Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigation of the effect of Self-Management Programs on Hope and Anxiety in Heart failure patients

Protocol summary

Study aim
Determining the effect of a self-management program on the level of hope and anxiety in patients with heart failure

Design
A clinical trial with a control group, with parallel groups, Unblinded, non-randomized, on 100 patients

Settings and conduct
Location: Selected hospitals by Shahid Beheshti University of Medical Sciences, Tehran. Patients will be randomly divided into intervention and control groups. In the intervention group, patients are provided with a self-management program along with standard Procedure, and in the control group, Solely the standard procedure is performed. After the intervention, the level of anxiety and hope will be measured using the Questionnaire and then the information will be compared using SPSS software version 26. The Researchers and Participants are Unblinded.

Participants/Inclusion and exclusion criteria
Entry Requirements: People between the ages of 18-80 years. Have the ability to use virtual messengers. Not having previous training in a self-management program. Suffering from Class 2 and 3 heart failure according to the file Non-Entry Conditions: Aggravation of the disease and transfer of the patient to the intensive care unit Reluctance to continue participating in the research

Intervention groups
In the experimental group, the self-management program was provided to the patients along with the usual care, and in the control group, the usual care was implemented.

Main outcome variables
Anxiety; Hope

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200727048221N1**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **retrospective**

Last update: **2022-11-22, 1401/09/01**
Update count: **0**

Registration date
2022-11-22, 1401/09/01

Registrant information

Name
Hanieh Molaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3339 5205

Email address
haniehmolaee991373@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
2020-11-21, 1399/09/01

Actual recruitment end date
2021-07-22, 1400/04/31

Trial completion date
2021-07-22, 1400/04/31

Scientific title
Investigation of the effect of Self-Management Programs on Hope and Anxiety in Heart failure patients

Public title

Investigation of the effect of Self-Management Programs on Hope and Anxiety in heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

People between the ages of 18-80 years. Have the ability to use virtual messengers. No previous training in a self-management programs. Suffering from Class 2 and 3 heart failure according to the file

Exclusion criteria:

Aggravation of the disease,the occurrence of other medicine disorders, and any emergency event that causes the patient to be transferred to the intensive care unit. Acute mental disorders such as psychosis and acute depression that require hospitalization. Reluctance to continue participating in the research

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The Random allocation of the two groups under study is done by block random allocation with SPSS software The Blocks are designed in quadruplets that are all randomly determined by SPSS Randomization Tool: SPSS Software How to build a random sequence: SPSS Software Explanation about the concealment: the allocated blocks are placed in the envelopes of the letter. After each person refers, an envelope is given to the researcher, then the envelope is opened and the person who refers is placed in one of the two groups. It should be noted that The researcher does not know the content inside the envelopes.

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

Shahid Beheshti University of Medical Sciences ethics committee

Street address

Valiasr Niayesh intersection

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.142

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

Anxiety is measured before and after the intervention

Method of measurement

Heart Anxiety Questionnaire

2

Description

Hope

Timepoint

Hope is measured before the intervention and after the intervention

Method of measurement

Hope Miller Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the experimental group, patients are provided with a self-management program along with routine care. The self-management program will be implemented by creating a group in WhatsApp or Telegram cyberspace in six sessions, which includes a self-management program, and patients are constantly monitored and followed up individually by phone call and up to Uncertainty does not end with a full understanding

of the training program, and if any problems occur in the process of conveying the concepts of the program, a face-to-face class will be formed.

Category

N/A

2

Description

Control group: The control group also receives routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Hanieh Molaee

Street address

Valiasr Street

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1996835119

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2

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

Shahid Beheshti School of Nursing and Midwifery , niyayesh intersection

City

Tehran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marzieh Pazokian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Marzieh Pazokian

Position
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Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
collegian

Latest degree
Bachelor

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
Not applicable

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