

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of nursing care package on medical expenditures in heart failure patients

Protocol summary

Study aim

Providing executive guidance to reduce the cost of care for heart failure patients

Design

Randomized clinical trials with parallel groups, not blind, uncontrolled, multi-centered.

Settings and conduct

The present study is a randomized clinical trial with intervention and control groups in Amiralmomenin Hospital and Amir Kabir Hospital in Arak among patients with heart failure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the desire to participate in the study; detection of heart failure according to a cardiologist; passed at least 6 months of diagnosis of heart failure; 40 to 75 years old; having a mobile phone equipped with Telegram software; reading and writing skills; having a phone at home Exclusion criteria: unwilling to participate in the study; hearing and speaking problems; history of mental disorders

Intervention groups

Intervention group: patients at the time of admission will receive care package includes face-to-face training for up to 30 minutes in the CCU and PCCU wards of the Amir Kabir and Amiralmomenin hospitals. The care package also includes phone follow up two weeks, one month, and two months after discharge. Control group: control group samples do not receive any interventions, but after completion of the intervention, the training package will also be available to them.

Main outcome variables

Caring costs in patients with heart failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180101038172N1**

Registration date: **2018-02-18, 1396/11/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-18, 1396/11/29**

Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

Name

Hamid Reza Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

h.heidari@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing care package on medical expenditures in heart failure patients

Public title

The effect of nursing care package on medical expenditures in heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study
 Detection of heart failure according to a cardiologist
 Passed at least 6 months of diagnosis of heart failure
 40 to 75 years old
 Having a mobile phone equipped with Telegram software
 Reading and writing skills
 Having a phone at home

Exclusion criteria:

Unwillingness to participate in the study
 Hearing and speaking problems
 History of mental disorders

AgeFrom **40 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

After explaining the method of work and the goals of the research and obtaining informed consent, the participants are randomly assigned to two groups of intervention and control by permuted block randomization.

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**

Ethics committee of Arak University of Medical Sciences

Street address

Alamolhoda St, Rah ahan Sq

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes**1****Description**

Treatment costs for patients with heart failure

Timepoint

Two weeks, one month and two months after the discharge

Method of measurement

Questionnaire made by researcher

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patients in the intervention group receive a care pack at the time of admission including face-to-face training for 30 minutes. The session was taught about how the heart works, the nature of the disease, the importance of drug and nutrition, and the change in lifestyle, the continuation of home treatment, the necessary skills for self-care, stress and its control methods, and the reasons for re-admission and its control methods. Gets Then a booklet containing the need for drug compliance, diet and lifestyle modifications are given at the time of discharge.

Category

Lifestyle

2**Description**

Control group: samples of the control group are patients who, according to the usual routine of the hospital, receive training on how to use drugs, diet and lifestyle modifications, and their nurse-training form is completed. It should be noted that in order to observe the ethical aspect of the study, after the end of data collection, the training book will be provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir-al-momenin Hospital
Full name of responsible person
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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Hamidreza Heydari
Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.

When the data will become available and for how long

The beginning of the access period is 24 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable

Hamidreza Heydari, MSc Student of Nursing, Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Arak, Iran. E-mail address: h.heidari@arakmu.ac.ir

What processes are involved for a request to access data/document

After receiving the email from the requester, the information will be sent within 5 to 10 business days.

Comments