

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Health Literacy INDEX-based Education on Knowledge, Self-care Behaviors and Readmission in Heart Failure Patients

Protocol summary

Study aim

Determining the effect of health literacy INDEX-based education on knowledge, self-care behaviors and readmission in heart failure patients

Design

Randomized clinical trial; with control group, parallel groups, without blindness

Settings and conduct

Selection of 90 patients with heart failure hospitalized and divided into two groups: control and intervention with simple random assignment. Educational intervention based on health literacy index, individual and group, with 8 to 12 patients in each group weekly with the presence of a family member in the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of heart failure diagnosis for at least one year; Have ability to read and write; Ejection fraction less than 40% diagnosed by a specialist; Class II and III of heart failure; No diagnosed psychological disorders; Hospitalization for the first time; Living with a family member. Exclusion Criteria: Dissatisfaction with the patient to continue cooperation at the time of the intervention; Patient entry to class IV heart failure; Not attending workshops even for one meeting; Patient death; Lack of access to the patient at the end of the intervention.

Intervention groups

The control group will receive care, medication orders and routine clinic recommendations. For the experimental group, individual training sessions based on the literacy index in 3 sessions based on the health literacy dimensions in the heart clinic class of the Amini Hospital of Langeroud Hospital will be performed once a week and with the presence of active member of the patient's family. Then, for exchanging information with peers, sharing information and expressing experiences, two workshops for the entire test group will be held on a weekly basis with 8 to 12 patients per group.

Main outcome variables

Self-care; knowledge about heart failure; readmission after 30 days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100725004443N27**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

Registration date

2019-05-28, 1398/03/07

Registrant information

Name

Masoumeh Zakerimoghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Health Literacy INDEX-based Education on Knowledge, Self-care Behaviors and Readmission in Heart Failure Patients

Public title

The Effect of Health Literacy INDEX-based Education on Knowledge, Self-care Behaviors and Readmission in Heart Failure Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with heart failure Patients who their illness has been diagnosed since the past year

Exclusion criteria:

Unwilling to presence in the research Age less than 18 years

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

The samples will be selected by continuous sampling and the patients will be placed in two groups of control and case by Block Balanced Randomization (BBR). By using the free web site <http://www.randomization.com/>, the assignment sequence will take place. In such a way that the number of subjects in each block will be set to 5, for the control group letter A and for the case group, the letter B will be considered, and finally by approving the Randomization Sequence in the system for 18 blocks , The assignment sequence will be created for the 90 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, allocation concealment will be considered and observed. Based on qualified samples, an Shuffling Envelope will be taken by the researcher accidentally. Finally, the random allocation method will be determined by the research samples.

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 Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Quds St, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.TUMS.FNM.REC.1397.106

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**

Self-care

Timepoint

Before the intervention and 3 weeks after the end of the intervention

Method of measurement

Self- care Heart Failure Index

2**Description**

Heart failure knowledge

Timepoint

Before the intervention and 3 weeks after the end of the intervention

Method of measurement

Dutch Heart Failure Knowledge Scale

3**Description**

Readmission
Timepoint
30 days after the end of the intervention
Method of measurement
Self report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training based on the health literacy index, using the educational manual and the general content, regarding that the dimensions of self-care includes maintenance (sustainability of physiological status), management (response to symptoms at the time of occurrence), and self-care confidence will be taught in 3 Individual 60-minute sessions and then exchange with peers, sharing information, expressing experiences in response to symptoms and self-care methods, after conducting an individual training session, two workshops for all the test group will be attended by 8 Up to 12 patients in each group on a weekly basis at the Clinic of the heart of Amini Hospital in the agreed hours and upon request by the nurse-researcher will be held. The group members will be held for at least 60 minutes. During counseling sessions, telephone counseling with patients (once a week) based on the needs of patients with content encouraging compliance with care education, hearing patient speeches and answering questions will be done.

Category

Behavior

2

Description

Control group: The control group, care, medication orders and routine clinic recommendations include advice on the timely use of medications and pamphlets associated with the disease.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Amini Hospital of Langeroud City
Full name of responsible person
Dr Seyyed Ali Mir Hashemi
Street address
Langeroud, Emam Khomeini st
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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vcr@sina.tums.ac.ir
Web page address
<http://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Roya Khorrami Estakhri
Position

Master Student of Critical Care Nursung

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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