Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of educational package on health literacy, quality of life and adherence in patients with heart failure.

Protocol summary

Study aim
Determination the effect of educational program on the health literacy and life quality and adherence in patients with heart failure.

Design
The present study is a clinical trial with a control group with parallel random groups of 60 people. The intervention is randomly assigned to two groups using a randomized block method (15 quadruple blocks).

Settings and conduct
This study is a randomized, controlled clinical trial. site of research is Kashan Shahid Beheshti Hospital and the Doctor's office in Aran and Bidgol and Kashan. The questionnaires are completed twice ; first before the training, then 4 weeks after completing the training

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of heart failure by a cardiologist, Age at least 18 years, Consent to participate in the study. Exclusion criteria: Participants' reluctance to continue the research, Acute illness or special conditions that lead to hospitalization or death, Absence of more than two sessions in training classes

Intervention groups
In the intervention group, training programs in groups of 10 people will be held in 5 sessions of face-to-face training of 30-45 minutes once a week by the first researcher in Kashan Shahid Beheshti Hospital. Control group: will not receive any intervention.

Main outcome variables
Health literacy; Qquality of life; Adherence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190606043829N1**
Registration date: **2021-08-07, 1400/05/16**
Registration timing: **registered_while_recruiting**
Last update: **2021-08-07, 1400/05/16**
Update count: **0**

Registration date
2021-08-07, 1400/05/16

Registrant information

Name
Amir Arsham Kobraei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of educational package on health literacy, quality of life and adherence in patients with heart failure.

Public title
The Effect of Education on Health Literacy, Quality of Life and Adherence in Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of heart failure by a cardiologist Age of at least 18 years Having the consent to participate in the study
Exclusion criteria:
Participants' reluctance to continue the research Acute illness or conditions requiring medical attention during the study period. Absence of more than two sessions in training classes

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method will be available (selection among patients with heart failure) and based on inclusion criteria. Then, the samples will be determined by block randomization method (15 blocks of four) and using the random number table of Allocation Random software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research (Allocation Concealment).The sample allocation ratio (Allocation 1:1) will be in two groups of intervention and control (Assignment). Then, based on the obtained blocks and in the order of allocation, the trainings will be given to the patients. Blinding will not occur in this study.

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 Kashan University of Medical Sciences

Street address
School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

City
Kashan

Province
Isfehan

Postal code
815981158

Approval date
2019-09-02, 1398/06/11

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1398.038

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50.9

ICD-10 code description
Heart failure, unspecified

Primary outcomes

1

Description
Health literacy

Timepoint
Pre-training and 4 weeks after completing the training

Method of measurement
Specific health literacy questionnaire for heart failure patients

2

Description
Quality of Life

Timepoint
Pre-training and 4 weeks after completing the training

Method of measurement
The minnesota living with heart failure questionnaire

3

Description
Adherence to treatment

Timepoint
Pre-training and 4 weeks after completing the training

Method of measurement
Madanlu treatment adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The study is a clinical trial study. Patients who are enrolled, receive a booklet that includes the following:1-When it is necessary to call or go to a doctor, 2- The main points about nutrition and fluid intake, 3- What should be done if symptoms get worse,

4-Complications that occur if you do not take medications, 5- Quality and quantity of activities throughout the day. They also attend five full-time teaching sessions that are based on the booklet. Variables will be compared before and 4 weeks after the end of training.

Category

Prevention

2

Description

Control group: The control group receive routine training, including oral instructions from the department or clinic in relation to heart failure, but they do not receive the manual and attendance training. They will receive the booklet at the end of the study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital, Kashan and Aran and Bidgol doctors' offices

Full name of responsible person

Amir arsham-kobraei

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School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

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Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Amir arsham-kobraei

Position

Master student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Other areas of specialty/work

Nursery

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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