Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of self management program on self efficacy, self care behaviors and health status in old patients with heart failure

Protocol summary

Summary

The aim of this study was to determine effect of self-management program on self-efficacy, self-care behaviors and health status of elderly patients with heart failure.This clinical trial research is applied parallel that has taken place in 2015 in 22 Bahman Hospitals in Neyshabour on 90 elderly patients with heart failure. Samples were selected from patients in the cardiology clinic and eligible for participation the study and With the appointment randomized into two groups using random blocks 1 (test) and 2 intervention (control) group. Inclusion criteria included age over 60 years, class 2 and 3 heart failure divided by the America Heart Association, not having motor disabilities and handicaps and desire to participate in the program. Data collection tools by demographic specification form, heart self-efficacy questionnaire; European questionnaires self-care behaviors in heart failure patients and health status questionnaires for patients with heart failure. The intervention included education face to face and group according to chronic disease self-management program at Stanford University for six weeks, every week was a 90 minute session. After intervention were followed by phone call and fill self-report check list in patients at home. Interventions consisted of provided the information about the diagnosis, treatment, diet, energy conservation methods and control negative emotions and relaxation and exercise. Questionnaires was completed in three stages: Before, after and two months after the intervention. Results were analyzed with statistical tests.

General information

Acronym

CDSM

IRCT registration information

IRCT registration number: **IRCT2016052628089N1**

Registration date: **2016-09-11, 1395/06/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-11, 1395/06/21

Registrant information

Name

Tayebe Aghamohamadi

Name of organization / entity

University of Social Welfare & Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2015-09-06, 1394/06/15

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self management program on self efficacy, self care behaviors and health status in old patients with heart failure

Public title

The effect of self management program on self efficacy, self care behaviors and health status in old patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: ability to read and write; age 60 years and older; no motor disabilities and handicaps; Class 2 and 3 heart failure; no previous training in the field of self-management; passing at least six months of the disease, willingness to participate in the program. Exclusion criteria: severity of the disease; died as a result of illness; unwillingness to continue the program

Age

From **60 years** old to **92 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, was performed inclusion criteria were randomized into two groups using random blocks 1 and 2 intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, koodakyar Blvd, Daneshjoo Stre, Evin Ave, Tehran.

City

Tehran

Postal code

1985713834

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.USWR Rec.1394.157

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

150.0

ICD-10 code description

Congestive heart failure

2

Description of health condition studied

Heart failure

ICD-10 code

150.1

ICD-10 code description

Left ventricular failure

3

Description of health condition studied

Heart failure

ICD-10 code

150.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Self Efficacy

Timepoint

Before, after and two month after intervention

Method of measurement

heart Self-Efficacy Questionnaire, Sullivan

Secondary outcomes

1

Description

Self care behaviore

Timepoint

Before, after and two month after intervention

Method of measurement

European questionnaire self-care behaviors in heart failure

2

Description

Health status

Timepoint

Before, after and two month after intervention

Method of measurement

Health Status Questionnaire cardiomyopathy Kansas City

Intervention groups

1

Description

The intervention group 2 (control group) received only usual care. This group completed with the group1, in parallel before, after and two months after intervention self-efficacy , heart failure self-care behaviors and health status questionnaires. At the end of two months of study and after completion of the investigation, according to moral considerations in research was placed management program to provide training manual intervention group 2.

Category

Lifestyle

2

Description

Chronic disease self-management program schedule at Stanford University. In this study, were divided research unit for random assignment into using random blocks in two intervention group 1 (test group) and intervention group 2 (control group). The intervention group 1 was held for the implementation of the program into three sub groups of 15 and self-management program in six weeks and each week a meeting for 90 minutes for each subgroup separately. Education was face to face and group. The content of the program include knowledge of disease, therapies, problem-solving process, diet, exercise, stress control and relaxation. Educational content were similar for all subgroups in intervention group. The opportunity to implement self-management program at home two months were given to them And were given self-reporting checklist to them. At this time, the researcher monitored the phone calls of the implementation of the program. The control group received only usual care. At the end of control group also were given an educational booklet. questionnaires was completed at three points in time: Before, after and two months after intervention and the data analyzed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Tayebe Aghamohamadi

Street address

22 Bahman Hospital, Emam Street, Neyshabour

City

Neyshabour

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Social Welfare and Rehabilitation Sciences, Tehran

Full name of responsible person

Khankeh Hamid Reza

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University of Welfare and Rehabilitation Sciences, koodakyar Blvd, Daneshjoo Stre, Evin Ave, Tehran.

City

Tehran

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, University of Social Welfare and Rehabilitation Sciences, Tehran

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

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Tayebe Aghamohamadi

Position

Master of Nursing Elderly

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