

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of multidisciplinary management on the symptom burden and medication adherence in patients with comorbid conditions associated with heart failure

Protocol summary

Study aim

To determine the effect of multidisciplinary management on the symptom burden and medication adherence in patients with heart failure

Design

In this randomized controlled clinical trial, with parallel groups, 100 patients with heart failure who are eligible to enter the study, will be assigned into one of the intervention or control groups by randomized stratified-blocking method.

Settings and conduct

100 included patients with heart failure, referring Shahid Madani Heart Hospital in Khorramabad, will be allocated into two groups of intervention and control. At the beginning of the study, all subjects of the two groups will be asked to complete the research questionnaires. Then, for the intervention group, the multidisciplinary management will be performed in three telephone follow-up and three visits. The control group would not receive any intervention from the researcher. After completing the intervention, research questionnaires will be completed for both groups and the results will be compared with each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having class of 2- 4 Heart failure, having at least two cardiac or non-cardiac diseases, taking more than three drugs Exclusion criteria: unwillingness to participate in the study, no previous history of participating in similar programs, psychiatric diagnosis requiring active treatment

Intervention groups

Intervention group: receiving three telephone follow-up in the first, fourth, and eighth week post-discharge and three visits by the multi-multidisciplinary management team at the clinic at the time of discharge, two, and six weeks after discharge Control group: does not receive any intervention from the researcher

Main outcome variables

Symptom burden; medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N13**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Mohammad Gholami

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 509 1279

Email address

gholami.m@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2020-01-15, 1398/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multidisciplinary management on the symptom burden and medication adherence in patients with comorbid conditions associated with heart failure

Public title

The effect of multidisciplinary management on the symptom burden and medication adherence in patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having class of 2 to 4 Heart failure Having at least two cardiac or non-cardiac diseases Taking more than 3 drugs

Exclusion criteria:

Unwillingness to participate in the study No previous history of participating in similar programs Psychiatric diagnosis requiring active treatment

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting patients with inclusion criteria and obtaining informed consent from them to participate in the study, they will be assigned to the study groups using a stratified random blocks method. layers will be considered in order to match the two groups according to sex, the class of cardiac failure and the patients' NIHA, and patients inside the layers will be assigned to the groups using random blocks of 2, 4 or 6. The random sequence list is extracted by the Statistician from the <https://www.sealedenvelope.com> and will be available to the researcher after identifying the above items (blocks and layers) with special codes (in order to allocation concealment).

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 Lorestan University of Medical Sciences

Street address

Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2019-01-11, 1397/10/21

Ethics committee reference number

IR.LUMS.REC.1397.153

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

Heart failure

ICD-10 code

I50.4

ICD-10 code description

Combined systolic (congestive) and diastolic (congestive) heart failure

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

Medication adherence score in Morisky 's questionnaire

Timepoint

During discharge, sixth, and eighth weeks after discharge

Method of measurement

Morisky 's questionnaire

2**Description**

Symptom burden score in Edmonton's questionnaire

Timepoint

During discharge, sixth, and eighth weeks after discharge

Method of measurement

Edmonton's questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: individuals in this group, on the day of discharge, will be visited by the cardiologist of the multidisciplinary management team and will receive medical and educational orders. The pharmacist of the team will check the medications for the interactions and side effects of the drugs and will provide the patient with the necessary recommendations. The nutritionist will evaluate the patient's body mass index and will give him/her nutritional advice on the patient's needs. Finally, the nurse will prepare the patient according to the booklet, which will be delivered to the patient, and the questionnaires will be completed and the telephone follow-up and team visits will be coordinated by him/her. This group will be followed by telephone at the first, fourth, and eighth weeks after discharge and on the second and sixth week after discharge, will be visited at the clinic and will complete the drug adherence questionnaire at three points (discharge, 6th week and 8th week).

Category

Behavior

2

Description

Control group: individuals in this group would not receive any intervention from the researcher and they only will complete the research questionnaires at three points (discharge, 6th week and 8th week).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Hospital

Full name of responsible person

Mohammad gholami

Street address

Shahid Madani Heart Hospital, Kheirabad , Imam Hossein Square

City

Khorramabad

Province

Lorestan

Postal code

6814713115

Phone

+98 66 3341 9123

Fax

+98 66 3341 9125

Email

gholami.m@lums.ac.ir

Web page address

http://www.lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mojtaba Khaksaarian

Street address

Vice chancellor for research and technology, Lorestan University of Medical Sciences, Pardis Campus, Khorramabad-Boroujerd Road, Khorramabad, Lorestan

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3312 0172

Fax

+98 66 3312 0172

Email

edu_res@lums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mohammad Gholami

Position

Ph.D. in Nursing, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressGround floor, Negarestan 20 Alley, Shahrdari St.,
Velayat Blvd**City**

Khorramabad

Province

Lorestan

Postal code

6817979663

Phone

+98 66 3322 9851

Fax

+98 66 3341 9141

Email

Gholami.m@lums.ac.ir

Web page address<http://www.lums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr Mohammad Gholami

Position

Ph.D. in Nursing, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressGround floor, 20th Negarestan Alley, Shahrdari St.,
Provincial Boulevard**City**

Khorramabad

Province

Lorestan

Postal code

6817676663

Phone

+98 66 3322 9851

Fax

+98 66 3341 9123

Email

Gholami.m@lums.ac.ir

Web page address<http://www.lums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Parvin Ghobadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street addressGround floor, 20th Negarestan Alley, Shahrdari St.,
Provincial Boulevard**City**

Khorramabad

Province

Lorestan

Postal code

6817676663

Phone

+98 66 3322 9851

Fax

+98 66 3341 9125

Email

parvinGhobadi@yahoo.com

Web page address<http://www.lums.ac.ir>**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/documentThe total potential data will be published after
unidentifying individuals in the form of information about
the main outcomes.**When the data will become available and for how long**

Access period will start since 2020

To whom data/document is availableAll researchers, teachers, and medical students can
receive the published article from the relevant journal**Under which criteria data/document could be used**Undisclosed data will be available to health science
researchers for meta-analysis.**From where data/document is obtainable**

Send email to Parvin ghobadi@yahoo.com

What processes are involved for a request to access data/documentAfter submitting the document by applicant researcher
through email, the data will be sent two weeks later.**Comments**