

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 sessions that included education and family support for family caregivers in the intervention group. The control group will receive routine care. Family caregiver burden will be assessed at pre-intervention, after intervention, and 3-month after intervention using the Zarit Burden Interview. To determine the effect of the intervention over a 3-month period between and among 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: 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 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**

Assosiate profossor, A faculty Member of Nursing and Midwifery

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

Nursing and Midwifery Faculty of Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran

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bahrami@mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing and Midwifery Faculty, Isfahan University of Medical Sciences

**Full name of responsible person**

Shahram Etemadifar

**Position**

Phd candidate in nursing, Msc in nursing

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

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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