Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of emotion regulation program on emotional self-efficacy, resilience and adherence to medication regimen of patients with chronic heart failure referring to Shahid Chamran Medical Education Center in Isfahan of 2023

Protocol summary

Study aim
effect of emotion regulation program on emotional self-efficacy, resilience and adherence to medication regimen of patients with chronic heart failure.

Design
A clinical trial with a control group, with parallel groups, a blind strain, randomized with a sample size of 70 people, 35 people in the intervention group and 35 people in the control group. The random assignment of the samples in two test and control groups will be by using a table of random numbers.

Settings and conduct
This research is an experimental study of the type of one-blind controlled clinical trial to investigate the effect of the emotion regulation program on emotional self-efficacy, resilience and adherence to the medication regimen of patients with chronic heart failure who visited Chamran Heart Hospital in Isfahan from Isfahan from March 2023 to July 2023.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patient must be willing to participate in the study, have chronic heart failure in class III and IV, be between 35 and 70 years old.
Exclusion criteria: have experienced severe stress in the past six months, have a past history of psychiatric illness.

Intervention groups
The emotion regulation program will be carried out during 6 sessions of 45 minutes to one hour and in the form of groups of four to seven patients for the intervention group and daily every afternoon by the student and with the supervision and accompaniment of the supervisor in the patient's room or the department's classroom. became. At the end of the session, the content of the sessions will be available to the members of the control group. Preferably, we will do sampling from separate parts.

Main outcome variables
Emotional self-efficacy, resilience and adherence to medication regimen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180601039934N3**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date
2023-02-18, 1401/11/29

Registrant information

Name
Mohammad Akbari

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotion regulation program on emotional self-efficacy, resilience and adherence to medication regimen of patients with chronic heart failure referring to Shahid Chamran Medical Education Center in Isfahan of 2023

Public title

effect of emotion regulation program on emotional self-efficacy, resilience and adherence to medication regimen of patients with chronic heart failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should be interested and consent to participate in the study. The patient has been diagnosed with chronic heart failure and is hospitalized in Chamran Hospital. The patient has been suffering from chronic heart failure for at least one year. Chronic heart failure in class III and IV. Age between 35 and 70 years. Have the ability to read, write and speak Persian. The patient has not participated in similar educational and therapeutic courses at the same time or previously. The patient does not have mental retardation or a history of psychiatric illness that has led to the use of drugs.

Exclusion criteria:

The patient doesn't willing to participate in the study. The patient has experienced severe stress such as divorce and death of loved ones in the past six months

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of samples in two groups, test and control, will be by using a table of random numbers. In this way, the researcher will determine at first that all the people who are given an odd number will be in the control group and those who will be assigned an even number will be in the test group. Then he will close his eyes and place his finger on one of the digits of the random number table. By moving in the table of random numbers, the researcher will choose the required number of even and odd numbers. All numbers will be placed in separate envelopes and all will be placed in one box. When the sample enters the study with easy entry conditions, then card number one will be returned to him and depending on whether this card has an even or odd number, he will be placed in one of the two test or control groups. Also, due to the possible reasons of samples dropping, the sample volume will be considered 10% more.

Blinding (investigator's opinion)

Single blinded

Blinding description

Those who collecting data and evaluating the outcome ,will not have any information about the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No. 40, Faculty of Nurshng, Isfahan University of Medical Sciences, Hezarjrib Street

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Approval date

2023-01-31, 1401/11/11

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.156

Health conditions studied

1

Description of health condition studied

patients with chronic heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Emotional self-efficacy of patients with chronic heart failure

Timepoint

Measuring the level of emotional self-efficacy of patients before, immediately and one month after the intervention

Method of measurement

In this study, the four-part data collection tool includes a demographic profile form and three questionnaires.The first part of the form is demographic information (age, gender, marital status, employment status, education level, family income, duration of chronic heart failure, type of residence, number of hospitalizations, who is taking care of you?).The second part is the emotional self-efficacy questionnaire of Beverly et al.

2

Description

Resilience of patients with chronic heart failure

Timepoint

Measuring the resilience of patients before, immediately and one month after the intervention

Method of measurement

The third part of the Connor-Davidson Resilience Scale is the CD-RISC. This questionnaire was designed by Connor and Davidson in 2003 (79). This scale has 25 questions, each item is classified based on a 5-point Likert scale from completely false to completely true, these options are scored 0, 1, 2, 3, and 4 respectively. To obtain the total score of the questionnaire, the total scores of all questions are added together. This score will have a range from 0 to 100. The higher this score is, the more resilient the respondent is, and vice versa. The cutoff point for this questionnaire is 50 points. In other words, a score higher than 50 indicates people with resilience, and the higher this score is, the higher the intensity of resilience and vice versa.

3

Description

Adherence to the drug regimen of patients with chronic heart failure

Timepoint

Measuring the compliance rate of patients' medication regimen before, immediately and one month after the intervention

Method of measurement

The fourth part of the questionnaire is the adherence to drug treatment by Moriski et al. This questionnaire was designed and compiled by Moriski, Eng and Wood (2008) in order to measure compliance with drug treatment (80). The medication adherence questionnaire has 8 questions and measures adherence to medication based on a Likert scale with questions such as (In the last two weeks, was there a day when you did not take your medication for any reason other than forgetting?) . The drug treatment compliance questionnaire includes seven two-choice questions (with yes and no answers) and one Likert-type question, and question number 5 is scored against the other questions. In questions 1 to 7, yes answers are given a score of 1 and no answers are given a zero score. Question 5 is scored in reverse. The range of its overall scores is between 0 and 8. The lower the obtained score, the more people's medication adherence will be.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this research, the researcher will go to the inpatient wards at certain hours of the day, and there he will select the samples from among the patients in the wards who are eligible for the study and while explaining the research method and objectives. to them, they will be invited to participate in the study, and after providing the necessary explanations about the goals and stages of this study, a written consent form will be provided to them, and after obtaining written and informed consent from them, a demographic information form and We will provide them with questionnaires. After randomly dividing the samples into two control and test groups, both groups will be asked to complete the questionnaires in the three stages before, immediately after and one month after the intervention. On average, it will take 20-30 minutes to answer the questions. The emotion regulation program will be carried out during 6 sessions of 45-60 minutes in the form of groups of four to seven patients for the intervention group and daily every afternoon by the student and with the supervision and accompaniment of the supervisor in the patient's room or ward classroom.

Category

Lifestyle

2

Description

Control group: At the end of the program, we will provide them with the content of the training sessions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Hospital, Isfahan

Full name of responsible person

Gholamreza Masoumi

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1

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Grant name
Isfahan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
An emotion regulation training booklet is provided for the patients of this project and the potential data can be shared after the people cannot be identified
When the data will become available and for how long
The access period will start 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Academic professors, medical staff and students are allowed to send requests to receive personal non-identifiable data or other documents, and the use of documents and data to improve the quality of life of patients and to improve nursing knowledge will be allowed.
From where data/document is obtainable
To receive the documents, it is necessary to refer to the main executive of this project and the relevant student, and applicants can submit their requests through the email of the main executive of the project
What processes are involved for a request to access data/document
Send the request by email and then respond and send the documents to the applicant within two weeks at the latest
Comments