

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Assessment of the effect of family-centered empowerment model on life style and illness perception of heart failure patients referred to heart clinic of Alzahra hospital in shiraz,1392-93

Protocol summary

Summary

This is an interventional study that aims to investigate the effect of family-centered empowerment model on life style and illness perception of patients with heart failure. 70 patients with diagnosis of heart failure refer to researcher from cardiologist. Inclusion criteria: age between 18-65y/o; at least in class II heart failure; at least literacy(writing&reading) for patient and one of active family member; predominant to Persian language. Exclusion criteria: to become manifest of physical and mental disease; progress to class IV heart failure and become more deteriorated. After completion of demographic, disease's perception and life style questionnaire by participants, divided to case and control group by randomized block. Case group and active family members participate in 5 sessions(1-2hours) about family-centered empowerment model for 5 weeks. Control group receive pamphlet about heart failure. after 45 days reassess life style and patient's perception.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072018468N3**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

Khadijeh Rahimi kordshouli

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of family-centered empowerment model on life style and illness perception of heart failure patients referred to heart clinic of Alzahra hospital in shiraz,1392-93

Public title

Effect of family-centered empowerment model on life style and illness perception of patients with heart failure.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: verifying heart failure by cardiologist; age between 18-65y/o; at least in class II heart failure; tendency of patient and one of(his/her) family member to participate in this study; at least

literacy(writing&reading) for patient and one of active family member; predominant to Persian language; absence of any physical and mental disease. Exclusion criteria: to become manifest of physical and mental disease; progress to class IV heart failure and become more deteriorated; lack of cooperation from patients and family members in participation of empowerment programme; absence of participation in problem-solving sessions and educational collaboration programme.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

seventh floor of Shiraz University of Medical Sciences and health services, next to red crescent organization, Zand blvd

City

Shiraz

Postal code

71345-1978

Approval date

2014-05-19, 1393/02/29

Ethics committee reference number

CT- 9378-7058

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

195-199

ICD-10 code description

197.1

Primary outcomes

1

Description

lifestyle

Timepoint

pre intervention and 45 days after intervention

Method of measurement

questionnaire

2

Description

illness perception

Timepoint

pre intervention and 45 days after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

lifestyle

Timepoint

pre intervention and 45 days after intervention

Method of measurement

questionnaire

2

Description

illness perception

Timepoint

pre intervention and 45 days after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention in case group: patients and active family members attend in 5 sessions (1-2 hours) for 5 weeks and 4 stages of family-centered empowerment model is done. First step: perception of threat in 2 sessions. First session: explantation of nature, pathophysiology, ethiology and clinical manifestations of disease. Second session: training about regimen and pharmacological treatment and side effects. After every session, reevaluate previous knowledge. Second step: self-efficacy: third session: grouping problem solving Third step: self-belief: fourth session: to ask the patients that

train the previous informations to active family members. Fourth step: evaluation Five session: general evaluation of patients and their accompanies.

Category

Lifestyle

2

Description

Intervention in control group: pamphlet and routine training about heart failure will receive.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

cardiac clinic of fatemeh holiness charity hospital

Full name of responsible person

Doctor Reza Mozafari

Street address

Fatemeh holiness charity hospital, blvd siboieh, Shiraz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholamreza Hatam

Street address

Seventh floor of Shiraz University of Medical Sciences and health services, Zand blvd

City

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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

Vice chancellor for research of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

khadijeh Rahimi Kordshouli

Position

Master science student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Mahnaz Rakhshan

Position

Phd in nursing

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