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 s 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
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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

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Postal code
1449614535
Phone
+98 21 86701
Email
adminsite@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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Morteza Hassanzadeh
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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
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