

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of education with using mobile software on medication adherence in patients' with hearth failure

Protocol summary

Study aim

Investigating the effect of education with using mobile software on medication adherence in patients' with hearth failure

Design

In this study, 80 patients with heart failure who meet the conditions for entering the study will be included in the study and will be randomly assigned to two intervention and control groups using color cards. In the intervention group, clients and their caregivers. In addition to receiving face-to-face educational materials and pamphlets, training will also be provided using mobile software, and in the control group of clients and their caregivers, educational materials will be provided face-to-face and pamphlets.

Settings and conduct

The present research will be carried out experimentally and by randomized clinical trial method in Ayatollah Taleghani Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Criteria for entering the research: suffering from heart failure, age over 18 years, access to a mobile phone with the ability to install software, reading and writing literacy

Intervention groups

In the intervention group, in addition to receiving face-to-face educational materials and pamphlets, clients and their caregivers will also be trained using mobile software.

Main outcome variables

medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N4**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Raziyeh Ghafouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 4520

Email address

ghafouri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of education with using mobile software on medication adherence in patients' with hearth failure

Public title

The effect of education with mobile software on medication adherence in patients' with hearth failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from heart failure
Age above 18 years
access to a mobile phone with the ability to install software
Literacy for reading and writing

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Before the start of the intervention, 40 white and 40 black cards are prepared and for randomization, all the cards are placed in an envelope, then the cards are drawn randomly and numbers from 1 to 80 are drawn in order. is placed Then each card is placed in a sealed envelope and its number is written on the card, and when each patient enters the study, a special envelope will be opened for him from 1 to 80 and assigned to the intervention and control group.

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**

Shahid Beheshti University of Medical Sciences
(Research Ethics Committees)

Street address

Shahid Arabi Street, Yemen Street, Shahid Chamran
Highway, Tehran, Iran

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Province

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Postal code

198571744

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.SBMU.SME.REC.1401.103

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**

medication adherence

Timepoint

At the time of discharge

Method of measurement

medication adherence questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, in addition to receiving face-to-face educational materials and pamphlets, clients and their caregivers will also be trained using mobile software. At the time of visiting the clinic, before hospitalization or during hospitalization, the link to receive the software through barcode will be provided to clients and after installing the software on the phones of the clients and their companion, the software will be introduced to them. In the software, the conditions of hospitalization in the department, the officials and the physical space of the department, heart diseases, measures, drugs, diet of heart patients, and the way of discharge and post-discharge care are described.

Category

Other

2**Description**

Control group: the clients and their caregivers will be provided with face-to-face educational materials and pamphlets.

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

(Ayatollah) Taleghani Educational Hospital

Full name of responsible person

Raziyeh Ghafouri

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Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Raziyeh Ghafouri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Shahid Beheshti 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Raziyeh ghafouri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for updating data**Contact****Name of organization / entity**

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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

By email to the corresponding author

When the data will become available and for how long

En After the publication of the article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

More research

From where data/document is obtainable

By email to the corresponding author

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

By email to the corresponding author

Comments