

# 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

Hemodynamic parameters, anxiety level and quality of life

#### 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 (SpO<sub>2</sub>) 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

#### 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)

##### Phone

+98 51 3271 0757

##### Email address

filabia1@mums.ac.ir

##### 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

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9176699199

###### **Phone**

+98 51 3801 2465

###### **Email**

MaamouriGh@mums.ac.ir

#### **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

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9137913316

###### **Phone**

+98 51 3802 2011

###### **Email**

ShabestariM@mums.ac.ir

#### **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.

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9138813944

###### **Phone**

+98 51 3274 2009

###### **Email**

Mosavim3@mums.ac.ir

### **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

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Email**

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**

Nursery

**Street address**

University Street, Faculty of Nursing and Midwifery

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

FilabiA1@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Akram MollaFilabi

**Position**

Nurse

**Latest degree**

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**Person responsible for updating data****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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**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

FilabiA1@mums.ac.ir

**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