Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 councelling 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 intervantion 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

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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

Isfehan

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 dischage

Method of measurement

sexual knowledge questionnaire in cardiac patient

2

Description

sexual quality of life

Timepoint

baseline and 2 month after dischage

Method of measurement

Abraham sexual quality of life questionnaire

Secondary outcomes

1

Description

depression

Timepoint

baseline and 2 month after dischage

Method of measurement

DASS21 quesionaire

2

Description
anxiety
Timepoint
baseline and 2 month after dischage
Method of measurement
DASS21 quesionaire

3

Description
stress
Timepoint
baseline and 2 month after dischage
Method of measurement
DASS21 quesionaire

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
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Sponsors / Funding sources

1

Sponsor
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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
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Mohsen Taghadosi
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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