Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 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 out comes 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 Highqway, 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

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3438319987

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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

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1373916632

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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