

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

**Street address**

Isfahan- Salman Farsi Street

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Khajavi.a94@gmail.com

**Web page address**

<http://chamran.mui.ac.ir/>

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Isfahan University Of Medical Sciences

**Street address**

Hezar jerib street- Isfahan University Of Medical Sciences,

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<https://mui.ac.ir/>

**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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