Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of using smartphone-based applications on medication adherence and quality of life in peopole 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 shoud 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

Country

Iran (Islamic Republic of)

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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 peopole with heart failure

Public title

The effect of using smartphone applications(software)on medication adherence and quality of life in peopole 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 Morrisky 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 Univercity 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
150

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 Morrisky 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

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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 Univercity 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
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Position
Post Graduate Student in Nursing

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Person responsible for scientific inquiries

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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