Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectivness of a supportive educative group intervention on family caregiver burden of patients with heart failure

Protocol summary

Summary

This randomized clinical trial tested the effectiveness of supportive educative group intervention in decreasing HF family caregiver's burden of caregiving This intervention consisted of four weekly, two- hour multi media training session that included education and family support for family caregiversin intervention group. Control group will recive routine care. Family caregiver burden will be assessed at preintervention,after intervention and 3-month after intervention using the Zarit Burden Interview. To determining of intervention effect over 3-month period between and inter-gruops, parametric and nonparametric statisticall tests will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021212452N1**
Registration date: **2013-03-18, 1391/12/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-03-18, 1391/12/28

Registrant information

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Recruitment status

Recruitment complete

Funding source
Research Deputy of Isfahan University of Medical Sciences

Expected recruitment start date

2012-12-07, 1391/09/17

Expected recruitment end date

2013-03-07, 1391/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectivness of a supportive educative group intervention on family caregiver burden of patients with heart failure

Public title

Designing and Implementation of Interventional Program Based On Family Caregiver Needs of Congestive Heart Failure Patients: A Mixed Methods Study

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: Having 18 years old; Being a main and family caregiver; Having several month experiences in caregiving; Financially supports the patient; having good comunication skill exclusion criteria: Sever physical and mental disorder; Unwillingness in ongoing participation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 the Isfahan University of Medical Sciences

Street address

Research Dupty of Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran.

City

Isfahan

Postal code

8174673461

Approval date

2012-06-24, 1391/04/04

Ethics committee reference number

391084

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

Primary outcomes

1

Description

family caregiver burden

Timepoint

preintervention, Immediately after intervention, 3-month after intervention

Method of measurement

zarit burden interview scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention for intervention group: The supportive educatiive group intervention program consisted of four weekly, two hour multimedia training sessions that included education, family support and held during four consecutive weeks. Four supportive educative groups of ten family caregivers were arranged with the same content, and the interventional program was conducted by a team consist of cardiologist, psychiatric nurse, cardiac nurse and clergy man in intervention group

Category

Other

2

Description

intervention for control group: This group will be recieved routine of hospital

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical and Training Hospital of Isfahan University of Medical Sciences

Full name of responsible person

Mrs. Zarin Tansaz

Street address

Patient and Family Education Center of Alzahra Hospital of Isfahan University of Medical Sciences, Sofe Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr peyman Adibi

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Research Dupty of Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran

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Grant name
فصل دوم برنامه تحقیقات دانشگاهی
Grant code / Reference number
1191-10506
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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

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Web page address

Person responsible for updating data

Contact

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