

# 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 III, 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)

##### Phone

+98 34 3132 6000

##### Email address

namjoo1618@gmail.com

##### 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 III 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

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5700

##### Email

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

##### City

kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3226 3815

##### Email

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

##### Street address

Unit 15 Block 2, Ashianeh Madar, Campus of Kerman

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**Email**

namjoo1618@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Roghaye Mehdipour Ph.D

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Campus of Kerman  
University of Medical Sciences, 7Bagh e Alavi

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**Person responsible for updating data**

**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

**Street address**

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**Postal code**

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**Phone**

+98 34 3286 1207

**Email**

namjoo1618@gmail.com

**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 (Roghayeh 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**