

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of self-care education with Teach Back method on the knowledge, Practice , reducing hospital readmission and Quality of Life in heart failure patients

Protocol summary

Study aim

Effect of self-care education with Teach Back method on the knowledge, Practice , reducing hospital readmission and Quality of Life in heart failure patients

Design

The Altman Nemogram method was used to determine the sample size. The sample size was 32 in each group, accounting for 10% of the sample loss in each group, 35 individuals in each group and a total of 70 in each group. After determining the sample size (70 samples), randomly (lottery) samples were placed in two 35 individuals in the intervention and control groups. (Random allocation) (first person in the experimental group and the second one in the control group)

Settings and conduct

The samples are placed in two groups of test and control based on the criteria and individual characteristics. Patients with heart failure admitted to Baqiyatallah Hospital.

Participants/Inclusion and exclusion criteria

Age 45 to 85 years, Patients who have been diagnosed for at least six months, The rate of discharge less than 45%, With a minimum reading and writing literacy, full of alertness and fluent in Persian. Diseases that alter the patient's quality of life and any reason that may lead to a violation of entry criteria during the study.

Intervention groups

At least 3 sessions of 30 to 45 minutes will be taught on heart failure issues and self-care as Teach Back.

Main outcome variables

Improvement of knowledge, performance, reduction of referral, quality of life for patients with heart failure, ability to enter the necessary and current care for patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180930041178N1**

Registration date: **2018-12-22, 1397/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-22, 1397/10/01**

Update count: **0**

Registration date

2018-12-22, 1397/10/01

Registrant information

Name

Masoud Sirati nir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 2139

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self-care education with Teach Back method on the knowledge, Practice , reducing hospital readmission and Quality of Life in heart failure patients

Public title

Effect of self-care education with Teach Back method

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Passed at least six months of diagnosis Drainage fraction less than 45% Reading and writing literacy Complete Consciousness Fluent in Persian

Exclusion criteria:**Age**

From **45 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the sample size (70 samples), randomly (lottery) samples were allocated in two 35 individuals in the intervention and control groups. (Random allocation) (first person in the intervention group and the second one in the 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**

The Ethics Committee of the Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Molasadra st, Vanak sq

City

Tehran

Province

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Postal code

14359195371

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.BMSU.REC.1396.268

Health conditions studied**1****Description of health condition studied**

Heart Failure

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self-care education with Teach Back method

Timepoint

Measurement at three points in the beginning of the study and 2 months and 4 months after the start of the study

Method of measurement

Questionnaires on quality of life and self-care knowledge

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Training on heart failure issues and self care based on Teach Back at least 3 sessions 30 to 45 minutes

Category

Rehabilitation

2**Description**

Control group: The control group is placed under the current training of the hospital. After the training, the self-care knowledge questionnaire will be completed and the amount of the changes will be determined.

Category

Rehabilitation

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

Baqiyatallah Hospital

Full name of responsible person

Hamidreza Taghipour

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Baqiyatallah Hospital, Molasadra st, Vanak Sq

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Position

Associate professor

Latest degree

Ph.D.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alireza Jalali

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Nosrat alley, Sheykhbahaye st, Molasadra st, Vanak sq

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EPRC_Research@bmsu.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Masoud Sirati nir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

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Other areas of specialty/work

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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

Data on the level of knowledge, performance, quality of
life, personal information and other data obtained from
the information questionnaire.

**When the data will become available and for how
long**

Start the access period 6 months after publishing the
results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Respecting copyright

From where data/document is obtainable

Research Department of the Baqiyatallah University of
Medical Sciences

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

Submit a written request and confirmation of the
institution

Comments