Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Oct 2026

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

Protocol summary

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
clusion 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
Increased sexual intimacy in women with type 2 diabetes

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 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

City

Yazd

Province

Yazd

Postal code

8915843554

Phone

+98 35 3828 0148

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

City

Yazd

Province

Yazd

Postal code

8915843554

Phone

+98 35 3828 0148

Email

F.heshmati@stu.ssu.ac.ir

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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Postal Code 8915843554, Unit 10, 4th Floor, Block 4, Farhang 6, Farhangian Complex, Mehravaran, Yazd

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Postal code

8915843554

Phone

+98 35 3828 0148

Fax

Email

f.heshmati@stu.ssu.ac.ir

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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Yazd

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Phone
+98 35 3828 0148

Fax

Email
f.heshmati@stu.ssu.ac.ir

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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Yazd, Mehravaran, Farhangian Complex, Farhang 6, Block 4, Unit 10, Postal Code 8915843554

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Province
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Fax

Email
f.heshmati@stu.ssu.ac.ir

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