Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of a supportive-palliative care program on hemodynamic indices and Anxiety and quality of life in patients with heart failure

Protocol summary

Study aim

1.Determining the effect of palliative support program on systolic and diastolic blood pressure and mean arterial pressure(MAP) in heart failure patients 2. Determining the effect of palliative support program on heart rate, breathing and Saturation of Peripheral Oxygen(SpO2) in heart failure patients 3. Determining the effect of palliative support program on the level of anxiety in heart failure patients 4. Determining the effect of palliative support program on the quality of life in heart failure patients

Design

A clinical trial with a control group, with parallel groups, randomized, on 70 patients, rand function of SPSS software was used for randomization.

Settings and conduct

This study will be conducted on heart failure patients of Qaim, Imam Reza and Hashminejad Hospitals in Mashhad, who are selected as available and then randomly assigned to intervention and control groups by spss software.

Participants/Inclusion and exclusion criteria

Entry criteria: All patients diagnosed with heart failure admitted to the hospital, fully conscious and in a stable stage,minimal reading and writing literacy, patient or family members access to a mobile phone with internet. Exclusion criteria: problems of critical and emergency conditions,use of neuropsychiatric drugs.

Intervention groups

In the intervention group, after the doctor's visit, a palliative support program will be implemented for 30 to 45 minutes in three sessions in person, along with a psychologist's visit and nutritional counseling in the hospital, after the patients' discharge, 4 support training sessions and follow-up for 4 weeks through The channel will be presented in a messenger for the patient and his family. In the control group of the center's routine educational programs, there will be doctors and nurses.

Main outcome variables

Hemodynamic parameters, anxiety level and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058177N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**
Update count: **0**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

Akram Mollafilabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of a supportive-palliative care program on hemodynamic indices and Anxiety and quality of life in patients with heart failure

Public title
The effect of support-palliative program on the treatment of heart failure patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients diagnosed with heart failure hospitalized Full consciousness and stable stage Not having audio and visual problems Minimum literacy Access of the patient or family members to a mobile phone with internet

Exclusion criteria:
Crisis and emergency situations Post-traumatic stress in the last 6 months Clearance and transfer before 24 hours Use of neuropsychiatric drugs Participation in another research project

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The selection of research units is based on available methods and their allocation to two study groups is random. Then, based on the random sequence generated by spss software, they will be assigned to one of the intervention and control groups. A random sequence will be prepared and kept in a sealed envelope. After ensuring the eligibility of each person, the door of the envelope is opened and according to that sequence, the respective group is allocated

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
Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences

Street address
University Street, Doctor's Crossroad, Ibn Sina Street, Faculty of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2023-02-14, 1401/11/25

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.006

Health conditions studied

1

Description of health condition studied
Heart failure diseases

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Hemodynamic parameters including systolic and diastolic blood pressure, breathing rate, heart rate, SPO2 and MAP

Timepoint
The patient's hemodynamic parameters will be measured before and after the intervention and at the time of patient discharge in both groups.

Method of measurement
Using Bedside monitoring

2

Description
Score of quality of life of cardiac patients

Timepoint
It will be measured before the intervention and after the intervention and one month after the patient's discharge in both groups

Method of measurement
SCALE quality of life in patients with heart failure

3

Description
Beck's anxiety score

Timepoint
It will be measured before the intervention and after the intervention and one month after the patient's discharge

in both groups

Method of measurement

Beck Anxiety Inventory (BAI)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: In the intervention group, after the doctor's visit, a palliative support program for 30 to 45 minutes will be implemented in person in the hospital in three sessions. Also, a psychologist and nutritional counseling will visit the patients in these three sessions. Fat will be given and other nutrition training will be performed by the patient at home. After the discharge of the patients, 4 sessions of training and follow-up for 4 weeks will be provided through the creation of a channel in the virtual messenger for the patient and his family, and the training will be provided in the form of videos, text and images. Also, the members of the palliative care team will be members of this channel. and they will give the necessary advice and explanations to the patient in order to support the patient. If the patients do not have a smart phone and are unable to use the phone, full explanations will be made with the patient and his family, and the patient's caregiver will be a member of the channel.

Category

Lifestyle

2

Description

Control group: For the patients of this group, the routine educational programs of the center, which will be presented in the form of educational pamphlets along with educational sessions in the form of lectures, will be implemented by doctors and nurses.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Mashhad Hospital

Full name of responsible person

GholamAli Maamouri

Street address

Ahmedabad Street, Ghaem Hospital

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahmoud Mohammadzadeh Shabestri

Street address

Imam Reza Hospital Square, Ibn Sina Street

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3

Recruitment center

Name of recruitment center

Hashminejad Hospital

Full name of responsible person

Seyyed Mohammad Mousavi

Street address

The end of Abu Rihan Blvd, Muftah St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Qureshi Building, Next to Howeiza Cinema, University Street

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GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Akram MollaFilabi
Position
Nurse
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
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