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 address
Ground 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 address
Ground 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 address
Ground 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/document
The 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 available
All 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/document
After submitting the document by applicant researcher through email, the data will be sent two weeks later.
Comments