

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effect of self-management education using Integrated and Compact disc approaches on quality of life in patients with chronic heart failure

Protocol summary

Summary

The purposes of this study is to compare the effectiveness of self-management education using Integrated and Compact disc approaches on quality of life in patients with chronic heart failure. In this randomized controlled trial will conduct in 120 subjects with chronic heart failure in Shahid Rajaei hospital in Tehran, Iran that 40 of them chose to join the Integrated education (In addition to conventional methods, Teaching strategies Lecture and the use of PowerPoint, photos, video in three consecutive sessions) group, 40 of them chose to join Compact (Education through CD) disc education group and 40 of them chose to join control (usual care) group. Two questionnaires will use to collect the data, which is the demographic questionnaire, and the quality of life questionnaire (Minnesota Living with Heart Failure Questionnaire). To investigate the effectiveness of the intervention, the collected data before and after 3 months follow up will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015032021521N1**

Registration date: **2015-05-23, 1394/03/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

Name

Alireza Abbasi Hosseinabadi

Name of organization / entity

Iran University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of self-management education using Integrated and Compact disc approaches on quality of life in patients with chronic heart failure

Public title

Effect of self-management education on quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; Confirmed diagnosis of heart failure by the physician (in records); Non-acute conditions (conditions for learning); The absence of sensory - conceptual problems; Ability to communicate and to read and write; The ability to use a computer by a patient or family member; Married

people; Living with a family member (spouse, child)
Exclusion criteria: Lack of attend one of the training sessions for the experimental groups and the lack of willingness to continue participation in the study for both groups.

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

tehran

Postal code

Approval date

2015-04-11, 1394/01/22

Ethics committee reference number

107/105/94/3

Health conditions studied

1

Description of health condition studied

Chronic heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

Primary outcomes

1

Description

Quality of Life

Timepoint

Three months after the intervention.

Method of measurement

Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Secondary outcomes

empty

Intervention groups

1

Description

Self-management education through an integrated approach: The purpose of Self-management education through an integrated approach is combination of lecture, question and answer, using PowerPoint, pamphlets, photos and videos with conventional training methods (face to face training and provide an educational pamphlet discharge). The content of the training includes anatomy and physiology of the heart, the introduction of chronic heart failure, risk factors, symptoms, disease management, diagnostic approach, diet, proper exercise, drug therapy and drug reactions, control of blood pressure, body mass index calculation method that by researcher in groups up to 10 persons (with the patient and one of his companions) for 45 to 60 minutes in three consecutive sessions offered.

Category

Other

2

Description

Self-management education with CD: The CD is designed to teach self-management. The content of the CD includes anatomy and physiology of the heart, Presentation of chronic heart failure, risk factors, symptoms, disease management, diagnostic approach, diet, proper exercise, drug therapy and drug reactions, blood pressure control method, the method of calculation BMI, videos, photos and animation training in patients with chronic heart failure. Researcher in a 20-15 minute sessions for patients and their companions on the CD-ROM training and asked them and their families use it after discharge at home during the Period of three months.

Category

Other

3

Description

Control group: received conventional training

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei Cardiovascular, Medical & Research Center

Full name of responsible person

Alireza Abbasi Hosseinabadi

Street address

Shaheed Rajaei Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School Of Nursing of Iran Medical Center

Full name of responsible person

Professor Forough Rafii

Street address

Rashid Yasemi Street

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

School Of Nursing of Iran Medical Center

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

Iran University of Medical Sciences

Full name of responsible person

Alireza Abbasi Hosseinabadi

Position

Master degree

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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00

Fax

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Web page address

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