

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effects of a web-baseline family educational and supportive program on adherence of treatment and readmission in patients with heart failure after discharge from Shahid Chamran Medical Education Center

Protocol summary

Study aim

Determining the effects of a web-baseline family educational and supportive program on adherence of treatment and readmission in patients with heart failure after discharge from hospital

Design

Clinical trial with intervention and control group, randomized. With 32 patients in each group

Settings and conduct

The researcher, refer to Shahid Chamran Medical Education Center in Isfahan, select patients with heart failure who have inclusion criteria and randomly divide them into two groups: intervention and control. For intervention group, the program is implemented but control group does not receive any intervention. Then data is collected by questionnaire and analyze.

Participants/Inclusion and exclusion criteria

Age of 30-75 years, Diagnosis of Heart Failure, no history of other chronic diseases except cardiovascular risk factors (diabetes, hypertension, and hyperlipidemia), grade II and III of heart failure based on American Heart Association Classification, having at least one family member capable of receiving the program

Intervention groups

The intervention group receive educational program after discharge from the hospital. The educational program include sending educational materials through Soroush's messenger and a weekly follow up by telephone. The control group receive only routine cares.

Main outcome variables

Adherence to therapeutic regimen; re-admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038890N1**

Registration date: **2018-08-10, 1397/05/19**

Registration timing: **retrospective**

Last update: **2018-08-10, 1397/05/19**

Update count: **0**

Registration date

2018-08-10, 1397/05/19

Registrant information

Name

Arman Khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5243 5119

Email address

khajavi.a94@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a web-baseline family educational and supportive program on adherence of treatment and readmission in patients with heart failure after discharge

from Shahid Chamran Medical Education Center

Public title

Effects of a web-baseline family educational and supportive program on adherence of treatment and readmission in patients with heart failure after discharge from hospital

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Medical diagnosis and registration of heart failure; Absence of other chronic diseases other than risk factors for heart failure (diabetes, high blood pressure, hyperlipidemia); Class II and III heart failure; Having at least one competent family member to receive the program.

Exclusion criteria:

Death Not wanting to continue cooperation Failure to receive the program in 3 consecutive days or 5 inconsecutive days

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random: Using the card number: the even numbers for experimental group and odd numbers for 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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2018-01-30, 1396/11/10

Ethics committee reference number

396843

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

Primary outcomes

1

Description

Adherence to the therapeutic regimen

Timepoint

Before the intervention and immediately after the intervention and one month after the intervention

Method of measurement

Thomas Questionnaire (2004)

2

Description

Re-admission

Timepoint

Immediately after the intervention and one month after the intervention

Method of measurement

Self-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: on the day of patients' discharge from the hospital, in an 1-hour justification session, researcher will explain for intervention group about how program is performed and how to access the content and communication channels. Then the application Soroush will be installed on the phone for the intervention group and will explain how to use it. Then the training program for the intervention group will be start from the first week after discharge and lasts for 1 month. The program consists of two parts. In the first part, the researcher will provide educational materials related to the function,

anatomy and physiology of the heart, treatment, medications and their complications, diet, activity and rest, the management of signs and symptoms and disease-related care. The content transmitted through Soroush's messenger will be provided daily to the intervention group in a text and multimedia format. 3 items on the topics listed will be sent to the intervention group daily from 9 am to 9 pm. In the second part, the intervention group will be also followed up weekly by telephone.

Category

Treatment - Other

2**Description**

Control group: This group will receive routine care.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Chamran Medical Education Center in Isfahan

Full name of responsible person

Arman Khajavi

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Isfahan- Salman Farsi Street

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

Esfahan University of Medical Sciences

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?**

No

Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mahin moeini

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Nursery

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Isfahan Hazard Jarib Street Azadegan Boulevard Alley of Banafsheh

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient information is confidential.

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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

General information about participants including age, sex, education, duration of illness and occupation, and the main outcomes including the degree of adherence to the regimen and their re-admission, are average in each group

When the data will become available and for how long

6 months after printing results

To whom data/document is available

People in the field of health

Under which criteria data/document could be used

No response

From where data/document is obtainable

Researcher (Arman Khajavi) khajavi.a94@gmail.com

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

A month after requesting information

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

Esfahan University of Medical Sciences

Full name of responsible person

Arman khajavi

Position

Student-Master

Latest degree

Bachelor

Other areas of specialty/work

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