Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative investigation of effect Orem self-care model with collaborative care model on quality of life in patients with heart failure

Protocol summary

Summary

This study is a randomized clinical trial In order to compare the effect of Orem self-care and collaborative care models in Improving the quality of life of heart failure patients referred to Tehran Heart Center is done.To compare the effects achieved from the three groups (two experimental groups and one control group) of patients with heart failure uses. Estimated sample size of 35 patients in each group and a total of 105 patients in the two groups , a control group was calculated . Initially, all patients with heart failure patients' QOL questionnaire demographic Minnesota (MLHFQ) are completed and then randomly divided into three groups . Intervention group was first trained based on a plan -based model of Orem Self Care , which includes reviewing , identifying nursing (care needs) , design and implement programs of care (in the form of six 45-minute sessions) and evaluated for the first month , 2 months at the end of the third month after it is placed . The second experimental group training program based on collaborative care model that includes four steps motivation , preparation, implementation and evaluation is involved , are given. Rate this group as one month , two months later , and the third is at the end of the month . In the third group, the control group , no intervention does not take place . The quality of life scores compared to all groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012216316N1**
Registration date: **2014-05-15, 1393/02/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-15, 1393/02/25

Registrant information

Name
Keyvan Abbasi
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
Phone
+98 21 8288 3856
Email address
k.abasi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation of effect Orem self-care model with collaborative care model on quality of life in patients with heart failure

Public title

The impact of training on quality of life in patients with heart failure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having a functional level 3 and 4 on the New York Heart Association classification; cardiac ejection fraction (Ejection Fraction) less than 30% (according to the patient file based on echocardiography); the final diagnosis of heart failure by a cardiologist for all samples; having reading and writing and ability to speak in Farsi language; treated by a physician, cardiologist; residing in Tehran; having normal hearing and vision. Exclusion criteria: participation in educational courses center on heart disease in the period under study; having a mental disorder known (according to the patient's medical records); malignant disease and other chronic diseases; valve disease requiring surgery; existence of is another disease that leads to a hospital stay; perform heart surgery or MI or stroke or died during the study.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tarbiat Modares University

Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran

City
Tehran

Postal code
331-14115

Approval date
2013-11-30, 1392/09/09

Ethics committee reference number
52/5058ↄ

Health conditions studied

1

Description of health condition studied
heart failure

ICD-10 code
I50.0

ICD-10 code description
Congestive heart failure

Primary outcomes

1

Description
Quality of life

Timepoint
Immediately after study and three months after the study

Method of measurement
Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Secondary outcomes

empty

Intervention groups

1

Description
Self care program based on the Orem self-care model that includes a set of data, behaviors, and practices based on the needs of patients with heart failure in six 45-minute sessions to be taught

Category
Lifestyle

2

Description
These interventions are designed and implemented based on a collaborative care model that includes three visiting sessions within two weeks and two follow-up visits one month apart is participatory

Category
Lifestyle

3

Description
In the control group during the intervention study has been done and only demographic questionnaire, the Minnesota Living with Heart Failure, before and after the test in order to assess the quality of life of these patients used

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Keyvan Abbasi
Street address
Tehran Heart Center, North Kargar ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Saeed Mousavian
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Keyvan Abbasi
Position
Nursing Graduate Student
Other areas of specialty/work
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran
City
Tehran
Postal code
111-14115
Phone
+98 21 82880
Fax
Email
K.abasi@modares.ac.ir; key1468@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Eesa Mohammadi
Position
PhD in Nursing (Associate Professor)
Other areas of specialty/work
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran
City
Tehran
Postal code
111-14115
Phone
+98 21 8288 3585
Fax
Email
mohamade@modares.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Keyvan Abbasi
Position
Nursing Graduate Student
Other areas of specialty/work
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway, Nasr (Gisha) Bridge, Tehran, Iran
City
Tehran
Postal code
331-14115
Phone
+98 21 8288 3585
Fax
Email
K.abasi@modares.ac.ir; key1468@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty