

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of consultation on sexual dysfunction in women with type 2 diabetes mellitus

Protocol summary

Summary

This is a quasi-experimental study with an interventional group and a control group. This medical research has been done for the analysis of the effect of the consultation on sexual function in women with type 2 diabetes mellitus. The study population included the married women with sexual dysfunction from 20 to 50 years old will be fill the sexual function questionnaire by Rosen. Available participants enrolled and then randomly divided in to both the intervention group and the control groups. Program of sex consultation in this study is 3 sessions will last 90 minutes once a week. In First meeting will be describe about anatomy of the female reproductive system, sexual cycle and the factors involved in its, second session on the types of sexual disorder and to describe the effect of diabetes on sexual function in women. Also the treatment strategies offered. In third session will be provided solutions for better courtship and more intimacy in relationships and summary and overview of previous contents Entries will be done. In this study, the control group received only the center's routine care. Impact assessment sessions will be conducted two months after the last training session (intervention group) and the control group, by refilling the FSFI questionnaire will be compared with previous surveys. At the end of the eight week training package will be given to the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403033037N7**
Registration date: **2014-05-16, 1393/02/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-16, 1393/02/26

Registrant information

Name

Mehrnaz Geranmayeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 1669

Email address

geranmay@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-04, 1393/02/14

Expected recruitment end date

2014-09-22, 1393/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of consultation on sexual dysfunction in women with type 2 diabetes mellitus

Public title

Effect of consultation on sexual function in women with type 2 diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: at least 6 months have passed their

Diagnosis of type 2 diabetes (doctor); not taking any medications that affect sexual function such as, antidepressant and anti hypertensive drug; not having disease such as heart disease, hyperthyroidism, hypothyroidism, liver and renal failure; couples are not addicted to drugs and alcohol; not pregnant, not lactation; married and living with spouse stable; couples living together have at least the past 1 year married; monogamy for men; during the last 6 months of emotional stress (such as the death of first-degree relatives) are not; no severe complications from diabetes, such as infection; having at least 20 years of age; the lack of menopause; lack of participation in training classes with a focus on sex education; not the spouses of women suffering from premature ejaculation or impotence; couples do not have a mental illnesses such as depression. Exclusion criteria: occurrence of diseases in women or their husbands' influence on sexual function, including cardiovascular disease, psychological, thyroid and cancers; start taking drugs that affect sexual functioning during this manner; serious marital dispute; history of a traumatic event during the past 6 months such as death of first-degree relatives; gynecologic problems, including vaginal bleeding; amputation during the follow-up; to become pregnant.

Age

From **20 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods St.,
Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2014-02-07, 1392/11/18

Ethics committee reference number

130/2640/92/5

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

sexual dysfunction in women with type 2 diabetes mellitus

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes mellitus

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

sexual function in women with type 2 diabetes mellitus

Timepoint

before intervention and then two month later

Method of measurement

FSFI questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group will receive sex consultation. Program of sex consultation in this study is 3 sessions will last 90 minutes once a week. In First meeting will be describe about anatomy of the female reproductive system, sexual cycle and the factors involved in its, second session on the types of sexual disorder and to describe the effect of diabetes on sexual function in women. Also the treatment strategies offered. In third session will be provided solutions for better courtship and more intimacy in relationships and summary and overview of previous contents Entries will be done.

Category

Treatment - Other

2**Description**

Control group will receive only the center routine care. At the end of the eight week training package will be given to the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Therapeutic Educational 5 Azar Hospital

Full name of responsible person

Maryam Moradi

Street address

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of tehran University of Medical Sciences

Full name of responsible person

Dr.Masoud yonesian

Street address

Keshavarz Blvd, Qods St., Tehran University of Medical Sciences

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of tehran 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

Contact

Name of organization / entity

Tehran Nursing and Midwifery Faculty

Full name of responsible person

Maryam Moradi

Position

The Masters of midwifery student

Other areas of specialty/work

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School of Midwifery and Nursing, Tohidsquar, Tehran

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Nursing and Midwifery Faculty

Full name of responsible person

Mehrnaz Geranmayeh

Position

Academic faculty member

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Moradi

Position

The master of Midwifery student

Other areas of specialty/work

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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