Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Training Based on Collaborative Care Model on Health Promotion Behaviors and Self-Efficacy in Heart Failure Patients Referred to Imam Khomeini Hospital in Saghez, 2019.

Protocol summary

Study aim
The purpose was to determine the effect of collaborative care model training on health promotion behaviors and self-efficacy in patients with heart failure.

Design
Randomized clinical trial with a control group, on 60 patients. Random numbers table was used for randomization.

Settings and conduct
The setting of project is Imam Khomeini hospital in Saqez, Kurdistan. Blinding has not been done.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. The desire to participation in the study 2. Definitive diagnosis of heart failure upon opinion of cardiologist 3. Possibilty of verbal and non-verbal communication Exclusion criteria 1. Patients with heart failure in 1 and 4 stages 2. History of participation in collaborative care model training sessions

Intervention groups
In experimental group, intervention was based on a collaborative model for 3 months and structural framework, namely the steps of motivation, preparation, involvement and evaluation to motivate clients to care and participate through needs assessment, training and evaluation,however, in the control group, the intervention will not be as before, but routine care and visits every two weeks without the knowledge of the intervention group were performed by a cardiologist.

Main outcome variables
Health Promotion Behaviors and Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200411047028N1**
Registration date: **2020-06-15, 1399/03/26**
Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**
Update count: **0**

Registration date
2020-06-15, 1399/03/26

Registrant information

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Semko Mohammadzadeh

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
2019-01-21, 1397/11/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
2019-01-21, 1397/11/01

Actual recruitment end date
2019-06-22, 1398/04/01

Trial completion date
2020-01-05, 1398/10/15

Scientific title
The Effect of Training Based on Collaborative Care Model on Health Promotion Behaviors and Self-Efficacy in Heart Failure Patients Referred to Imam Khomeini Hospital in Saghez, 2019.

Public title
Collaborative Care Model in Heart Failure
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the study Definitive diagnosis of heart failure based on opinion of a cardiologist, clinical and paraclinical evidence (echocardiography) with a jump in the left ventricle less than 45% Age range 18 to 65 years Possibility of verbal and non-verbal communication
Exclusion criteria:
Unwillingness to participation with study method Patients with heart failure in 1 and 4 stages Physical or mental illness or physical disability that restricts cooperation in research project Patients with impaired level of consciousness Malignant diseases such as cancer Simultaneous participation in heart failure training programs Participation history in collaborative care model training sessions
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: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After preparing a list of all patients with inclusion criteria, a simple random sampling method of a random number table will be used. Thus members of the community are numbered from 1 to N, then a row and a column are randomly selected, the intersection of the row and the column is the starting point for sampling. From this point and at the choice of the researcher, one direction (top, bottom, right or left) will continue to select the samples until the desired number (60) is reached.Because the samples were obtained from a larger population and based on the allocation of numbers to individuals, they are placed in the table from the beginning, and even the researcher himself does not know from the beginning of the study who the assigned number belongs to, using a random table of numbers to get a sample of the homogeneous community (the community has similar conditions for entering the study) so that the chances of being selected as a sample are the same for all and the condition of random selection of the sample is observed, in the next step, after obtaining the required 60 samples, the odd and even methods will be used to assign the samples to the intervention and control groups. In this way, based on the contractual procedure, the obtained odd numbers (thirty persons obtained from the random table of numbers) are assigned to the intervention group and the obtained even numbers (thirty pairs obtained from the random table of numbers) are assigned to the control group. That is, the randomization process is first selected to select the required sample based on the random table of numbers, and in the next step, the sample obtained based on the odd and evenness of the specific number obtained from the random table of numbers is assigned to two groups of intervention and control. The purpose of this work is to observe randomness and equal chance in both stages
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 Sanandaj University of Medical Sciences
Street address
Pasdaran street, opposite the hotel Shadi
City
Sanandaj
Province
Kurdistan
Postal code
6617764671
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.MUK.REC.1398.228

Health conditions studied

1

Description of health condition studied
Heart Failure Patients
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Health Promotion Behaviors
Timepoint
Pre test- Post test
Method of measurement

Health Promotion Lifestyle Profile II (HPLP II)

2

Description
Self-Efficacy
Timepoint
Pre test- Post test
Method of measurement
Sullivan self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention gruop:in this group intervention containing education-based on collaborative care model will be performed in a systematic framework for three months in the forms of sessions a) Educational-Participatory visits and b) Follow-up visits.The educational-participatory sessions themselves include two stages of motivation and readying, which include 3 sessions with an interval of 10 days. In the first session, which is the first stage, ie the motivational stage, in a two-hour session, with the help of a clinical psychologist, cardiologist and nurse, the samples will be stimulated by identifying the needs to express the importance of client participation in the care process.In the second stage, readying, in 2 one-hour sessions with the help of cardiologist and nurse will be paid to inform clients about participatory educational visits as lectures, group discussions, powerpoint, photos and videos about heart failure, treatment process and the importance of long-term care. Follow-up visits include the last two stages of the collaborative care model, the involvement and evaluation stages. The involvement phase will include 4 sessions with two-week intervals, which is in fact a continuation of the preparation phase, with the aim of continuing the training of the care process, modifying programs, and transferring experiences. The evaluation stage is the last stage of this model, which will be in two forms of step by step and final evaluation.Step-by-step evaluation is in fact one of the first follow-up visits to improve programs and meetings and encourage the clients to continue participating in the training program. The final evaluation will be at the end of the third month and the questionnaires will be re-implemented
Category
Lifestyle

2

Description
Intervention group: In this group members, will not recieve any education or intervention, but routine care and visits to maintain minimal resemblance to the structure of participatory care sessions by a respected cardiologist will be performed once a month for two weeks and, like the intervention group, in the control group. Also, after the end of the third month, the questionnaires will
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
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Sponsors / Funding sources

1

Sponsor
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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
Sanandaj 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
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Sanandaj University of Medical Sciences
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Semko Mohammadzadeh
Position
Master student of surgical-internal nursing
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Observance of the principle of confidentiality
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
We have not
When the data will become available and for how long
We have not
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments
-