

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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. Possibility 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

Name

Semko Mohammadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 2441

Email address

semkomohamadzade@gmail.com

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

2

Description

Self-Efficacy

Timepoint

Pre test- Post test

Method of measurement

Sullivan self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: 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 receive 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

Full name of responsible person

Dr. Anwar Bahrami

Street address

Parastar street

City

Saghez

Province

Kurdistan

Postal code

6618786

Phone

+98 87 3622 0120

Email

semkomohamadzade@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

Pasdaran street, opposite the hotel Shadi

City

Sanandaj

Province

Kurdistan

Postal code

6617764678

Phone

+98 87 3366 4653

Email

maleki43@yahoo.com

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****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Semko Mohammadzadeh

Position

Master student of surgical-internal nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran street, opposite the hotel Shadi

City

Sanandaj

Province

Kurdistan

Postal code

6617764671

Phone

+98 87 3622 0997

Email

semkomohamadzade@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Nazila Olyaei

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran street, opposite the hotel Shadi

City

Sanandaj

Province

Kurdistan

Postal code

6617764671

Phone

+98 918 872 2616

Email

nazilaolyaie58@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Semko Mohammadzadeh

Position

Master student of surgical-internal nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran street, opposite the hotel Shadi

City

Sanandaj

Province

Kurdistan

Postal code

6617764671

Phone

+98 936 863 8021

Email

semkomohamadzade@gmail.com

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

-