

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of family-centered empowerment model and usual care on hope and quality of life for patients with failure

Protocol summary

Summary

The objective of this study is to investigate the effect of family-centered empowerment model on hope and quality of life of patients with heart failure. In this clinical trial after obtaining permission from the authorities, hospitals and code of ethics and informed consent of the person subject to inclusion criteria, Of heart failure patients admitted to the CCU government hospitals in Ahvaz, the purposive sampling method randomly selected samples of family-centered empowerment model runs. Samples randomly are divided into two groups and training required will be implemented in accordance with the four-step model of family-centered empowerment. Inclusion criteria are patients' age above 40 years, at least 6 months after heart failure improvement, without history of mental illnesses such as schizophrenia, having full knowledge and access to the telephone tool, Ability to communicate and answer questions, ejection fraction between 20%-40%. Exclusion criteria are an unwillingness to cooperate, readmission, mortality. The intervention group contains 4 to 10 subjects groups during 4 weekly sessions will be presented within a month, also for 4 weeks, we have to follow up weekly phone calls. Two questionnaires including inventory Minnesota for quality of life and Schneider life expectancy measurement are used in 4 time points including before the intervention, the end of the second session, four and three months after intervention. The control group will complete two questionnaire in two time points. No training program will hold for control group, they only receive routine treatment. The primary outcome variable include quality and life expectancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071028862N1**

Registration date: **2017-04-29, 1396/02/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-29, 1396/02/09

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered empowerment model and usual care on hope and quality of life for patients with failure

Public title

Assesment of the effect family-centered Empowerment model on hope and quality of life in patient with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients older than 40 years; at least 6 months after the last in the family is sick heart failure patients; history of mental illnesses such as schizophrenia do not have, having full knowledge and access to the telephone instrument; Ability to communicate and answer questions; ejection fraction less than or equal to 40% of heart patients is not the disease is debilitating complications such as heart ejection fraction of 20% or less. Exclusion criteria: an unwillingness to cooperate; readmission; mortality.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Boulevared, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.AJUMS.REC. 1395. 158

Health conditions studied

1

Description of health condition studied

Hope and quality of life in patient with heart failure

ICD-10 code

none

ICD-10 code description

none

Primary outcomes

1

Description

Hope of life

Timepoint

Before, the second session, the fourth session and 3 months after intervention

Method of measurement

Questionnaire and respond to questions, and reduced hospitalizations by 70% within a month

2

Description

Quality of life

Timepoint

Before, the second session, the fourth session and 3 months after intervention

Method of measurement

Questions and answer the questionnaire 70%

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the control group received usual care hospitals and related questionnaires filled out twice.

Category

N/A

2

Description

Patients in the intervention group received weekly sessions of relevant training and follow-up phone call fall.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital
Full name of responsible person
Zhaleh Mehrabzadeh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Ahvaz Jundishapur
University of Medical Sciences
Full name of responsible person
Behzad Sharif Makhmalzadeh
Street address
Golestan Boulevarde
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Grant name
13000000
Grant code / Reference number
none
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice chancellor for research of Ahvaz Jundishapur
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

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Person responsible for updating data

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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