

# 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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##### Email address

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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

**Postal code**

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**

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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**  
 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

**Name of organization / entity**  
 School of Nursing and Midwifery  
**Full name of responsible person**  
 Salar Alizadeh  
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 Master of Scince in Nursing  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor  
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## Person responsible for updating data

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**Full name of responsible person**  
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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