# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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
**Age**
From **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**
IR.ARAKMU..REC.1396.223

## 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**
Abolfazl Mohtarami
**Street address**
Basij Sq. Sardasht Region
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3601
**Email**
it-amiralmomenin@arakmu.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**
Amir Kabir Hospital
**Full name of responsible person**
Alireza Kamali
**Street address**
Alamolhoda St. Rah ahan Sq.
**City**
Arak
**Province**
Markazi
**Postal code**
3819693345
**Phone**
+98 86 3313 4715
**Email**
info@arakmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Mohammad Arjomandzadegan
**Street address**
Basij Sq. Sardasht Region
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3638
**Email**
Rsearch@arakmu.ac.ir
**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**
MSc Student of Nursing
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Basij Sq. Sardasht Region
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3505
**Email**
z.zeinali@arakmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Hamidreza Heydari
**Position**
MSc Student of Nursing
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Basij Sq. Sardasht Region

**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3505
**Email**
z.zeinali@arakmu.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Hamidreza Heydari
**Position**
MSc Student of Nursing
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nursery
**Street address**
Basij Sq. Sardasht Region
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3417 3505
**Email**
z.zeinali@arakmu.ac.ir

## 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**