

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Effect of Individual Sexual Counselling on Psychosocial Status of Post MI Patients- Single-Blinded Randomised Clinical Trial

Protocol summary

Summary

This study is designed to determine the individual sexual consultation effect on psycho social condition of post MI patients. This study is a single blinded RCT research that samples will be random allocated to control and intervention groups. Inclusion criteria are to be married, suffering MI and to have sexual activity before MI. Exclusion criteria are erection disorder and urinary tract disease. Sample size is determined according to similar studies which is 25 patients per group. Intervention in this study is individual consultation for intervention group for 20 minutes in four days after admission in hospital. Output of this study will be psycho social condition (anxiety, depression, quality of life and sexual satisfaction) of the MI patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508246801N3**

Registration date: **2015-11-10, 1394/08/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-10, 1394/08/19

Registrant information

Name

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Name of organization / entity

Tabriz university of medical sciences and health services

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences - research administration

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Individual Sexual Counselling on Psychosocial Status of Post MI Patients- Single-Blinded Randomised Clinical Trial

Public title

The Effect of Individual Sexual Counselling on Psychosocial Status of Post MI Patients- Single-Blinded Randomised Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Marriage ; 20 years and older ; Suffering MI ; To have sexual activity before MI ; Ability for reading and writing
Exclusion criteria : Erection disorder ; Urinary inconsistency ; Uncured psychological illness ; Motor disorder

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Tabriz

City

Tabriz

Postal code

Approval date

2014-09-20, 1393/06/29

Ethics committee reference number

9386

Health conditions studied

1

Description of health condition studied

Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Sexual satisfaction

Timepoint

Before intervention and 6 weak after intervention

Method of measurement

NSSS Questionnaire

Secondary outcomes

1

Description

Anxiety, Depression, Quality of Life

Timepoint

Before intervention and 6 weak after intervention

Method of measurement

HADS and QOLI IV Questionnaires

Intervention groups

1

Description

Intervention in this study is verbal and written individual exercise and sexual consultation for 20 minutes for per sample in intervention group.

Category

Rehabilitation

2

Description

In control group don't practice any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shahid Madani Educational Hospital

Full name of responsible person

Dr Hassankhani, Hadi

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohgan Mirghafoorvand

Street address

research adminstration

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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

Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty