

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effects of Cardiac Rehabilitation on Quality of Life and Self-care management based on Orem's theory in Elderly with CHF referring to Shiraz hospitals- 2013

Protocol summary

Summary

This study is a quasi-experimental and Double-blind study. Goal of the study: to determine the effect of Cardiac Rehabilitation on Quality of Life and Self-care management based on Orem's theory in Elderly with CHF referring to Shiraz hospitals. Sampling methods: samples (90 patients) will randomly assign to two groups: case & control with the blocking method. After obtaining informed consent, questionnaires completed by researcher before intervention. Inclusion criteria are willingness to participate in the study and fluent in speaking and understanding Persian; age above 60 years and ejection fraction below 40% with a confirmed diagnosis of CHF. Exclusion criteria are weakness of the extremities; cognitive or psychological abnormalities; death or recurrence of illnesses; doesn't participate more than two sessions in cardiac rehabilitation program. Each group will followed for two months (no intervention for control group their care will be based on hospital's routine), for the cases intervention will be based on Orem's theory, they participate in cardiac rehabilitation program and at the same time researcher will teach them by face to face method and give them a booklet containing all information they needed. After intervention (2 months) the QOL & self-care questionnaires will complete by two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306297531N2**

Registration date: **2013-09-13, 1392/06/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-13, 1392/06/22

Registrant information

Name

Iran Jahanbin

Name of organization / entity

University of Medical Sciences Shiraz

Country

Iran (Islamic Republic of)

Phone

+98 917 313 7399

Email address

jahanbii@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research affairs, Shiraz University of Medical Sciences, Shiraz, Iran.

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Cardiac Rehabilitation on Quality of Life and Self-care management based on Orem's theory in Elderly with CHF referring to Shiraz hospitals- 2013

Public title

The effects of cardiac rehabilitation on elderly with congestive heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients with congestive heart failure admitted in hospitals affiliated to Shiraz University of Medical Sciences that diagnosis of disease are confirmed by cardiologists & based on heart failure classification (NYHA) in class 1 to 3 with left ventricular ejection fraction less than 40 %. 2) Physical therapist or cardiologist allowed them for participates in rehabilitation program. 3) Must be aged 60 years old or older. 4) The patient doesn't participate in the same study in the same time. 5) The ability to communicate & Perception in Persian. 6) The patient doesn't have other known problems such as orthopedic disorders, physical or cognitive disorders that limited physical or learning activities. 7) Willingness to participate in the intervention, and written informed consent form is completed. Exclusion criteria: 1) Lack of willingness to cooperate to participate in the study. 2) Absence in more than 2sessions in rehabilitation programs. 3) Worsening of the patient's condition for continued participation in the study, so that makes it impossible. 4) Cognitive and mental diseases. 5) Extremities weakness whatever the reason, any disorder or defect so that the desired activities could be limited. 6) Death of the patient, Recurrence or hospitalization.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand

Boulevard, Shiraz, Iran.

City

Shiraz

Postal code

71348-14336

Approval date

2013-05-14, 1392/02/24

Ethics committee reference number

92/56660

Health conditions studied

1

Description of health condition studied

Congestive heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart diseaseRight ventricular failure (secondary to left heart failure)

Primary outcomes

1

Description

Quality of life

Timepoint

Before interventions, after the end of interventions

Method of measurement

SF36 QOL questionnaire

2

Description

Self Care Ability

Timepoint

Before interventions,After the end of interventions

Method of measurement

EHFScB Questionnaire (Self Care Scale)

Secondary outcomes

empty

Intervention groups

1

Description

The case groups participate in cardiac rehabilitation therapy in 8 weeks consecutive, 3 sessions in each week that takes 1 hour. At the same time, in each session the researcher give them necessary education based on primary needs evaluation & Orem's theory by face to face training then a booklet that Prepared by researcher containing the definition of heart failure , signs & symptoms ,causes of disease ,risk factors & the ways of control, treatment, medication, pain management and non-pharmacological management of heart failure, how to control body weight, diet, smoking cessation ,

traveling, social interaction, activity and rest, exercise, when consult their doctor or nurse, identifying sign & symptoms of worsening condition and the need to visit physician, proper use of assistive devices and healthy lifestyle.

Category

Rehabilitation

2

Description

Control group: they will receive only routine care after discharge from the hospital or outpatient departments.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Faqihi hospital

Full name of responsible person

Dr. Key noosh Homayouni

Street address

Karim Khan Zand Boulevard, Next to Medical School, Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Vice Chancellor for Research affairs, Shiraz University of Medical Science, Zand Boulevard, Shiraz, Iran.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Rasti

Position

Geriatric Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery Hazrat Fatemeh, Namazi Square, Shiraz, Iran.

City

Shiraz

Postal code

Phone

+98 78 2452 7455

Fax

Email

rasti_ma@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Iran Jahanbin

Position

Faculty instructor

Other areas of specialty/work

Street address

School of Nursing and Midwifery Hazrat Fatemeh, Namazi Square, Shiraz, Iran.

City

Shiraz

Postal code

13119-71936

Phone

+98 71 1647 4251

Fax

+98 71 1647 4252

Email

jahanbii@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Rasti

Position

Geriatric Nursing Graduate Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery Hazrat Fatemeh,
Shiraz, Iran.

City

Shiraz

Postal code

Phone

Fax

Email

rasti_ma@sums.ac.ir

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