the evaluation of physical and mental conditions of the participants as well as their attitude towards the nature of the disease,by definition,warning signs,nursing and medical care and complications of the disease.(through 3-5 sessions,including 3-5 patients with a family member and each sessions takes about 45-60 minutes) 2-Self efficacy:problem solving group study in groups of 3-5 people during the 3-5 one-hour sessions will be held for patients and patients with problems and the process of solving the problem encountered and their participation in the selection of solutions. 3-Self-esteem:patients through the use of problem-solving from the previous steps to achieve a practical solution. 4-Assessment:The entire process takes place one month after the intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr hospital

Full name of responsible person

Mamak ghobadi

Street address

Mazandaran-Ghaemshahr-Sari street

City

Ghaemshahr

2

Recruitment center

Name of recruitment center

Fateme Zahra hospital

Full name of responsible person

Mamak ghobadi

Street address

Army Blvd-next to court

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research - Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammad-Hassan Emamian

Street address

Shahroud University of Medical Sciences, Hafte-Tir Square

City

Shahroud

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 - Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Bagheri

Position

PhD in nursing education

Other areas of specialty/work

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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