

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of self-care education on the awareness, attitude, and adherence to self-care behaviors in hospitalized patients due to heart failure with and without depression

Protocol summary

Summary

Title: The effect of self care education on the knowledge, attitude, and adherence to self care behaviors in cardiac patients with and without depression. Objective: the effect of self care education on the knowledge, attitude, and adherence to self care behaviors in hospitalized cardiac patients with and without depression. Design: non randomized, Non blind, No placebo controlled, multi center, Phase II and III clinical trials. Method: Setting and conduct: Sample: 70 cardiac patients who met the inclusion criteria. Major inclusion criteria are: a definitive diagnosis of heart failure by cardiologist; ejection fraction Less than 40%. Major Exclusion criteria are: patients with trouble in hearing and speaking; discharge from hospital less than one week. Sample size: 70 persons. Intervention: In the intervention group, the self care behaviors will determine and then a four session educational intervention will be held individually for both groups; finally, the questionnaires will be complete again through visiting the patients at their home 12 weeks after discharge. Primary outcome: knowledge, attitude, and adherence to self care behaviors

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014082318887N4**
Registration date: **2014-10-06, 1393/07/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-06, 1393/07/14

Registrant information

Name

amene barfidokht

Name of organization / entity

mashhadad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Email address

barfidokhta901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-09-20, 1392/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-care education on the awareness, attitude, and adherence to self-care behaviors in hospitalized patients due to heart failure with and without depression

Public title

The effect of self-care education on knowledge, attitude and adherence to self-care behaviors in cardiacpatients with and without depression

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: definite diagnosis of heart failure according to cardiologist, ejection fraction less than 40 based on the echocardiography, a resident of the Zahedan and Available for follow-up, at least 20 years of age, have at least literate, alert and full orientation. Exclusion criteria: patients with trouble in hearing and speaking, discharge from hospital less than one week, physical disability, dialysis, and previous participation in rehabilitation programs.

Age

From **19 years** old to **69 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

To recruit subjects, available sampling method was used continuously for hospitalized patients during April to October 2013

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Zahedan

Street address

Dr Hesabi square, Zahedan

City

Zahedan

Postal code

9816913396

Approval date

2014-02-24, 1392/12/05

Ethics committee reference number

6054

Health conditions studied

1

Description of health condition studied

Heart diseases

ICD-10 code

I05, F32

ICD-10 code description

Chronic heart diseases, Depressive episode

Primary outcomes

1

Description

knowledge, attitude and adherence to self-care behaviors

Timepoint

Before and twelve weeks after the intervention.

Method of measurement

self-care behaviors Questionnaires

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: The educational intervention was provided for both groups during 4 one- hours sessions through individually face-to-face training program using an educational booklet and CD.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliebne Abitaleb Hospital

Full name of responsible person

Fariba yaghoobinia

Street address

Dr Hesabi square, Zahedan

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Islamic Azad University of Zahedan

Full name of responsible person
Ahmad Mehraban

Street address
Daneshgah street, Islamic Azad University

City
Zahedan

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 Islamic Azad University of Zahedan

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
Zahedan University of Medical Sciences

Full name of responsible person
Ali Navidian

Position
Associate Professor

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