

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of couples counseling based on CHARMS model on quality of sexual life and marital satisfaction of wives of men with myocardial infarction referred to Seyed Al-Shohada Heart educational and medical Center in Urmia

Protocol summary

Study aim

Determination the effect of couples counseling based on CHARMS model on sexual quality of life and marital satisfaction of wives of men with myocardial infarction

Design

A controlled, parallel-group, unblinded, randomized clinical trial of 90 women. Even and odd method will be used for randomization.

Settings and conduct

This two-group, unblinded, clinical trial study will be conducted on 90 spouses of MI patients at Seyed al-Shaheda hospital in Urmia. The intervention group will receive 6 sessions of sexual training and counseling based on the CHARMS model, but the control group will receive only routine training.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being between 35 and 65 years old
Living with spouse at the time of research
Definite diagnosis of Myocardial infarction for husband
At least 6 months have passed since husband Myocardial infarction.
Exclusion Criteria: Having psychological trauma in the last 6 months for couples and Participating in similar research projects in the last three months

Intervention groups

Intervention group: 6 sexual counseling sessions based on the CHARMS method, 45 minutes per session, including: heart attack disease, the effect of the disease on the sexual activity of couples, establishing communication and gaining the trust and cooperation of couples, assessing the mental and physical health of people, discovering sexual problems, providing solutions
Strengthening the empathetic and open-ended conversation, sexual conversation with the spouse, explaining the secrets of attractiveness and fashion, helping to maintain the verbal and emotional relationship with the spouse, and emphasizing the importance of

flirting and making love about the warning signs of heart disease during intimacy. Control group: They will only receive training, counseling and routine care.

Main outcome variables

sexual Quality of life, Marital Satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240218061046N1**

Registration date: **2024-02-26, 1402/12/07**

Registration timing: **prospective**

Last update: **2024-02-26, 1402/12/07**

Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name

delniya ghafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3222 3750

Email address

ronak.ghafari65@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-10, 1402/12/20

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of couples counseling based on CHARMS model on quality of sexual life and marital satisfaction of wives of men with myocardial infarction referred to Seyed Al-Shohada Heart educational and medical Center in Urmia

Public title

The effect of couples counseling based on CHARMS model on quality of sexual life and marital satisfaction of wives of men with myocardial infarction

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being between 35 and 65 years old Living with spouse at the time of research Definite diagnosis of Myocardial infarction for husband At least 6 months have passed since husband Myocardial infarction

Exclusion criteria:

Having psychological trauma in the last 6 months for couples Participating in similar research projects in the last three months

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

90 spouses of myocardial infarction patients will be assigned to two intervention and control groups (45 people in each group) based on the criteria for entering the study and using the convenience selection method. In this way, the spouses of odd codes will be placed in the intervention group and the spouses of even codes will be in the control group, and it will continue until the number 90.

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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, at the end of Jihad St, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2023-07-10, 1402/04/19

Ethics committee reference number

IR.UMSU.REC.1402.101

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

Myocardial infarction

ICD-10 code

I25.2

ICD-10 code description

Old myocardial infarction

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

sexual quality of life

Timepoint

Before and one month after the intervention

Method of measurement

The Sexual Quality of Life-Female (SQoL-F) questionnaire (Symonds et al 2005)

2**Description**

Marital Satisfaction

Timepoint

Before and one month after the intervention

Method of measurement

ENRICH Marital Satisfaction Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 sexual counseling sessions based on the CHARMS method, 45 minutes per session, including: heart attack disease, the effect of the disease on the sexual activity of couples, establishing communication and gaining the trust and cooperation of couples, assessing the mental and physical health of people, discovering sexual problems, providing solutions Strengthening the empathetic and open-ended conversation, sexual conversation with the spouse, explaining the secrets of attractiveness and fashion, helping to maintain the verbal and emotional relationship with the spouse, and emphasizing the importance of flirting and making love about the warning signs of heart disease during intimacy.

Category

Lifestyle

2

Description

Control group: They will only receive training, counseling and routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyedoshohada Hospital

Full name of responsible person

Dr.Alireza Mahoori

Street address

In front of Shahid Samadzadeh Street, 17 Shahrivar Boulevard, Urmia

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Yousef Mohammadpour

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Delnya Ghafouri

Position

Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Soheila Rabieipour

Position

Professor

Latest degree

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Other areas of specialty/work

Reproductive Health

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available