

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The Effectiveness of sexual counseling using PLISSIT model on sexual quality of life and sexual function of women with type 2 diabetes mellitus

Protocol summary

Summary

This randomized clinical trial aimed to evaluate the effectiveness of PLISSIT based sexual counseling on sexual quality of life and sexual function among women aged 35-55 with diabetes type 2. The participants will be recruited in Bamonar hospital based on inclusion criteria after giving informed consent. Random allocation will be done and 55 diabetic women will include in each intervention or control group. Intervention group will receive three, 45 minute sexual counseling sessions 1 weekly. In three times; before, 4 weeks and 8 weeks after intervention SQOL-F, FSFI and Beck II Depression questionnaires will be filled out. Control group just will receive a general health educational pamphlet and 1 sexual counseling session after the study. The effects of counseling between two groups and among groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070231662N4**

Registration date: **2017-08-02, 1396/05/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-02, 1396/05/11

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences will fund this project.

Expected recruitment start date

2017-08-21, 1396/05/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of sexual counseling using PLISSIT model on sexual quality of life and sexual function of women with type 2 diabetes mellitus

Public title

The Effectiveness of sexual counseling using PLISSIT model on sexual quality of life and sexual function of diabetic women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: writing and reading literacy in Persian; being sexual active; aged 35-55; having at least one sexual problem and desire to talk about that. Exclusion criteria: participating in similar classes influencing in sexual function; pregnancy during study; severe conflict in marital relationship and/ or divorce.

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Alborz University of Medical Sciences

Street address

North Taleghani-Azimiyeh

City

Karaj

Postal code

Approval date

2017-04-19, 1396/01/30

Ethics committee reference number

Abzum.Rec.1396.6

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E9

ICD-10 code description

With unspecified complications

Primary outcomes

1

Description

Sexual quality of life

Timepoint

before, 4 weeks , and 8 weeks after intervention

Method of measurement

SQOL-F

2

Description

Sexual function

Timepoint

before, 4 weeks , and 8 weeks after intervention

Method of measurement

FSFI questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

Before, 4 weeks and 8 weeks after intervention

Method of measurement

Beck II Depression questionnaire

Intervention groups

1

Description

Intervention group: 55 diabetic women with at least one sexual problem will receive three 45 minute individual sexual counseling based on PLISSIT model weekly. Contents of counseling sessions will be anatomy and physiology of genital tract, sexual cycle response, thoughts and emotions, relaxation, Kegel exercise, and sensate focus.

Category

Behavior

2

Description

Ccontrol group: 55 diabetic women with at least one sexual problem will receive a general health educational pamphlet and also one session sexual counseling.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine clinic of Shahid Bahonar Hospital

Full name of responsible person

Maryam Mehrabi

Street address

Shora Blvd., Azimieh, Karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

North Taleghani street-Azimyeh

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz 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

Alborz University of Medical Sciences- School of Nursing and Midwifery

Full name of responsible person

Maryam Mehrabi

Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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