

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

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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 caregivers in intervention group. Control group will receive routine care. Family caregiver burden will be assessed at preintervention, after intervention and 3-month after intervention using the Zarit Burden Interview. To determine the effect of intervention over 3-month period between and inter-groups, parametric and nonparametric statistical tests will be used.

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

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

Name

Shahram Etemadifar

Name of organization / entity

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2969

Email address

Scientific title

The effectiveness 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 communication skill exclusion criteria: Severe 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 educative 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

Street address

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

City

Isfahan

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**Contact****Name of organization / entity**

Nursing and Midwifery Faculty, Isfahan University of Medical Sciences

Full name of responsible person

Masoud Bahrami

Position

Associate professor, A faculty Member of Nursing and Midwifery

Other areas of specialty/work**Street address**

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Position

Phd candidate in nursing, Msc in nursing

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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