

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

To compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged from hospital

Protocol summary

Summary

The present study aimed to compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged from hospital. In this study, 110 available hospitalized patients with heart failure were selected and were simple randomly divided into two intervention and control groups. Inclusion criterion was heart failure diagnosed by a cardiologist while those with a chronic progressive disease, except heart failure, as well as those who were not trainable were excluded from the study. The intervention which was carried out by a trained nurse included training patients or their families about heart failure disease, drugs being used, self care plan, diet, signs of disease recurrence and improvement as well as changing patient's life style according to the disease and also enabling families to take on care needs. This continuous care and educational plan was carried out in four-home visits over a nine-month period for the patients in the intervention group. Quality of life at baseline and end of study was evaluated by SF36 questionnaires . The rate and cost of hospital readmission of patients in both groups were evaluated at the end of the study by an information form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012612279N1**

Registration date: **2013-09-16, 1392/06/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-16, 1392/06/25

Registrant information

Name

Hoseinali Mehralian

Name of organization / entity

Shahr -e-Kored University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 1150

Email address

mehralian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research, Shahr-e-Kored University of Medical Sciences

Expected recruitment start date

2006-10-27, 1385/08/05

Expected recruitment end date

2007-04-09, 1386/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the effect of continuous care and educational intervention (home visit) over a nine-month period on the rate of re-admissions, health care costs and quality of life in heart failure patients discharged

from hospital

Public title

Continuous care and educational intervention and treatment costs and quality of life in heart failure patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1- Heart failure diagnosed by cardiologist 2- Ejection fraction less than 45% 3- Literacy 4- Full consent to participate in the study Exclusion criteria 1- Having chronic progressive disease except heart failure 2- Heart surgery 3- Lack of mental health 4- No accessibility to the patients 5- Medical staff

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Ethics Committee of Shahr-e-Kord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Ave, Shahrekord

City

Shar-e-Kord

Postal code

8815713471

Approval date

2005-07-23, 1384/05/01

Ethics committee reference number

1-5-1384

Health conditions studied

1

Description of health condition studied

Ischemic Heart Failure

ICD-10 code

I25.9

ICD-10 code description

Chronic Ischaemic heart diseases

Primary outcomes

1

Description

quality of life

Timepoint

Beginning and end of the study

Method of measurement

SF 36 questionnaire

2

Description

Hospital Readmission

Timepoint

During the study

Method of measurement

Hospital Admission Form

3

Description

health care costs

Timepoint

At the end of the study

Method of measurement

Health Care Costs Form

Secondary outcomes

empty

Intervention groups

1

Description

The intervention which was carried out by a trained nurse included training patients or their families about heart failure disease, drugs being used, self care plan, diet, signs of disease recurrence and improvement as well as changing patient's life style according to the disease and also enabling families to take on care needs. This continuous care and educational plan was carried out in four-home visits over a nine-month period for the patients in the intervention group. SF36 questionnaire were completed for all participants at beginning and end of study.

Category

Behavior

2

Description

In control group, there was no intervention. SF36 questionnaire were completed for all participants at beginning and end of study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital affiliated shahr-e-kored Medical Sciences

Full name of responsible person

Hoseinali Mehralian

Street address

Hajar hospital, Parastar Ave, Shahrekord

City

Shar-e-Kored

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of research,Shahr-e-Kored University of Medical Sciences

Full name of responsible person

Hosenali Mehralian

Street address

Vice Chancellor of research,Shahr-e-Kored University of Medical Sciences,Kashani Ave, Shahrekord

City

Shar-e-Kored

Grant name

شهرکرد-خیابا کاشانی -معاونت پژوهشی دانشگاه علوم پزشکی شهرکرد

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of research,Shahr-e-Kored 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

Shahr-e-Kored University of Medical Sciences

Full name of responsible person

Hoseinali Mehralian

Position

Master of Science in nursing (academic member)

Other areas of specialty/work

Street address

Shahrekord University of Medical Sciences, Kashani Ave, Shahrekord

City

Shar-e-Kored

Postal code

8815713471

Phone

+98 38 1333 1150

Fax

+98 38 1333 1150

Email

mehralian@skums.ac.ir; mehralian_2003@yahoo.com

Web page address

www.skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahr-e-Kored University of Medical Sciences

Full name of responsible person

Shahriar Salehi tali

Position

PhD student in nursing and academic member

Other areas of specialty/work

Street address

Shahrekord University of Medical Sciences,Kashani Ave.,Shahrekored

City

Shar-e-Kored

Postal code

8814834566

Phone

+98 38 1334 9321

Fax

+98 38 1334 6714

Email

sh_salehitali@yahoo.com; sh_salehi@skums.ac.ir

Web page address

www.skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahr-e-Kored University of Medical Sciences

Full name of responsible person

Shahriar Salehi Tali

Position

phD student in nursing and academic member

Other areas of specialty/work**Street address**

Shahrekord University of Medical Sciences, Kashani
Ave, Shahrekord

City

Shar-e-Kored

Postal code

8814834566

Phone

+98 38 1334 9321

Fax

+98 38 1334 6714

Email

sh_salehitali@yahoo.com ; sh_salehi@skums.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