Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of implementing a self-management program based on Model 5A on self-management ability and symptoms of heart failure in the elderly with chronic heart failure

Protocol summary

Study aim
The effect of self-management program based on 5A model on self-management ability and Symptoms of heart failure of the elderly with chronic heart failure

Design
A randomized clinical trial with community based and control group, non-blind. For randomization, the method of non-transparent sealed envelopes with random sequence will be used.

Settings and conduct
This study will be performed on the elderly with heart failure. In the intervention group, a self-management program based on Model 5A (including five stages: Assess, Advise, Agree, Assist and Arrange) will be implemented. This program includes theoretical and practical training, as a program with the pursuit of behavioral goals set during 12 weeks (in the1st week, 1st, 2 and 3 stage will performed in an individual session, in the 2 and 3 week, will performed 4 stage in a group and an individual session and the 5 stage will performed from 4 to 12 week of follow-up in Face-to-face meeting and phone call by researcher. Data will be collected using a questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: over 60 years; At least a third of secondary education; Lack of hearing and speech disabilities; Class 2 and 3 heart failure; No previous training in the field of self-management; passing at least six months of the disease; Being treated with heart failure drugs; Being in cognitive health condition. Exclusion criteria: Changes in medications taken during the intervention; Having a fatal disease (eg, cancer); Having a severe chronic illness (such as obstructive pulmonary disease, asthma);

Intervention groups
Conventional care will be performed in the control group. In the intervention group, the self-management program based on 5A model will be implemented.

Main outcome variables
Self-management ability and symptoms of heart failure in the elderly with heart failure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211122053151N1**
Registration date: **2021-12-27, 1400/10/06**
Registration timing: **prospective**

Last update: **2021-12-27, 1400/10/06**
Update count: **0**

Registration date
2021-12-27, 1400/10/06

Registrant information

Name
Darya Shojaee

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
2022-01-10, 1400/10/20

Expected recruitment end date
2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing a self-management program based on Model 5A on self-management ability and symptoms of heart failure in the elderly with chronic heart failure

Public title

The effect of self-management program based on 5A model on self-management ability and Symptoms of heart failure of the elderly

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years At least a third of secondary education the city of Babol and related countryside areas Have cognitive health based on the Abbreviated Mental Test (AMT), ability to perform daily life activities (using ADL daily life activities tool) Having second- and third-degree heart failure who have been ill for at least six months. Do not have severe chronic illness (such as obstructive pulmonary disease, asthma (affecting the severity of respiratory symptoms and fatigue)

Exclusion criteria:

Participation of individuals in similar studies Having a fatal disease (eg, cancer)

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sequentially (numbered, opaque, sealed envelopes) In this study, samples will be assigned to the intervention and control groups using sealed envelopes. In this way, 40 cards with the english letter A and 40 cards with the english letter B will be prepared and placed in sealed envelopes, and each patient will choose one of these cards at random without insertion, and if The choice of the letter A will be in the intervention group and if the card B is selected in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of social welfare and rehabilitation sciences

Street address

University of Social Welfare and Rehabilitation Sciences, koodakyar Blvd, Daneshjoo Stre, Evin Ave, Tehran.

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2021-11-17, 1400/08/26

Ethics committee reference number

IR.USWR.REC.1400.212

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-management ability

Timepoint

Before and after intervention

Method of measurement

Self-management ability scale (SMAS)

2

Description

Fatigue severity

Timepoint

Before and after intervention

Method of measurement

Fatigue severity scal(FSS)

3

Description

Dyspnea

Timepoint
Before and after intervention
Method of measurement
Modified Medical Research Council(MMRC)

Secondary outcomes

1

Description
Hypertention
Timepoint
Before and after intervention
Method of measurement
Blood pressure machine

Intervention groups

1

Description
Intervention group: The self-management program based on model 5A, which includes 5 stages of assess, advise, agree, assist and arrange, will be implemented in the intervention group. In the first stage or assess, the problems of each person are identified, in the second stage based on the results of previous stage, the client is instructed about the problems and stressors. In the third stage or agree, the researcher and the client agree on the behavioral goals and plans to achieve those goals. In the fourth stage or assist, advice is given based on the needs of patients, by face-to-face oral instruction or handing out brochures. Finally, in the fifth stage, Follow-up will be done by phone and visit in the clinic. This program includes theoretical and practical training, as a program with the follow up of behavioral goals set during 12 weeks. In the first week, stage 1 ,2 and 3 will performed in an individual meeting (90 minutes). In the second and third week, will performed stage 4 in a group meeting (2 hours) and an individual meeting (60 minutes) and the stage 5 will performed from fourth to twelfth week of follow-up in next 2 months by phone call (daily phone call, in the first two weeks; twice a week phone call, in the next two weeks and then monthly calls) and face-to-face meeting (every four weeks).
Category
N/A

2

Description
Control group: The control group will receive the usual training (what is routinely taught in the clinic; such as reading educational pamphlets if desired).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
The clinic of Shahid Beheshti Hospital in Babol
Full name of responsible person
Darya shojaee
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Sponsors / Funding sources

1

Sponsor
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University of social welfare and rehabilitation sciences
Full name of responsible person
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Web page address
https://www.uswr.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Darya shojaee
Position
Master student of geriatric nursing
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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
Not applicable
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