

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effect of applying of Orem's self -care program on congestive heart failure patients' quality of life

Protocol summary

Summary

The aim of this study is to investigate the effect of self-care program based on Orem's theory on the quality of life in patients with heart failure. In this quasi-experimental study, 60 patients, will be divided randomly into two intervention and control groups, randomly. After getting written consent, they will complete demographic and quality of life questionnaire will be completed. Then, self-care program education will be carried out based on Orem theory for intervention group and the control group will receive usual nursing cares. After two months, questionnaire of quality of life will be completed for both group and the results will be evaluated statistically. After the intervention, a package that includes brochures and pamphlets about the disease and its care will be delivered to patients in the control group.

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences and Health Services

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081929420N1**

Registration date: **2016-11-03, 1395/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-03, 1395/08/13

Registrant information

Name

Salar Alizadeh

Name of organization / entity

Nursing and Midwifery Faculty of Urmia

Country

Iran (Islamic Republic of)

Phone

Scientific title

Effect of applying of Orem's self -care program on congestive heart failure patients' quality of life

Public title

Effect of Orem's self -care program on congestive heart failure patients' quality of life

Purpose

Prevention

Inclusion/Exclusion criteria

Include criteria: The diagnosis of heart failure class II and III, according to consulting doctor; The lack of a history of mental illness and physical disabilities based on patient records; The lack of a history of heart surgery in the last 6 months based on patient records; Residence in the city of Orumiyeh; Lack of cognitive, hearing, and vision impairment; Lack of education in the department of medicine; Lack of formal training in heart failure patients; Having the ability and willingness to participate in the study; Ability to make phone calls Exclude criteria: Lack of access with the patient by telephone and his family during the study (several times in a few days) ;

Patient's unwillingness to continue participation in the study; Death due to illness or the occurrence of any event and the deterioration of the patient

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

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**

Urumia University of Medical Sciences and Health Services

Street address

Emergency district, Resalat Blvd, Urmia

City

Urmia

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5714783734

Approval date

2016-06-04, 1395/03/15

Ethics committee reference number

ir.umsu.rec.1395.118

Health conditions studied**1****Description of health condition studied**

Heart Failure

ICD-10 code

i27.9

ICD-10 code description

Pulmonary heart disease, unspecified

Primary outcomes**1****Description**

Quality of Life

Timepoint

before intervention and 2 months after intervention

Method of measurement

MacNew Quality of Life questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Self-care program based on Orem's self-care model that includes a selection of information, attitudes and practices that Based on the needs of heart failure patients in 4 to 6 sessions of 45 minutes taught them

Category

Lifestyle

2**Description**

control group will receive usual nursing cares

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Seyyedolshohada Educational and Treatment Center

Full name of responsible person

Salar Alizadeh

Street address**City**

Urmia

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Reserch Council of Urmia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Staff of Urmia University of Medical Sciences, Emergency Distract, Resalat Blvd, Urmia

City

Urmia

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Reserch Council of Urmia University of Medical Sciences
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

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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