Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of palliative care at home on the quality of life of the elderly with heart failure discharged from the heart wards

Protocol summary

Study aim
Determining the effect of palliative care at home on the quality of life of the elderly with heart failure discharged from heart wards

Design
Randomized clinical trial with control group, with parallel groups, without blinding

Settings and conduct
Selection of 100 patients with heart failure referred to the cardiac ward of Kerman University of Medical Sciences and divided into two groups of control and intervention

Participants/Inclusion and exclusion criteria
1.The elderly with a definitive diagnosis of chronic heart failure by a cardiologist, class III or IV heart failure in the New York Heart Association classification. 2.Ability to communicate and no speech or hearing problems. 3.Have the mental ability to complete the questionnaire. 4.No mental illness and no use of drugs that affect the psyche. Exclusion criteria: death or withdrawal of participants from the study, lack of cooperation during the research

Intervention groups
The main purpose of palliative care in patients includes pain relief, physical symptoms, patient support and giving The meaning and concept of life is the end of life. The pretest questionnaire will be provided to the patient and he/she will be asked to complete the questionnaire form. With prior coordination for home care from hospital to home and with a well timed schedule, patients in the intervention group will receive eight individual sessions twice a week for eight and a half hours, in addition to receiving routine medical care. But patients in the control group will receive only routine medical intervention during this period. Finally, after the last care session and 1 month after the intervention, the quality of life questionnaire is completed by both groups to assess the quality of life.

Main outcome variables
Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211213053389N1**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
mohammad hossein khajehpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 4703

Email address
khajehpoor_m@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-05-05, 1401/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of palliative care at home on the quality of life of the elderly with heart failure discharged from the heart wards

Public title
The effect of palliative care at home on the quality of life

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The elderly with a certain diagnosis of chronic heart failure Ability to communicate and non - speech problems and hearing problems Lack of mental illness Full consciousness at the time of research Willingness to participate in research

Exclusion criteria:
In case of unstable physical and emergency conditions (change in vital signs and inability of the patient to attend class) Failure to attend more than two training sessions Failure to answer more than a third of the questions

Age
No age limit

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
Samples will be selected by continuous sampling, and patients will be divided into control and test groups by Block Balanced Randomization (BBR). The allocation sequence will be done using the free web system http://www.randomization.com/. In this way, the number of subjects in each block is determined by 5 people and the letter A will be considered for the control group and the letter B will be considered for the experimental group. The assignment sequence will be created for 100 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, the Allocation Concealment will be considered and observed. Based on the eligible samples, an envelope shuffling envelope will be randomly removed by the researcher, and the method of randomly assigning the research samples will be determined.

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 Kerman University of Medical Sciences

Street address
Beginning of Ibn Sina Street, first Jihad Blvd., Somayeh intersection, Kerman

City
Kerman

Province
Kerman

Postal code
7815789957

Approval date
2022-02-07, 1400/11/18

Ethics committee reference number
IR.KMU.REC.1400.633

Health conditions studied

1

Description of health condition studied
Heart Failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Quality of life score in the Ferrans and Powers quality of life index, cardiac version - IV

Timepoint
Measurement of quality of life at the beginning of the study (before the intervention), after the intervention and 1 month after the intervention

Method of measurement
Ferrans and Powers quality of life index, cardiac version - IV

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the initial visit, which will be

performed jointly by a cardiologist and a researcher, in addition to receiving routine care in heart failure, they will be placed in palliative care twice a week for eight and a half hours in eight individual sessions. The educational content will first be narrated by experts in the field of palliative care to determine the validity and quality of education and then will be implemented by the researcher. The intervention includes the following topics: 1. Familiarity with heart failure, 2. Providing an introduction to the importance and necessity of self-care training in psychological and physical dimensions and monitoring symptoms, 3. Needs assessment of care of various organs of the body, physical effects, Psychology and Behavior of the Elderly and Family, 4. Assessing the Self-Care Ability, Stressful Situations, Social Interactions and the Elderly Relationship and Life and the Effects of Death Anxiety and Family Support and Emotional and Spiritual Support, 5. Implementing the Elderly and Family Client Education Programs Based on self-care needs, 6. Review coping strategies in stressful situations, and ways to cope with stress and depression, 7. Strengthen self-confidence, self-esteem, coping with anxiety and inefficiency. 8. At the end, review the previous sessions, prepare the family to complete the group sessions, focus on performing self-care activities. At the beginning of the sessions, patients will be members of the virtual groups. The researcher asks them to inform him / her if he / she has any questions about the research, and also asks the patients to express their successful and unsuccessful experiences in relation to the issues raised. Finally, after the intervention, patients will be followed for a month, during which the researcher will answer possible questions from patients in virtual groups.

Category

Behavior

2

Description

Control group: After the initial visit, which will be performed jointly by a cardiologist and a researcher, patients will be provided with routine care in heart failure.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Mahmoud Nekouei Moghaddam

Street address

Kowsar Blvd., Kerman

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shafahospital@kmu.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malek Pour Afshar

Street address

Deputy of Research and Technology, The beginning of Ibn Sina Street, Somayeh Intersection (Tahmasb Abad), Kerman

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Web page address

https://kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad hossein Khajehpoor

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Esmat Nouhi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

Nursery

Street address

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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