

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigating the Efficacy of a combined training program on Clinical Outcome of Patients with Heart Failure

#### Protocol summary

##### Study aim

Investigating the efficacy of a combined training program on clinical outcomes on patients with heart failure in selected teaching hospitals affiliated to Shahid Beheshti University of medical sciences

##### Design

The study is a single blinded parallel clinical trial the sample size is 136 people and the samples are randomly assigned to two intervention and control groups based on block randomization.

##### Settings and conduct

A parallel clinical trial study is blinded (data analyzer). The place of study is selected educational hospitals affiliated to Shahid Beheshti University of Medical Sciences. The researcher randomly divides the patients into Intervention and control groups. The clients of the intervention group are trained for 8 weeks through messengers, in addition to providing the necessary group training in the platform of this messenger in relation to various aspects of the disease and treatment the learning assessment of the client is also done. If there is a problem during the review of the feedback, the researcher conducts remote monitoring through a phone call with the participant so that the patient is referred to a doctor if necessary.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: class 1 to 3 heart failure patients who have access to a smart phone and internet and have completed the study tool completely and do not suffer from other chronic and major disorders. Exclusion criteria: Facing severe physical problems or death during study, Hospitalization of the patient for any reason or change in treatment process

##### Intervention groups

the study consist of two intervention and control group. the intervention group will receive training and evaluation by phone and internet for 8 weeks and the control group will only received the routine care.

##### Main outcome variables

Adherence to treatment, Self care

#### General information

##### Reason for update

this update has been made regarding the contact information and address of the sampling center and the information related to the person responsible for the clinical trial.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230221057476N1**

Registration date: **2023-06-28, 1402/04/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-30, 1402/04/09**

Update count: **1**

##### Registration date

2023-06-28, 1402/04/07

##### Registrant information

##### Name

Zohreh Shahbazi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 936 372 5619

##### Email address

nrszohreshahbazi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2023-08-21, 1402/05/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the Efficacy of a combined training program on Clinical Outcome of Patients with Heart Failure

**Public title**  
Effectiveness of combined training program in patients with heart failure

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having at least 18 years old of age with confirmation of the diagnosis of heart failure Class 1 to 3 heart failure based on NYHA functional classification Access to a smart phone and the internet and the ability to use it Not suffering from other chronic and major disorders such as cancer, depression, mental disability and vision or hearing problems.  
**Exclusion criteria:**  
Facing severe physical problems or death during study Hospitalization of the patient for any reason or change in treatment process

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **136**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
it is of random block type into intervention and control groups, the list of blocks was obtained by a statistical consultant. 34 cards are created in random order from 1 to 34, each card contains a combination of 4 in 34 different envelopes. it is transparent. in order to maintain the random sequence the outer surface of the envelopes has been numbered in the same order. in this way after the arrival of each patient according to the block prepared in the previous step the patient is randomly placed in the intervention or control group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
the study was blinded and the data analyst was blinded.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Biomedical Research Shahid Beheshti University of Medical Sciences

##### Street address

Tehran, Shahid Chahmran Highway, Yaman St, Arabi St

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

#### Approval date

2023-06-22, 1402/04/01

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.247

## 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

Adherence to treatment

#### Timepoint

Before the start of the intervention and one month after the end of the intervention.

#### Method of measurement

Morisky Medication Adherence Scale

### 2

#### Description

self care in patients with heart failure

#### Timepoint

Before the start of the intervention and one month after the end of the intervention.

#### Method of measurement

European Heart Failure Self-Care Behavior Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For 8 weeks, every week in a group they will receive an educational content related to various aspects of the disease including drug treatment, diet, physical activity, etc on the platform of one of the available mass messengers, but the feedback from the content presented individually will be taken from the patients every week in the same messenger and also questions related to the symptoms experienced related to the disease during the last week will be asked to monitor the health status of the patients so that they can contact the patients if necessary. they should be taken on the phone and their clinical condition will be evaluated so that the patient can be referred to the treatment center if necessary. Patients enter the study at the time of visiting the clinic, and until the next visit, which takes an average of 2 to 3 months, during this time, the researcher does not have face-to-face training. All training communication is done and tracked on a virtual and remote platform.

#### Category

Lifestyle

### 2

#### Description

Control group: during the period of 8 weeks they will not receive any training or follow up either through messengers or through phone calls and they will be visited only if they go to the clinic in person and they will receive the necessary recommendations according to the previous routine at the time of the visit. at the end of the study and after completing the questionnaires all the content taught to the intervention group will be available to the members of the control group as well.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Modares Hospital

##### Full name of responsible person

Zohreh Shahbazi

##### Street address

Tehran, Yadgar Imam highway, Saadat Abad interasection

##### City

Tehran

##### Province

Tehran

##### Postal code

3438319987

##### Phone

+98 21 2207 4087

#### Email

nrszohreshahbazi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Tehran - Shahid Chamran highway, Yemen St. - Shahid Arabi St. - Building No. 2 - 5th floor

##### City

Tehran

##### Province

Tehran

##### Postal code

1373916632

##### Phone

+98 21 23871

##### Email

info@sbmu.ac.ir

#### 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

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Zohreh Shahbazi

##### Position

Nursing student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Faculty of Nursing, Shahid Beheshti University of Medical Sciences

##### City

Tehran

**Province**  
Tehran  
**Postal code**  
1996835119  
**Phone**  
02188655366-70  
**Fax**  
**Email**  
nrszohreshahbazi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Zohreh Shahbazi  
**Position**  
Nursing student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Faculty of Nursing, Shahid Beheshti University of  
Medical sciences  
**City**  
Tehran  
**Province**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**

Zohreh Shahbazi  
**Position**  
Nursing student  
**Latest degree**  
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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

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

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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