

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### A Study of the Effectiveness of the HEART Application Use on Clinical Outcomes and Quality of Life of Patients with Heart Failure

#### Protocol summary

##### Study aim

Increasing the quality of life and controlling the symptoms in patients with congestive heart failure

##### Design

Randomized, double-blind, parallel group controlled trial using balanced block randomization table on 40 patients with congestive heart failure

##### Settings and conduct

40 patients with congestive heart failure referring to cardiology clinic of Rasool-E-Akram hospital who meet the inclusion criteria will enter the study, and then will get divided into two case and control groups using balanced block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : diagnosis of congestive heart failure according to American Heart Association (AHA) guidelines age between 50 to 75 years old diagnosis of the disease at least one year prior to the study having access to smartphone and knowledge of using mobile applications Exclusion criteria: diagnosis of heart failure with preserved ejection fraction having underlying diseases such as HIV, cirrhosis, kidney transplant,... not having access to a smartphone, or not being able to use one.

##### Intervention groups

Patients meeting the inclusion criteria will be divided into two case and control group and will be followed for 6 months. The HEART application will be installed on the smartphone of patients in the case group, will be instructed to use it daily on a regular basis. Patients of the control group will receive the pdf file and will be told to contact the physicians as needed.

##### Main outcome variables

Controlling the clinical symptoms; preventing disease progress, and preventing hospitalization due to decompensation of heart failure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210427051097N1**

Registration date: **2022-06-15, 1401/03/25**

Registration timing: **retrospective**

Last update: **2022-06-15, 1401/03/25**

Update count: **0**

##### Registration date

2022-06-15, 1401/03/25

##### Registrant information

##### Name

Arefeh Zavari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4447 0530

##### Email address

zavari.hd@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Study of the Effectiveness of the HEART Application Use on Clinical Outcomes and Quality of Life of Patients with Heart Failure

**Public title**

Evaluation of the using HEART Application in Patients with Heart Failure

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having Heart Failure According to AHA Criteria Age between 50 to 75 years old At Least 1 Year has Passed from Diagnosis Having Access to a Smartphone and knowledge to Use it

**Exclusion criteria:**

Lack of Access to Smartphone Having Heart Failure with Preserved Ejection Fraction Having Rare Disease such as HIV, Liver Transplantation and ...

**Age**

From **50 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After signing an informed consent, patients will be recruited in the study. This study will have two assigned groups (treatment or T, and control or C). A block with the size of 4 patients will be defined, and all possible balanced combinations of assignment within the blocks will be calculated. Then, patients will be assigned to one of the two groups, using a random number table, by a third person (rather than the physician and the researcher).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants: Each target and control group participant will receive a file for the assigned intervention (application or the PDF booklet). If a patient needs companionship to receive the file, only one companion will be allowed in the room. To sum up, only the interventionist, the patient, and a maximum of one companion will be present in the room. Patients will be assigned visit times with a 30-minute interval to prevent crowding. With each patient being visited at separately assigned visit times, the goal of a minimum chance of patients seeing each other will be achieved. Patients will receive the required explanations to avoid talking to the physician about the assigned intervention, and in case of speaking of it, only refer to it as the "intervention". After receiving the file (target or control), patients will leave

the location. Clinical caregiver: The physician will be blinded to the intervention type in all stages of the intervention including visiting and follow-up till the end of the study. The physician will be instructed to avoid speaking about the type of intervention to the patients, and in case of talking about it, refer to it as the "intervention". Data analyst: After gathering all data, the data analyst will receive a version of the data with blinded intervention groups and with no personal information. Then, the data analyst reports the results. Interventionist: The interventionist will be aware of the intervention groups and type of the intervention in both groups. Application developer: Designing the application will be done before patient selection and randomization. The developer will be blinded to the intervention groups until the end of the study. All people involved in the study will be banned from sharing information regarding the assigned groups until the end of the study.

**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**

NO 52, first west 12 metri, second south 16 metri, west chaharbagh Blvd, south Jannat Abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1474713361

**Approval date**

2021-02-21, 1399/12/03

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.765

**Health conditions studied****1****Description of health condition studied**

congestive heart failure

**ICD-10 code**

I50.32

**ICD-10 code description**

Chronic diastolic (congestive) heart failure

## Primary outcomes

### 1

#### Description

score of SF-36 (Short-Form-36) questionnaire

#### Timepoint

calculating the score of SF-36 questionnaire during a 6 month period

#### Method of measurement

using SF-36 questionnaire

### 2

#### Description

score of MLHFQ questionnaire (Minnesota Living with Heart Failure Questionnaire)

#### Timepoint

calculating the score of MLHFQ questionnaire during a 6 month period

#### Method of measurement

using MLHFQ questionnaire

### 3

#### Description

score of EHF.ScB-9 questionnaire (European Heart Failure Self-care Behavior Scale-9)

#### Timepoint

calculating the score of EHF.ScB-9 questionnaire during a 6 month period

#### Method of measurement

using EHF.ScB-9 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: using HEART APPLICATION . We are trying to encourage patients with heart failure to better control their weight, blood pressure, and diet, improve their compliance to medication, and increase their physical activity level. We hypothesize that this intervention and these lifestyle modifications will prevent disease progression, hospitalization due to decompensated heart failure, and death. This application will be used daily. Every morning, each patient will enter the information regarding their symptoms including leg swelling, dyspnea, night-time sleep quality, etc., along with the other features of the application. After entering the information, the patients will see their performance based on the score they earn by answering the questions. The performance will display with different colors. If the displayed color is red, the patient must refer to the hospital for seeking medical care, or call the third person of the study for guidance. Also, a reminder will be set to remind the patients twice daily, once in the morning and once at night, to take their medications.

The aim of the study is to help the patients adhere to the lifestyle modifications, and no new medication or substance is used in the study. We also do not interfere or change the medication regimen of the patients, and they will take their medications as prescribed by their doctor.

#### Category

Lifestyle

### 2

#### Description

Control group: transferring a pdf file containing healthy life style recommendations for congestive heart failure patients, to the smartphone of patients of the control group. To provide a similar file, the patients in the control group will receive an educational file containing 180 short sentences (lifestyle modification tips), and they will be suggested to read one sentence each day, and try to adapt to that. Same as the intervention group, the patients will not receive any medication or substance. Also, no change will be made in the medication regimen of the patients, and they will take their medications as prescribed by their doctor.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrat Rasool-e-Akram Hospital

##### Full name of responsible person

Arefeh Zavari

##### Street address

Rasool-e-Akram Hospital, Mansouri Ave, Sattarkhan Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

zavari.hd@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyyed Abbas Motevalian

##### Street address

Iran University of Medical Science, Hemmat Exp, Tehran

**City**  
Tehran  
**Province**  
Tehran  
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1449614535  
**Phone**  
+98 21 86701  
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admins@iums.ac.ir

**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  
**Full name of responsible person**  
Morteza Hassanzadeh  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
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Rasool-E-Akram Hospital, Niyayesh Ave, Sattarkhan Blvd, Tehran  
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**Province**  
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**Postal code**  
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**Phone**  
0098 21 64351  
**Email**  
drmhxim@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences

**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
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1445613131  
**Phone**  
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drmhxim@gmail.com

## 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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data of this study will be available, publishable and reachable upon request, with respect to patients' privacy and without revealing their names or personal information.

**When the data will become available and for how long**

Access period starts six months after the results are published

**To whom data/document is available**

Employees of academic institutions and people working

in industry

**Under which criteria data/document could be used**

Only those in charge will have access to the data.

**From where data/document is obtainable**

Arefeh Zavari Phone Number: 0098 21 9214341399

Email Address: zavari.hd@gmail.com

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

Introduce yourself and your job position Authentication Submission of a letter from the legal authorities to the responsible person Review the application for a maximum of 6 months Sending requests after a written commitment not to misuse information scientifically and financially

**Comments**