

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of PLISSIT sexual counseling model on Sexual self-perception and Adjustment, and Sexual Function of women with acute coronary syndromes

Protocol summary

Study aim

GENERAL OBJECTIVES: Determining Effectiveness of PLISSIT sexual counseling model on Sexual self-perception and Adjustment, and Sexual Function of women with acute coronary syndromes SPECIFIC OBJECTIVES: 1) Determine and compare the level of Sexual self-perception and Adjustment of women with acute coronary syndromes before, one month and three months after the intervention in the intervention and control group. 2) Determine and compare the sexual function of women with acute coronary syndromes before, one month and three months after intervention in the intervention and control group

Design

Randomized, controlled clinical trial, in parallel with a control group

Settings and conduct

Samples were randomly assigned to control and control groups in Shahid Rajaie Heart Hospital of Karaj, who were hospitalized for diagnosis of acute coronary artery disease.

Participants/Inclusion and exclusion criteria

Married women who live in Karaj Every woman has to a reading and writing literacy sexual active before admitted A definitive diagnosis of acute coronary syndrome based on angiography, dynamic band changes, serial serum elevations of enzymes, previous angiographic records, exercise tests, or previous positive scans with angina pectoris Aged between 30-65

Intervention groups

Sexual counseling with the PLISSIT model will be performed for an intervention group within three weeks and counseling sessions will be held for one hour. The questionnaires will be completed before the intervention and again within a month and three months later.

Educational curiosity will be given to the control group

Main outcome variables

sexual function self sexual perception

General information

Reason for update

Acronym

PLSSIT

IRCT registration information

IRCT registration number: **IRCT20161230031662N6**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlutfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of PLISSIT sexual counseling model on Sexual self-perception and Adjustment, and Sexual Function of women with acute coronary syndromes

Public title
Effectiveness of Sexual Function and Adjustment

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Married women who live in Karaj Every woman has to a reading and writing literacy sexual active before admitted A definitive diagnosis of acute coronary syndrome based on angiography, dynamic band changes, serial serum elevations of enzymes, previous angiographic records, exercise tests, or previous positive scans with angina pectoris Aged between 30-65
Exclusion criteria:
 There are symptoms of heart failure or pulmonary edema or cardiogenic shock (shortness of breath, runny ear in the lung, hypotension) The patient's unwillingness to continue to be present in the research Missing more than one meeting in consultation Serious psychological problems Serious problems affecting sexual function Participate in similar studies or receive similar care with research intervention Sexual abnormalities in the patient's wife

Age
From **30 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Accidentally with random blocks

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

Alborz University of Medical Sciences

Street address

North Taleghani- Azimiyeh

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.ABZUMS.REC.1397.030

Health conditions studied

1

Description of health condition studied

Acute coronary syndromes

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention, one month and three months after intervention

Method of measurement

Female Sexual Function Index

2

Description

Sexual self_perception and adjustment

Timepoint

Before intervention, one month and three months after intervention

Method of measurement

Sexual self_perception and adjustment questionarie

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 women with acute coronary syndrome entered the study according to entry criteria.

They will be admitted to the third to fifth day and will be consulted within three weeks(weekly). Each counseling session will take about an hour. Consultation sessions will proceed according to the PLISSIT method until the third step.

Category

Behavior

2

Description

Control group: 30 women with acute coronary syndrome entering the study are enrolled. This tutorial will be given to this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Karaj Shahid Rajaee Hospital

Full name of responsible person

Fatemeh soleymaninejad

Street address

Shahid Rajaie Hospital, Shahid Rajaie Street, Hesarak, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

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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

Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Fatemeh soleymaninejad

Position

BSc. in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Razieh Lotfi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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1st Street Golestan, Eshteraki Boulevard, Baghestan,
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

he 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 for researchers working in academic and scientific
institutions

Under which criteria data/document could be used

scientific studies

From where data/document is obtainable

Using Email Address: fatima.s.n65@gmail.com

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

Up to a week after sending the email address

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Fatemeh soleymaninejad

Position

BSc. in Midwifery

Latest degree

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Other areas of specialty/work

Midwifery

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