Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of home-based cardiac rehabilitation on fatigue of patients with Coronary Heart Disease

Protocol summary

Summary

This study is a one-group before-after clinical trial will be done to determined the effect of home-based cardiac rehabilitation on fatigue in patients with coronary heart disease.Samples consisted of 50 patients are according to inclusion criteria among patients with coronary heart disease who had referred to the Khorramabad cardiac rehabilitation center will be selected using purposive sampling method. Inclusion criteria included age 70-35 years, stable status of patients to participate in a rehabilitation program, passing 4-6 weeks after discharge, no patient with uncontrolled heart failure, arrhythmias, and unstable angina, non-treated patients with fatigue and sedative agents such as amantadine and the absence of local and systemic reactions in a patient after surgery. Exclusion criteria is non-compliance with recommended sports training and physical disorders and the incidence. Intervention, 4 one-hour sessions over 4 consecutive days face to face training and individual performance. Data will be collected by demographic characteristics questionnaire,patient self-report form at home and Piper Fatigue Scale (PFS). Fatigue before and 8 weeks after the intervention will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081618520N1**
Registration date: **2015-04-26, 1394/02/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-26, 1394/02/06

Registrant information

Name

Saeedeh Piri

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3342 2872

Email address

s_piri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Assistant, School of Nursing and Midwifery martyr Beheshtiresearcher

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of home-based cardiac rehabilitation on fatigue of patients with Coronary Heart Disease

Public title

Effects of cardiac rehabilitation in the management of fatigue in patients with Coronary Heart Disease

Purpose

Supportive

Inclusion/Exclusion criteria

(Inclusion criteria: Patients aged 35-70 years; The patient's vital signs (pulse and respiration) are stable for the rehabilitation program; 6-4 weeks after the last

patient is discharged; The patient does not have disease limited mobility; Patients with uncontrolled heart failure, arrhythmia's and angina are not flaky;absence of Mental disorders and related drugs; Patients not treated with drugs that reduce fatigue and sedatives such as amantadine and .... ; The patient has the ability to understand speech in Farsi; The patient is literate; The patient's ability to conduct training sessions of rehabilitation . Patients have access to a phone; Local and systemic complications after surgery is not present and Exclusion criteria: Failure to follow the recommended training and exercise; cancellation and unwillingness to continue the study; the incidence of mental disorders such as hypertension, hyperglycemia, etc.)

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Shahid Beheshti University of Medical Sciences

Street address
next to the Ayatollah Taleghani Hospital, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran

City
Tehran

Postal code

Approval date
2014-12-08, 1393/09/17

Ethics committee reference number
1393-1-86-13393

Health conditions studied

1

Description of health condition studied
CORONARY HEART DISEASE

ICD-10 code
I20-I25

ICD-10 code description
Chronic Ischaemic Heart Disease

Primary outcomes

1

Description
Fatigue

Timepoint
Before and 8 weeks after intervention

Method of measurement
Piper Fatigue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The study included 4 one hour education sessions of face to face in 4 consecutive days with content of home-based cardiac rehabilitation and followed for 8 weeks after discharging at patient’s home. First session includes learning about diseases, (side effects/ complications) and treatment, and cardiac rehabilitation simply. The second session includes education and prevention of risk factors, including smoking (smoking cessation training set), high blood lipids, hypertension, weight gain and stress. The third session consisted of diet and drug regimen in these patients. The fourth session included instruction on simple physical activity with an emphasis on hiking, sports are allowed in this group of patients and how to control pulse during exercise. At the end of the fourth session review and discuss the three sessions before and training manual of run training sessions are available to patients and Then the patient is asked for planned exercise three times per week for 8 weeks. According to above and the need to measure learning in different time intervals, immediately after training the evaluation of patients' rehabilitation center will be performed. Also, after the completion of the rehabilitation program at the end of the fourth week once home visit by the researcher will be made to control the rehabilitation program, trainings presented, solve problems and answers to possible questions. Then the patient will be asked to mark the adhere to teaching in the home care form that will be give to patients.Note that this form will also be available to researchers and During the 8-week intervention, the researcher will contact with patients once a week to emphasize on the

concepts taught, ensure of doing the exercises and in the event of a problem, go back to their homes.Also the phone number of researcher will give to patients to contact in case of any problem or question. At the end of 8 weeks of intervention with visit the patients in their homes , they will be asked to fill questionnaire fatigue again

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac Rehabilitation Centre (Heart Healthy Clinic)

Full name of responsible person

Mehrdad Namdari Doctor

Street address

Khorramdabad, Heart Healthy Clinic

City

Khorramdabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masomeh simbar doctor

Street address

School of Nursing and Midwifery,to the Hospital of Shahid Rajai, intersection Niayesh, Valiasr street, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti 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

Faculty of Nursing and Midwifery Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeedeh Piri

Position

Master degree

Other areas of specialty/work

Street address

School of Nursing and Midwifery,to the Hospital of Shahid Rajai, intersection Niayesh, Valiasr street, Tehran

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

+98 21 8820 2521

Email

s_piri@sbmu.ac.ir ; saeedepiri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery Shahid Beheshti University of Medical Sciences

Full name of responsible person

saeedeh piri

Position

Master degree

Other areas of specialty/work

Street address

School of Nursing and Midwifery,to the Hospital of Shahid Rajai, intersection Niayesh, Valiasr street, Tehran

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

+98 21 8820 2521

Email

s_piri@sbmu.ac.ir ; saeedepiri@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty Nursing and Midwifery Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeedeh Piri
Position
Master degree
Other areas of specialty/work
Street address
School of Nursing and Midwifery,to the Hospital of Shahid Rajai, intersection Niayesh, Valiasr street, Tehran
City
Tehran
Postal code
1985717443
Phone
+98 218865536671
Fax
+98 21 8820 2521
Email
s_piri@sbmu.ac.ir ; saeedepiri@yahoo.com
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