

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of family-center self-care training through smartphones on health literacy and self-care status of patients with heart failure

Protocol summary

Study aim

Determining the effect of family-oriented self-care education through smartphones on health literacy and self-care status of heart failure patients in Jahrom city in 2023

Design

The clinical trial has a control group, with parallel groups without blinding, randomized on 60 patients, which will be written in a list for randomization, and one in the middle will be assigned to the intervention and control groups.

Settings and conduct

In this research, researchers first refer to Imam Reza Art Clinic and Clinic, located in Jahrom City, and add the patients who meet the inclusion criteria to the study with the help of a cardiologist. After completing the samples and performing randomization, a group will be formed for the families of the patients in the intervention group in ITA, and training sessions, which include three sessions, will be sent to them on a weekly basis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study
Age 18 to 65 years
Not having known psychological problems
Being in the 2nd class of heart failure as diagnosed by a cardiologist
Having a primary caregiver (such as a spouse or children)
The ability of primary caregivers to access smartphones
Being literate in reading and writing
Exit criteria: Absence in more than two training sessions
death of the patient

Intervention groups

In the intervention group, self-care training will be sent to the first-class members of the patients who have access to a smartphone in the Eita messenger, but the control group will only undergo routine training provided to them by the attending physician.

Main outcome variables

Education via smartphone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210114050037N2**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Ali asghar Rahmanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 3628

Email address

lynurse8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-center self-care training through smartphones on health literacy and self-care status of patients with heart failure		Fars	
Public title		Postal code	
The effect of family-center self-care training through smartphones on health literacy and self-care status of patients with heart failure in Jahrom city in 2023		7414846199	
Purpose		Approval date	
Education/Guidance		2023-08-21, 1402/05/30	
Inclusion/Exclusion criteria		Ethics committee reference number	
Inclusion criteria:		IR.JUMS.REC.1402.054	
Willingness to participate in the study Age 18 to 65 years		Health conditions studied	
Not having known psychological problems Being in the 2nd class of heart failure as diagnosed by a cardiologist		1	
Having a primary caregiver (such as a spouse or children) The ability of primary caregivers to access smartphones Being literate in reading and writing		Description of health condition studied	
Exclusion criteria:		Heart Failure	
Absence in more than two training sessions death of the patient		ICD-10 code	
Age		I50.1	
From 18 years old to 65 years old		ICD-10 code description	
Gender		Left ventricular failure	
Both		Primary outcomes	
Phase		1	
N/A		Description	
Groups that have been masked		health literacy	
No information		Timepoint	
Sample size		Measuring health literacy before the implementation of the educational intervention and one month after the implementation of the educational intervention	
Target sample size: 60		Method of measurement	
Randomization (investigator's opinion)		Heart failure health literacy questionnaire	
Randomized		2	
Randomization description		Description	
Random allocation of samples is done using the block method and through statistical software.		self-care status	
Blinding (investigator's opinion)		Timepoint	
Not blinded		Measuring the state of self-care before the implementation of the educational intervention and one month after the completion of the educational intervention	
Blinding description		Method of measurement	
Placebo		Questionnaire to measure the self-care status of patients with heart failure	
Not used		Secondary outcomes	
Assignment		empty	
Parallel		Intervention groups	
Other design features		1	
Secondary Ids		Description	
empty		Intervention group: An active member of the family who can participate in education is selected. It means the patient's family members, child, spouse, or one of the causal or relative relatives who accompany him in the treatment process in order to get better and improve his level of health. This person should be more capable than others in terms of companionship, decision-making power, giving importance, and understanding the	
Ethics committees		2	
1			
Ethics committee			
Name of ethics committee			
Ethics committee of Jahrom University of Medical Sciences			
Street address			
At the end of Ostad Motahari Boulevard			
City			
Jahrom			
Province			

patient's condition. The educational content in this group is fully provided to the active member of the family and he is asked to implement the learned instructions for the patient. After selecting the first-degree relatives, a group will be formed for all patients of the intervention group in a virtual space (preferably Eita software) and all the members of the group will be members of it. The trainings are uploaded in the form of audio files on a certain day of the week in the group and family members are given the opportunity to review it. One to two days after uploading the file, the researchers communicate with the family members by phone to make sure that they have listened to the material and given appropriate feedback and transferred it to the patient. Number of training sessions 3 sessions and duration Each session will be 20 to 30 minutes. In addition, the group is open during the meetings and family members will have the opportunity to discuss and express their concerns.

Category

Other

2

Description

Control group: During the time that the patients are being trained through the smartphone, the patients of the control group only receive routine training provided by the doctor and nurses and are not under any training by the researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Honari Specialty and sub specialty clinic

Full name of responsible person

Ali asghar Rahmanian kushkaki

Street address

Ostad Motahari Boulevard, above Ostad Motahari Hospital, corner of the alley25

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

kavoos solhjoo

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Solhjoo@JUMS.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Ali asghar Rahmanian kushkaki

Position

Non faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available