

# 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**

130/2640/92/3

**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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mehrnaz Geranmayeh

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Academic faculty member

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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The master of Midwifery student

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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*