

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of self care educational program on sexual function and quality of life in patients with ischemic heart disease

Protocol summary

Summary

(1) Objective: The aim of this Experimental study is to compare the quality of life and sexual function in patients with ischemic heart disease before and after of self-care training program. (2) Design: This study is a randomized controlled clinical trial. (3) Setting and conduct: This study will be done at heart rehabilitation of Qom Shahid Beheshti hospital. Eligible subjects will be randomized to receive self-care training program and routine care in control group. (4) Participants including major eligibility criteria: This clinical trial will be carry out on 60 married patients with ischemic heart disease of both sex and aged more than 30 years. (5) Intervention: sixty patients with ischemic heart disease will be allocated randomly into two groups (intervention and control) and receive one of the following; self-care training program and routine care. In self-care training group, within first week of rehabilitation, sexual guideline will be provided by oral explanation and CD within only 60-minutein. Project manager speak to experimental group about heart disease and the risk of cardiac events during sexual activity, right time of start sex, precautions before it, medications and their side effects, the importance of choosing the correct location, correct positions, changes in vital signs and warning signs during sexual activity. (6) Main outcome measures: Angina specific quality of life and sexual function will be measured before and one month after receiving self-care training program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090129581N2**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

leila ghanbari afra

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3884 9038

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Qom University of Medical Sciences

Expected recruitment start date

2016-09-20, 1395/06/30

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of self care educational program on sexual function and quality of life in patients with ischemic heart disease

Public title

Self care and sexual function in patients with ischemic heart disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: married; Lack of known mental illness; patients who have diagnosed coronary artery disease by cardiologists. Exclusion criteria: patients with congenital heart disease or valvular abnormalities after angiography.

AgeFrom **30 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

N/A

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 Qom University of Medical Sciences

Street address

Research deputy of Qom university of Medical Sciences, number 3, Safashahr street, Qom.

City

Qom

Postal code

3713614975

Approval date

2016-05-03, 1395/02/14

Ethics committee reference number

IR.muq.Rec.1395.48

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

Ischaemic heart disease

ICD-10 code

I20.0, I21

ICD-10 code description

Unstable angina, Acute transmural myocardial infarction of anterior wall, Acute transmural myocardial infarction of inferior wall, Acute transmural myocardial infarction of other sites, Acute transmural myocardial infarction of unspecified site, Acute sub

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

Sexual function

Timepoint

Before the intervention and a month after the study

Method of measurement

Arizona sexual function questionnaire (ASEX)

2**Description**

Quality of life

Timepoint

Before the intervention and a month after the study

Method of measurement

Seattle quality of life questionnaire (SAQ)

Secondary outcomes

empty

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

Within first week of rehabilitation, sexual guideline will be provided by oral explanation and CD within only 60-minute. Project manager speak to intervention group about heart disease and the risk of cardiac events during sexual activity, right time of start sex, precautions before it, medications and their side effects, the importance of choosing the correct location, correct positions, changes in vital signs and warning signs during sexual activity.

Category

Lifestyle

2**Description**

The control group did not receive any training.

Category

N/A

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

SHahid Beheshti hospital

Full name of responsible person

Leila GHanbari Afra

Street address

Educational ward, SHahid Beheshti hospital, SHahid Beheshti street, Qom.

City

Qom

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

Qom University of Medical Sciences

Full name of responsible person

Leila GHanbari Afra

Street address

Qom University of Medical Sciences, shahid lavasani street, Qom.

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Qom

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qom 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**

Qom University of Medical Sciences

Full name of responsible person

Leila GHanbari Afra

Position

MSc in Critical Care Nursing / Educational Supervisor

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

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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