

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of sexual counseling on knowledge, Sexual Quality of Life and DASS21 score in post CABG and PTCA patients (men)

Protocol summary

Study aim

determine the effect of counselling program on sexual knowledge and quality of life and DASS21 score of patients(men) after Invasive coronary intervention

Design

This study is a clinical trial (phase 3) with a control group, with parallel groups, single-blind, randomized, on 56 patients. All male patients with inclusion and exclusion criteria were entered into the study and randomly allocated to the groups by the Rand calculator function.

Settings and conduct

In the post cath ward of Shahid Beheshti hospital in Kashan, at the time of discharge, patients were evaluated and after being allocated to study groups, the researcher provided training and counseling to patients.

Participants/Inclusion and exclusion criteria

Married male patients; aged 35-65 years; undergoing CABG and PTCA treatment; no severe physical illness, addiction, known psychiatric problem, or previous sexual dysfunction at the time of discharge.

Intervention groups

Patients who received sexual activity guidance counseling at discharge were called an intervention group, and the control group was provided with routine nursing training, and no intervention counseling was provided.

Main outcome variables

Sexual knowledge; sexual quality of life

General information

Reason for update

adding extra secondary outcome

Acronym

IRCT registration information

IRCT registration number: **IRCT20100829004655N8**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **prospective**

Last update: **2021-07-20, 1400/04/29**

Update count: **1**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Mohsen Taghadosi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2018-09-06, 1397/06/15

Trial completion date

2018-11-22, 1397/09/01

Scientific title

Effect of sexual counseling on knowledge, Sexual Quality of Life and DASS21 score in post CABG and PTCA patients (men)

Public title

Effect of discharge counselling on knowledge and Sexual Quality of Life and DASS21 score in patients (men)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

patient can read and write patient must be married and living with partner

Exclusion criteria:

heart, liver, pulmonary and kidney failure or malignancy or any systemic disease use of antipsychotic or cytotoxic drug severe heart failure (function class III or IV (NYHA)) alcohol or opium abuse (based on the patient statement) existence of current depression, anxiety, stress based on DASS-21 score (depression score<10 or anxiety score<8 or stress score<15) current known sexual dysfunction current known psychological disorder

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was continuous, and all male patients admitted during the study who had inclusion criteria were admitted to the study at the time of discharge and remained in the study if they did not have exclusion criteria. Then they were allocated to the intervention or control group randomly by random computer numbers (calculator). Conventionally in the study, random multiple numbers 2 placed the patient in the intervention group, and non-multiple random numbers 2 placed the patient in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients were aware that they were participating in the study and that the intervention was a form of counseling. But he did not know which group he belonged to. In this way, the members of both groups were visited by the researcher at the time of discharge and 2 months later by the follow-up of the researcher. But in the intervention group, during the researcher's visit, counseling and training were also provided. In the control group, routine nursing training was repeated during the researcher's visit and no counseling was provided.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.97

Health conditions studied

1

Description of health condition studied

Chronic ischemic heart disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description

sexual knowledge

Timepoint

baseline and 2 month after discharge

Method of measurement

sexual knowledge questionnaire in cardiac patient

2

Description

sexual quality of life

Timepoint

baseline and 2 month after discharge

Method of measurement

Abraham sexual quality of life questionnaire

Secondary outcomes

1

Description

depression

Timepoint

baseline and 2 month after discharge

Method of measurement

DASS21 questionnaire

2

Description

anxiety

Timepoint

baseline and 2 month after discharge

Method of measurement

DASS21 questionnaire

3

Description

stress

Timepoint

baseline and 2 month after discharge

Method of measurement

DASS21 questionnaire

Intervention groups

1

Description

Intervention group: Providing face-to-face counseling to the patient during discharge in 1 session for 20 minutes - In addition to face-to-face educational counseling, patients also received an educational package containing DVD videoclip and an educational brochure containing scientific information.

Category

Rehabilitation

2

Description

Control group: Receiving the usual training program during discharge that lasted 20 minutes in 1 session and routine nursing and training information that is provided to all patients was provided to this group of patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center of Kashan University of Medical Sciences

Full name of responsible person

Taghadosi Mohsen

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Arctic Blvd Ravandi, Kashan University of Medical Sciences

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sadatinejad71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidi Gholamali

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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

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghadosi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Farrokhian Alireza

Position

Faculty member

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Sadatinejad Seyyed Mohsen

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academia and academia.

Under which criteria data/document could be used

If you observe the trust and mention the source, data is available for researchers.

From where data/document is obtainable

Send the following e-mail to the following address: taghadosi_m@kaums.ac.ir

What processes are involved for a request to access data/document

After receiving the letter via email, your request will be reviewed within 2 weeks and the data will be sent to the applicant at the discretion.

Comments