

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of using smartphone-based applications on medication adherence and quality of life in people with heart failure

Protocol summary

Summary

The main objective of the study is to investigate the effect of smartphone applications on the quality of life and drug compliance of people with heart failure in ccu and post ccu. 2. this study as a randomized clinical trial with the control group. 3. How to do : 120 patients with heart failure that randomly divided into control and intervention groups. 4. Patients aged 18-65 years with heart failure have both class 2 and 3 heart failure should be approved by their physician. These people should have at least a literacy of reading, writing, and using smartphone or tablet. 5- Interventions: In the intervention group Routine treatment reception, plus the application installation on the patient's smartphone Follow-up of the program and sending motivational messages on the education of heart failure patients for 3 months. The usual care will be done to the control group in 3 months. 6- The variable is the primary outcome of quality of life and drug compliance

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061934647N1**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Mahboube Davoudi

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using smartphone-based applications on medication adherence and quality of life in people with heart failure

Public title

The effect of using smartphone applications (software) on medication adherence and quality of life in people with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Having age of 18 to 65 years : Patients of two groups should not be under any investigation or research: Having at least a reading and writing literacy :In 2 and 3 HF classes'. Patients should be admitted by a physician due to an exacerbation of heart failure. : Patient should has a smartphone or tablet with Android system that the application can be installed on it : The

ability to use the smartphone and learn how to use the application by the patient : Not having any other chronic disease that requires frequent hospitalization, such as Cancer, Severe Renal Disease and Dementia! Gain score less than 8 from the Morisky scale MMAS-8 (poor and moderate drug compliance) : Earn more than 24 scores from" MLHFQ" (low and moderate quality of life).
Exclusion criteria: Failure to use the application for one week (each patient will be log in with his own password and will be monitored) :Expired : Hospitalization for any cause other than the illness studied, such as recent surgery

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: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Science, Shahid Hemmat highway, Tehran

City

Tehran

Postal code

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.IUMS.FMD.REC1396.9411449003

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

2

Description of health condition studied

Congestive heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

3

Description of health condition studied

Left ventricular failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

4

Description of health condition studied

Heart failure, unspecified

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

quality of life

Timepoint

before the intervention AND 3 month after intervention

Method of measurement

MLHFQ Scale

2

Description

medication adherence

Timepoint

before the intervention AND 3 month after intervention

Method of measurement

Morrisky Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in trial group, the application will be installed on the patient's smartphone, and then, for 3 months, patients will receive motivational messages and care messages for the management of the therapeutic and drug therapy of heart failure. Questionnaire of Minnesota's heart failure and Morisky Medication Adherence Scale will be completed by the two groups before and three months after the onset of the intervention.

Category

Lifestyle

2

Description

Control group :Patients will receive only current training, which includes oral explanations for illness and pamphlet, and then the Minnesota and Morisky questionnaires will be completed before of Intervention and three months later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Mashhad

Full name of responsible person

Mahboube Davoudi Kang Sofla

Street address

Daneshgah St. , Mashhad , Iran

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Of Research, Iran University of Medical Sciences

Full name of responsible person

Seyyed Ali Javade Moosavi

Street address

Iran University of Medical Science, Shahid Hemmat highway, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor Of Research, Iran University of Medical

Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing & Midwifery of Iran University of Medical Science

Full name of responsible person

Mahboube Davoudi Kang Sofla

Position

Post Graduate Student in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty