Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of self-care education by teach back and multimedia method on the level of self-care, quality of life and readmission of patients with advanced heart failure

Protocol summary

Study aim

Comparison the effect of self-care education by teach back and multimedia method on the level of self-care, quality of life and readmission of patients with advanced heart failure

Design

Randomized clinical trial, continuous sampling without blinding, 120 patients, by random block method with size 6

Settings and conduct

120 patients with advanced heart failure in five CCU departments of Shahid Rajaei Cardiovascular Center in 1402 were randomly assigned to three groups of 40 people (teach back and multimedia and control group) by randomization using random blocks of size 6. Training with the same content will be carried out in two intervention groups in the evening of two consecutive days for one hour each time at the patient's bedside. Demographic questionnaire, European self-care questionnaires in heart failure and quality of life of Minnesota heart failure patients before the intervention in person and in writing, by the patient and one month later by the researcher and by phone, and the readmission of the patient (and the number of times) to The cause of advanced heart failure is also investigated. The analysis is done by SPSS24 software and statistical tests.

Participants/Inclusion and exclusion criteria

Admission: age 18 to 65 years - suffering from advanced heart failure according to the diagnosis of a cardiologist and EF less than 30% - no history of mental disorders based on the patient's self-report - no speech, hearing, cognitive and memory deficits Exit: the patient's unwillingness to continue participating in any stage of the research - the inability to communicate by phone during the follow-up period - the patient's death

Intervention groups

Self-care training in groups:teach back - multimedia - control

Main outcome variables

Self-care score and quality of life score one month after the intervention, readmission one month after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230808059079N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

mahsa satari gholami

Name of organization / entity

Shaheed Rajaie Cardiovascular, Medical & Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 4895

Email address

mahsa.satari.gh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of self-care education by teach back and multimedia method on the level of self-care, quality of life and readmission of patients with advanced heart failure

Public title

Self-care training in patients with advanced heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Patient alertness Minimum literacy Having advanced heart failure according to the diagnosis of a cardiologist and EF less than 30% Not having a history of mental disorders based on the patient's self-report Not having an education in the department of medical sciences Not having speech, hearing, cognitive and memory defects Having a smart mobile phone and being able to use it

Exclusion criteria:

The patient's unwillingness to continue participating in any stage of the research It is not possible to communicate by phone during the follow-up period death of the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the inclusion criteria, patients with advanced heart failure will be divided into three groups of 40 people based on randomization using random blocks of size 6, and the patients will be allocated to each of the two teachback and multimedia intervention groups and A control group is performed. In this way, 20 blocks of 6 by computer program CREATE A RANDOMISATION LIST will be created. (https://www.sealedenvelope.com/simple-randomiser/v1/lists) and then the samples will be placed in one of the groups in the order provided by this program (an example of a sequence of random numbers in each It consists of 6 blocks: AABBCC, ABCABC, ABACBC, ACBCAB, etc.).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Cardiovascular Medical Research Training Center

Street address

NO. 120, pars Building, marvdasht street, moalem street, shariati street, tehran

City

Tehran

Province

Tehran

Postal code

1639766669

Approval date

2023-08-05, 1402/05/14

Ethics committee reference number

IR.RHC.REC.1402.043

Health conditions studied

1

Description of health condition studied

heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

2

Description of health condition studied

Left ventricular failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

3

Description of health condition studied

Systolic (congestive) heart failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

4

Description of health condition studied
Heart failure, unspecified
ICD-10 code
I50.9
ICD-10 code description
Heart failure, unspecified

5

Description of health condition studied
Diastolic (congestive) heart failure
ICD-10 code
I50.3
ICD-10 code description
Diastolic (congestive) heart failure

6

Description of health condition studied
Combined systolic (congestive) and diastolic (congestive) heart failure
ICD-10 code
I50.4
ICD-10 code description
Combined systolic (congestive) and diastolic (congestive) heart failure

7

Description of health condition studied
Acute systolic (congestive) heart failure
ICD-10 code
I50.21
ICD-10 code description
Acute systolic (congestive) heart failure

8

Description of health condition studied
Chronic systolic (congestive) heart failure
ICD-10 code
I50.22
ICD-10 code description
Chronic systolic (congestive) heart failure

9

Description of health condition studied
Acute diastolic (congestive) heart failure
ICD-10 code
I50.31
ICD-10 code description
Acute diastolic (congestive) heart failure

10

Description of health condition studied
Chronic diastolic (congestive) heart failure
ICD-10 code
I50.32
ICD-10 code description
Chronic diastolic (congestive) heart failure

11

Description of health condition studied
Acute on chronic diastolic (congestive) heart failure
ICD-10 code
I50.33
ICD-10 code description
Acute on chronic diastolic (congestive) heart failure

Primary outcomes

1

Description
Self-care score
Timepoint
Before the start of the intervention, 30 days after the intervention
Method of measurement
European questionnaire of self-care behavior in heart failure

2

Description
Quality of life score
Timepoint
Before the start of the intervention, 30 days after the intervention
Method of measurement
Questionnaire of the quality of life of Minnesota heart failure patients

3

Description
Readmission due to heart failure (Number of readmissions)
Timepoint
One month after the patient's discharge
Method of measurement
Verbal interview with the patient/check through the hospital's HIS system

Secondary outcomes

1

Description
Not available
Timepoint
Not available
Method of measurement
Not available

Intervention groups

1

Description

The first intervention group: Self-care training in advanced heart failure patients using teach back method, 40 of these patients were trained by the researcher in the evening of two consecutive days for one hour each time in the ward where the patient is hospitalized and at the patient's bed during hospitalization. And they will receive face-to-face, interactive, question and answer, repetition and practice. After two one-hour training sessions, a pamphlet with the same content taught to the patients will be presented. The patient will be followed up by the researcher for one month after discharge, so that the researcher will call the patient once a week and review the educational content by phone and based on teach back . Self-care education includes the description of heart function, definition of heart failure, The causes and symptoms of this disease and its treatment control, drug treatment tips, diet tips, fluid intake, daily note of fluid intake and daily urine volume, how to perform physical activity, daily weighing, training to avoid smoking and alcohol consumption, annual injection Flu vaccine and other health and safety tips.

Category

Lifestyle

2

Description

The second intervention group: self-care training in advanced heart failure patients by multimedia method, 40 of these patients, training by the researcher in the evening of two consecutive days for one hour each time in the ward where the patient is hospitalized and at the patient's bedside. They will receive the prepared multimedia (film, image, audio, text, moving images, etc.) individually with the same conditions by laptop, and at the end, if the patients have any questions, they will be answered. The training content will be sent to this group in the form of a link by SMS, and the patients will receive the same multimedia training content by opening this link. This link includes the content of the self-care program: the nature of heart failure disease, its causes and manifestations, exercise and physical activity, drugs, diet, safety and health tips and lifestyle, which are presented in two sessions at the patient's bedside in the form of video, photos, audio, The text, moving images will be played, and this link will be made with the help of respected professors and advisors. After the last training session, the patient will be monitored for one month and the researcher will follow up once a week to review the multimedia content through the link sent.

Category

Lifestyle

3

Description

Control group: 40 patients with advanced heart failure will receive the department's routine training including diet, activity, bathing, daily weight control, how to take medications in the form of a two-page training booklet by the department's nurses.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shaheed Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person
fidan shabani

Street address
Shaheed Rajaie Cardiovascular Medical and Research Center, Valiasr Ave , Niayesh Intersection, Tehran

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Email
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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shaheed Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person
fidan shabani

Street address
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Email
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Web page address
http://www.rhc.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shaheed Rajaie Cardiovascular, Medical & Research Center
Proportion provided by this source
50
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
Shaheed Rajaie Cardiovascular, Medical & Research Center
Full name of responsible person
mahsa satari gholami
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
mahsa satari gholami
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mahsa.satari.gh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For the use of researchers and people who decide to help correct the lifestyle of people with advanced heart failure.

From where data/document is obtainable

E-mail: mahsa.satari.gh@gmail.com

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

Finally, the documents will be sent within two weeks.

Comments