# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of education by smartphone-based application on self-care behaviors in patients with heart failure

## Protocol summary

**Study aim**
Improve self-care behaviors in patients with heart failure
**Design**
Randomized controlled clinical trial
**Settings and conduct**
Patients admitted to ccu or post ccu will be investigated. Then, 110 patients with eligibility criteria will be selected using the sequential method after signing written informed consent form. Then patients will be allocated into two groups: intervention and control.
**Participants/Inclusion and exclusion criteria**
Having a smartphone or tablet under the Android system can be installed on the application and can be used. Having a weak to moderate self-care based on self-care questionnaire for European cardiac insufficiency. Having ages 18 to 65 years. In class 2 and 3 of HF classes.
**Intervention groups**
Patients in the control group will be under the routine care of the hospital and patients in the intervention group will receive a smartphone application in addition to the usual care of the application program
**Main outcome variables**
Self-care behaviors

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20171225038069N1**
Registration date: **2018-07-22, 1397/04/31**
Registration timing: **prospective**

Last update: **2018-07-22, 1397/04/31**
Update count: **0**
**Registration date**
2018-07-22, 1397/04/31

**Registrant information**
**Name**
Nahid Kiyarousta
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-07-23, 1397/05/01
**Expected recruitment end date**
2019-02-20, 1397/12/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of education by smartphone-based application on self-care behaviors in patients with heart failure

**Public title**
Effect of smartphones applications on heart failure
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients of two groups should not be under any investigation or research Having a smartphone or tablet under the Android system where the application can be installed and capable of using it Having fluency in Persian The patient is admitted at least once due to Heart Failure disease. Patients should be admitted by a

physician due to an exacerbation of heart failure Having a weak to moderate self-care based on self-care questionnaire for European heart failure Having ages 18 to 65 years Having class 2 and 3 in Heart Failure classes Patients have been admitted for an exacerbation of heart failure to the hospital and are not at the compensatory phase of the disease. Not having any other chronic disease that requires frequent hospitalization, such as cancer, severe kidney disease and dementia

**Exclusion criteria:**

The patient's admission for any reason other than the illness studied

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples were allocated to the intervention and control groups using the block randomization method with the block size of four.

**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 Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway

**City**

Tehran

**Province**

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**Postal code**

1449614535

**Approval date**

2017-08-23, 1396/06/01

**Ethics committee reference number**

IR.IUMS.FMD.REC 1396.9411449006

## 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**

self care

**Timepoint**

Measure self-care (before intervention) and 3 months after using the application

**Method of measurement**

European self-care questionnaire for patients with heart failure (12 items) Jarasma et.al

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Patients in the intervention group will receive an Android application in addition to the usual care of the application on the smartphone. This application is a software application that can transmit educational content in the form of media, text, audio and video, and so on,besides training, the ability to evaluate patient symptoms, medication reminders, appointments with a doctor, and tests. In addition, patients can contact the care team through this program and interact with the questions they are asked to receive and receive answers through this process. A 20-30 minute session will be taught to patients admitted to the cardiac care unit on how to use this program. The following day, the hospital will be contacted and questions will be asked about the patient's problems in using this application to resolve potential problems. Every week for 6 weeks, and after that, the patient will be in contact for 10 to 15 minutes for a further 2 months with the patient, and will emphasize the need for the program to be used. The daily use of the studied patients will be reviewed by the application program and will provide health messages and incentives for the program to be applied. In this way, the interaction between patients and peer reviewers will be done, which will be tailored to the needs of patient sand their conditions. Patients will use this program for 3 months, after a period of five months, they will contact the patients in the intervention group and the control group will be contacted with the help of the peer reviewer. It will be useful for them to use the European

Questionnaire Complete and send to the reader. A smartphone-based application for patients in the control group is also sent after completion of data collection to be installed.

**Category**

Other

**2**

**Description**

Control group: patients in the control group will be placed under the common care of the hospital.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Rasoul hospital

**Full name of responsible person**

Nahid Kiaroosta

**Street address**

Rasoul hospital., Mansoury Ave., Niyayesh Ave., Sattar khan Ave

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**2**

**Recruitment center**

**Name of recruitment center**

Firouzgar Hospital

**Full name of responsible person**

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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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**

Iran 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**

Iran University of Medical Sciences

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**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Critical Care Nursing

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available