Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ghafuri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3222 3750

Email address

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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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West Azarbaijan

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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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research@umsu.ac.ir

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

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Position
Professor

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Other areas of specialty/work
Reproductive Health

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Latest degree
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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