

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

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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

52/5058

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

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Tehran Heart Center, North Kargar ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Saeed Mousavian

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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

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

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Position

Nursing Graduate Student

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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