

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of implementation of follow-up care model on self-management in patient with chronic heart failure disease

Protocol summary

Study aim

Determination the Effect of follow up care model on self-management in Patients With chronic Heart Failure disease

Design

Randomized control Trial for 90 participants divided into two groups study and control by Block Random Assignment

Settings and conduct

AL-Imam AL-Hussain Medical City in Karbala Iraq was the setting of the current study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who were diagnosed with heart failure since 6 month and more 2. Patients who were accepted to attended in study 3. patients who were conscious 4. patients with stage three and four heart failure. Exclusion criteria: 1. patients who were reluctant to attended in the study. 2. patients without mental disorders

Intervention groups

Control group: The patients in the control group received the usual care at Al-Imam Al-Hussain Medical City Study group: The patients in the study group received an educational booklet based on heart failure self-management. The intervention consisted of providing two training sessions, each of which was scheduled to last one hour. Patients in the study group were contacted by phone and sent weekly messages for a period of three months for the purpose of following up with them. Twelve contacts were established with each patient over the course of three months. Additionally, each patient received 24 messages over the course of 12 weeks, divided between two messages per week. Finally, the success of the intervention was evaluated by using SCHFI questionnaire for measuring and comparing self-management. One, two and three months after the intervention, a questionnaire were completed for both groups.

Main outcome variables

Self-maintenance; self-care management; self-care confidence; symptoms perception; number or re-hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230829059300N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **retrospective**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Mohammed Khanjary

Name of organization / entity

Alameed University

Country

Iraq

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

2022-12-01, 1401/09/10

Actual recruitment end date

2023-05-05, 1402/02/15

Trial completion date

2023-05-05, 1402/02/15

Scientific title

Effect of implementation of follow-up care model on self-management in patient with chronic heart failure disease

Public title

Effect of follow-up care on self management for heart failure patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who were diagnosed with heart failure since 6 month and more Patients who were accepted to attended in study Patients who were conscious Patients with stage three and four heart failure.

Exclusion criteria:

Patients who were reluctant to attended in the study.
Patients without mental disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the sample size, the patients were assigned into blocks each block containing the same number of participants. Blocks were then randomly chosen to determine the patients' assignment into the control and study groups.

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**

Research ethical committees of school of nursing and

midwifery and rehabilitation - TUMS

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Nosrat st. Tohid sq. Tehran

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Postal code

1419733171

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.TUMS.FNM.REC.1401.090

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

Heart failure (can be attributed to various cardiovascular diseases, however, it consistently leads to the same cardiac irregularities, regardless of whether they affect the heart's contractile capacity (systole), filling capacity (diastole), or both.

ICD-10 code

I50

ICD-10 code description

Heart failure

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

self-management: is the control and responsibility that an individual takes on for the management of their conditions and behaviors

Timepoint

before the intervention and one, two three month after the intervention

Method of measurement

the self management measured by the selfcare of heart failure index version 7.2 scale

Secondary outcomes**1****Description**

number of re-hospitalizations in last three months for the heart failure patients

Timepoint

before the intervention and after three month

Method of measurement

the demographic questionnaire

Intervention groups**1****Description**

Intervention group: The patients in the intervention group received an educational booklet based on heart failure self-management. The intervention consisted of providing two training sessions, each of which was scheduled to last one hour and take place at a training facility located within Al-Imam AL-Hussain Medical City in Karbala. Sessions cover topics such as understanding the disease's progression, the importance of medication and getting to know the drugs, the best way to take them, and any potential side effects, as well as managing the disease through changes in diet, fluid intake, daily weight, exercise, and symptom management. Patients in the research group were contacted by phone and sent weekly messages for a period of three months for the purpose of following up with them. The number of contacts that were made with the patient was sufficient to allow for the establishment of weekly communication with each patient. The duration of each patient's phone call varied based on their individual circumstances and the number of questions they had about their condition. Twelve contacts were established with each patient over the course of three months. Additionally, each patient received 24 messages over the course of 12 weeks, divided between two messages per week. Patients and their fellows were provided a written outline of the training sessions' contact schedule during the study. Finally, the success of the intervention was evaluated by using the SCHFI questionnaire for measuring and comparing self-management. One, two, and three months after the intervention, a questionnaire was completed for both groups.

Category

Other

2

Description

Control group: The patients in the control group received the usual care at Al-Imam AL-Hussain Medical City but at the end of the intervention, they had access to the educational material.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

AL-Imam AL-Hussain medical city

Full name of responsible person

Taqwa Khudair Abdel Karim

Street address

al-shuhdaa st.

City

Karbala

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56001

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Lali Syadai

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Nikbakht Nasrabadi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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)

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

in IPD the Demographic information including age, gender, marital status, level of education, stage of heart failure, duration of heart disease, side of heart failure, number of hospitalizations during the last three months, and occupation Status will be shared.

When the data will become available and for how long

when the research is published and won't be removed

To whom data/document is available

researcher and the health care provider

Under which criteria data/document could be used

the data will be available for all researchers and the health care provider without any criteria

From where data/document is obtainable

contact with this Email: ac_milan515@yahoo.com

What processes are involved for a request to access data/document

data will sent to the applicant after receiving his request

Comments