

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### The effect of online counseling based on mindfulness approach on sexual intimacy of diabetic women

#### Protocol summary

Increased sexual intimacy in women with type 2 diabetes

##### Study aim

The effect of online counseling based on mindfulness approach on sexual intimacy of diabetic women

##### Design

A clinical trial with a control group, with parallel groups, not blinded, randomized randomized block allocation on 60 patients (women) is done by visiting <http://www.randomization.com>.

##### Settings and conduct

The research site is Yazd Diabetes Center. The sample size is 60 people who are randomly assigned, 30 people in the experimental group and 30 people in the control group and the intervention in the form of 8 counseling sessions for one and a half hours and online with the approach Mindfulness is done in WhatsApp space and the control group will receive 4 training sessions through an educational pamphlet. (Active control group) The measured instrument is a demographic information questionnaire and a sexual intimacy questionnaire that is evaluated as pre-test and post-test, before the intervention, immediately after the intervention and one month after the intervention in the experimental group and compared with the control group. will be.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: • Women of reproductive age 18 to 49 years • Having type 2 diabetes • Have at least one year of living together. Inclusion criteria: • You and your spouse are addicted to drugs according to the patient • Consumption of psychiatric drugs by oneself and one's spouse according to the patient • Participate in simultaneous psychological and psychiatric interventions

##### Intervention groups

The intervention is done in the form of 8 sessions of counseling for one and a half hours and online with WhatsApp mindfulness approach on sexual intimacy of women with type 2 diabetes, and the control group will receive 4 sessions of online training through an educational pamphlet.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211222053483N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

##### Registration date

2022-06-21, 1401/03/31

##### Registrant information

##### Name

Fereshteh Heshmati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3828 0148

##### Email address

f.heshmati@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-06, 1401/04/15

##### Expected recruitment end date

2022-09-06, 1401/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of online counseling based on mindfulness approach on sexual intimacy of diabetic women

### Public title

The effect of online counseling based on mindfulness approach on sexual intimacy of diabetic women

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women of reproductive age 18 to 49 years Having type 2 diabetes The person's blood sugar is controlled. Have at least one year of living together. Have access to smart phones and the Internet. Willingness to participate in virtual meetings. Fill out a voluntary and informed written consent form online.

#### Exclusion criteria:

His and his wife's drug addiction, according to the patient Consumption of psychiatric drugs by himself and his wife, according to the patient Participate in simultaneous psychological and psychiatric interventions Pregnancy Systemic diseases or disease exacerbations Having erectile dysfunction in the spouse

### Age

From **18 years** old to **49 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Random allocation method: The specified sample size includes 60 people (women), each person can be assigned a number between 1 and 60, which is done by referring to the online site random allocation. Assignment Model Due to the fact that this study is in two groups (experimental and control group), the first generation randomization model is used that each sample (female) is placed in a treatment group called block randomization and [Http://www.randomization.com](http://www.randomization.com) The software randomly assigns each person to one of the two groups A and B, which means that the allocation of people to each of the two groups in the order AB occurs. It does not fall but is done in the order in which the software output is placed.

### 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

Research Ethics Committees of Shahid Sadoughi University of Medical Sciences

##### Street address

Unit 10, 4th Floor, Block 4, Farhang 6, Farhangian Complex, Mehravaran, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8915843554

#### Approval date

2022-01-26, 1400/11/06

#### Ethics committee reference number

IR.SSU.REC.1400.223

## Health conditions studied

### 1

#### Description of health condition studied

Women with type 2 diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

The effect of online counseling based on mindfulness approach on sexual intimacy of diabetic women

#### Timepoint

The sexual intimacy of the subjects will be assessed before the intervention, immediately after the intervention and one month after the intervention.

#### Method of measurement

Invalid sexual intimacy questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention is done in the form of 8 counseling sessions for one and a half hours and

online with a mindfulness approach in the WhatsApp space.

**Category**

Behavior

**2****Description**

Control group: Sexual health trainings such as male and female device anatomy, sensory points and sexual response cycle, etc. are received as an educational pamphlet in 4 sessions in WhatsApp and online (active control group) and after the intervention if Willingness to be consulted.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yazd Diabetes Center

**Full name of responsible person**

fereshteh Heshmati

**Street address**

Unit 10, 4th Floor, Block 4, Farhang 6, Farhangian Complex, Mehravaran, Yazd

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**Postal code**

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**Email**

f.heshmati@stu.ssu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Mirzaei

**Street address**

Unit 10, 4th Floor, Block 4, Farhang 6, Farhangian Complex, Mehravaran, Yazd

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Fereshteh Heshmati

**Position**

obstetrician

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fereshteh Heshmati

**Position**

Midwife

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fereshteh Heshmati

**Position**

Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Fax**

**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data, such as information about the main  
outcome, can be shared.

**When the data will become available and for how  
long**

Access period starts 6 months after the results are  
published

**To whom data/document is available**

Researchers working in academic and scientific  
institutions and people who are also involved in industry.

**Under which criteria data/document could be used**

Analysis on the data is allowed provided that ethical  
principles are maintained and the source is mentioned.

**From where data/document is obtainable**

Fereshteh Heshmati, contact number: 09185554741

Email address: F.heshmati99@gmail.com

**What processes are involved for a request to access  
data/document**

Applicant request by phone or e-mail, explanation of how  
to conduct their research, coordination with the Vice  
Chancellor for Research of Yazd University of Medical  
Sciences and obtaining permission from them, providing  
the requested information and data to the applicant.

**Comments**