

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Survey of the Impact of a nurse-led home- based self- care program on Quality Of Life and physiological indicators of Heart Failure patients

Protocol summary

Study aim

This study was designed with the aim of determining the effect of a self-care program at home with the guidance of a nurse on the quality of life and physiological indicators of patients with heart failure at the Heshmat educational-therapeutic center in Rasht in 2023

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized and will be conducted in 2 phases and on 58 patients. . The online randomization service of Sealed Envelope Ltd will be used to generate the randomization list.

Settings and conduct

The location of this project is the inpatient wards of Dr. Heshmat Rasht Hospital and the follow-up nurse's room, and it is measured through general and specific quality of life questionnaires and blood pressure and pulse oximetry devices.

Participants/Inclusion and exclusion criteria

inclusion criteria: age range of 20-70 years with a diagnosis of heart failure who is not a candidate for heart surgery and according to the ICD in the category of heart failure and based on the NYHA classification in the category II-III of heart failure and have not participated in another research project with this content, their living area is Rasht city and its suburbs, and in terms of history of suffering from the disease, they are in the weak classification of the Charleston criteria are included in this study

Intervention groups

In the intervention group, before discharge, nurse-oriented trainings are given in seven areas mentioned subjects is also given to the patients on the day of discharge, and after discharge, these trainings will be repeated for the patients over the phone in eight weeks. The control group will receive only routine interventions according to hospital guidelines.

Main outcome variables

physiological index(blood pressure, pulse rate, breathing

rate, oxygen saturation level of arterial blood); General and private quality of life

General information

Reason for update

Acronym

nurse-led home- based self- care program

IRCT registration information

IRCT registration number: **IRCT20101019004971N6**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Mohamadtaghi Moghadabnia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 2088

Email address

moghadamnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of the Impact of a nurse-led home- based self-care program on Quality Of Life and physiological indicators of Heart Failure patients

Public title

Survey of the Impact of a nurse-led home- based self-care program on Quality Of Life and physiological indicators of Heart Failure patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Be in the age range of 20-70 years. With the diagnosis of heart failure, they should not be candidates for heart surgery. According to the International Classification of Diseases (ICD), fall into the category of heart failure. According to the NYHA classification, they are classified as II-III heart failure. have not participated in another research project with this content The area of their residence should be the city of Rasht and its suburbs. In terms of the history of suffering from the disease, they should be in the weak classification of the Charleston criterion. (This criterion has three classifications: weak, moderate and severe).

Exclusion criteria:

Be in the age range of under 20 years and over 70 years According to the NYHA classification, they are classified as I and IV heart failure In terms of history of suffering from the disease, they should be in the moderate and severe classification of the Charleston criteria.(This criterion has three classifications: weak, moderate and severe). The living area of the patients should be outside the city of Rasht and its suburbs.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible people will be divided equally (ratio 1:1) into two groups of self-care program at home under the guidance of a nurse and control using the block randomization method with the size of 4 and 6 blocks. Sealed Envelope Ltd online randomization service and random sequence sealed opaque envelopes (SNOSE) will be used to generate the randomization list.

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**

Ethics committee of guilan university of medical sciences

Street address

Shahid Beheshti Highway, Student Street, Shahid Beheshti College of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.GUMS.REC.1402.008

Health conditions studied**1****Description of health condition studied**

Heart failure

ICD-10 code

I59

ICD-10 code description

Cardiac, heart or myocardial failure NOS

Primary outcomes**1****Description**

Physiological indicators (systolic blood pressure, pulse rate, breathing rate, arterial blood oxygen saturation level)

Timepoint

The measurement of this index is done before the discharge of the patients and eight weeks after the intervention.

Method of measurement

The method of measurement is by using a mercury sphygmomanometer and a pulse oximetry device and paying attention to the up and down movements of the chest.

Secondary outcomes

1

Description

General quality of life

Timepoint

This index will be done before the discharge of the patients and eight weeks after the discharge of the patients and one month after the completion of the intervention

Method of measurement

Measuring the general quality of life will be done using a 12-question general quality of life questionnaire.

2

Description

specific quality of life

Timepoint

This index will be done before the discharge of the patients and eight weeks after the discharge of the patients and one month after the completion of the intervention.

Method of measurement

Specific quality of life measurement will be done using the Minnesota Heart Failure Questionnaire

Intervention groups

1

Description

Intervention group: self-care program at home under the guidance of a nurse. the intervention is carried out in two stages before discharge and after discharge Pre-discharge intervention in the form of nurse-centered self-care programs training in seven areas, which include 1- identifying dangerous symptoms of the disease and consulting symptoms and tests, 2- drug regimen, 3- diet, 4- activity and sports activity, 5- control stress and anxiety, 6- education about sexual issues and 7- life style modification, In the intervention group, after stabilization of the clinical condition and on day of discharge will be given. And an educational booklet focusing on the mentioned topics is also given to the patients on the day of discharge Also, post-discharge training will be repeated for this group patients through telephone calls, weekly for eight weeks and with the training of one area of the mentioned training program (except for the last week).

Category

Lifestyle

2

Description

Control group: Patients with heart failure who will only receive routine interventions based on hospital guidelines.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Rasht educational-therapeutic center

Full name of responsible person

MohammadTaghi Moghaddamnia

Street address

Shahid Beheshti Highway, Rasht, Student Street, Shahid Beheshti College of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Phone

+98 13 3355 3202

Email

moghadamnia@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari

Street address

Shahid Beheshti Highway, Student Street, Shahid Beheshti Faculty of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Phone

+98 13 3355 3202

Email

nursing@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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

+98 13 3355 3302

Email

moghadamnia@gums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghaddamnia

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Highway, Shahid Beheshti College of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Phone

+98 13 3355 3202

Email

Moghadamnia@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghaddamnia

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Highway, Student Street, Shahid Beheshti College of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Phone

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghaddamnia

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti Highway, Student Street, Shahid Beheshti College of Nursing and Midwifery

City

Rasht

Province

Guilan

Postal code

4146939814

Phone

+98 13 3355 3202

Email

moghaddamnia@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering that the collected data is used only for this study, its confidentiality will be maintained and will not be published.

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

No - There is not 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

Not applicable

Data Dictionary

Not applicable