Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effect of telenursing on caregivers’ burden and anxiety and depression in patients with heart failure

Protocol summary

Study aim
Determine the effect of telenursing on caregivers’ burden and anxiety and depression in patients with heart failure.

Design
Clinical trial with control group, simple randomization on 100 patients, parallel group, Supportive

Settings and conduct
In this study, patients with heart failure which are discharged from hospitals affiliated to Kerman University of Medical Sciences will participate the study. Patients enrolled in two intervention and control groups and this process will continue until the sampling is complete. Demographic information questionnaire, hospital anxiety and depression scale (HADS) and caregivers burden scale (SDS) will be distributed between them and thus the pre-test will be measured. After one month of intervention, the researcher will be measured post-test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 16, Patients with heart failure at least grade |||, Caregivers are be able to use the social network, live with the heart failure patient for at least 6 months; Exclusion criteria: Patients with anxiety and depression disorder (Diagnosis of specialist).

Intervention groups
In this study, the text of training during discharge of patients with heart failure, which will be provided by the research team, in 15 separate sections with associated photos and several educational videos via a social network for intervention group patients and their caregivers will be sent.The content is simple and understandable and one day among the patients for the intervention group will be uploaded. Patients and their caregivers will be asked at least once and at most 3 times, read the content carefully, see related photos and educational videos. patients in the control group will receive only care and discharge training.

Main outcome variables
Anxiety and depression scores obtained from the HADS; Caregivers burden score obtained from SDS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181008041278N1**
Registration date: **2018-12-15, 1397/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-15, 1397/09/24**
Update count: **0**

Registration date
2018-12-15, 1397/09/24

Registrant information

Name
Mohaddeseh Namjoo

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-11, 1397/08/20

Expected recruitment end date
2018-12-31, 1397/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of telenursing on caregivers' burden and anxiety and depression in patients with heart failure

Public title
The effect of telenursing in cardiac patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to participate in the study and fill informed consent able to read and answer the questionnaire, as well as communicate in Persian Patients with heart failure at least grade ||| live with the heart failure patient for at least 6 months and not related to the patient or were an employee (i.e., foreign housemaid or special nurse) The caregivers have smartphone and be able to use the social networks
Exclusion criteria:
Patients with anxiety and depression disorder (Diagnosis of specialist)
Age
From **16 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Campus of Kerman University of Medical Sciences, 7bagh e Alavi
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2018-10-01, 1397/07/09
Ethics committee reference number
IR.KMU.REC.1397.212

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
The percentage of participants who have an anxiety score of more than 7 received from the hospital anxiety and depression scale.
Timepoint
Measurement of anxiety at the beginning of the study (before the intervention) and after one month of intervention.
Method of measurement
Hospital Anxiety and Depression Scale

2

Description
The percentage of participants who have an depression score of more than 7 received from the hospital anxiety and depression scale.
Timepoint
Measurement of depression at the beginning of the study (before the intervention) and after one month of intervention.
Method of measurement
Hospital Anxiety and Depression Scale

3

Description
The percentage of participants who have an caregiver Burden score of more than 21 received from the Caregiver Burden Scale.
Timepoint
Measurement of caregiver Burden at the beginning of the study (before the intervention) and after one month of intervention.
Method of measurement
Caregiver Burden Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Researcher will choose patients with heart failure who have inclusion criteria and are admitted to the hearts wards of the "Shafa" educational hospital; Then they will be randomly assigned to two groups of intervention and control. The Demographic information questionnaire, Hospital anxiety and depression scale and Caregivers burden scale is distributed among them, and so the pre-test will be measured. In this study, the training during discharge of patients with heart failure, which will be provided by the research team, in 15 separate parts with relative photos and few educational videos are send to patients in intervention group and one of the family members.Simple and understandable contents will be uploaded every other day among the patients in the intervention group. Patients and their families will be asked to read the contents, see photos and watch educational videos at least once and at most 3 times.The researcher will send a reminder message to each participant in the intervention group immediately after uploading the contents.The researcher will remind to the participants of the intervention group that will answer their possible questions at any time of the day. After one month of intervention, the researcher will evaluate the post-test by referring to the patients in the intervention group.

Category

Rehabilitation

2

Description

Control group: Patients in the control group will receive only standard hospital care. The pre-test and post-test in control group will be the same as the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Educational, therapeutical shafa hospital

Full name of responsible person
Roghaye Mehdipour Rabori

Street address
End of shafa street

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Kerman

Province
Kerman

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7616913555

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+98 34 3132 5700

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rm41321@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhty

Street address
Campus of Kerman University of Medical Sciences, 7bagh e Alavi

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kmu_research@yahoo.com

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
Mohaddeseh Namjoo

Position
Master Science of Nursing Student

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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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
Yes - There is 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The study protocol is fully shared after the completion of the project.

When the data will become available and for how long
The Study Protocol will be access 6 months after publish the results.

To whom data/document is available
Academic Researchers.

Under which criteria data/document could be used
Academic researchers and students are allowed to access.

From where data/document is obtainable
Email: rm41321@yahoo.com (Roghayyeh Mehdipour Ph.D)

What processes are involved for a request to access data/document
Send a request to the email with personal and academic info/ The request will be answered within a week.

Comments