

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of of Psycho-spiritual approach in improving sexual performance, sleep quality and depression in women with type 2 diabetes: randomized clinical trial

Protocol summary

Study aim

Determining the effect of the psycho-spiritual approach in improving sexual function, sleep quality, and depression in women with type 2 diabetes

Design

The clinical trial, with parallel groups, single-blind, randomized, on 60 patients, will be used for randomization from <https://www.sealedenvelope.com>.

Settings and conduct

This research will be done at Alborz Shahid Rajaei Hospital. Before the implementation of the intervention, the level of sexual performance, sleep quality, and depression of the participants will be filled by the relevant questionnaires. Then, the intervention will be done in the intervention group, and immediately after the end of the intervention, and 3 months after the intervention, the questionnaires will be completed again in both groups.

Participants/Inclusion and exclusion criteria

Entering criteria: married women aged 18 to 45 with type 2 diabetes, diagnosis of diabetes by a doctor and at least one year of diabetes diagnosis, being interested in participating in the study, and not having a mental disability including any kind of mental or cognitive disorder that hinders participation in the process of mutual interaction, adherence to the program, or giving informed consent to participate in this study, having a Farsi dialect
Exclusion criteria: participation in unusual educational programs or similar research while conducting research, inability to continue participating in the study, and Failure to participate in all meetings

Intervention groups

In the control group, routine care will be done. In the intervention group, for 10 weeks, a 45-90 minute session with a psycho-spiritual approach will be conducted by a psychologist and a psycho-nurse with experience in the field of psycho-spiritual approach and in a group.

Main outcome variables

Sexual performance; Sleep quality; Depression

General information

Reason for update

Acronym

PSA (Psycho-Spiritual Approach)

IRCT registration information

IRCT registration number: **IRCT20220704055367N2**

Registration date: **2022-09-10, 1401/06/19**

Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**

Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Fatemeh Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

fatemeh.abdi87@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of of Psycho-spiritual approach in improving sexual performance, sleep quality and depression in women with type 2 diabetes: randomized clinical trial

Public title

The effect of Psycho-spiritual approach in women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women aged 18 to 45 with type 2 diabetes
Diagnosed with diabetes by a doctor and at least one year has passed since the diagnosis of diabetes
Being interested in participating in the study
Not having mental incompetence, including any kind of mental or cognitive disorder that prevents participation in the interaction process, adherence to the program, or giving informed consent to participate in this study
Having Persian dialect

Exclusion criteria:

Participating in unusual educational programs or similar research while conducting research
Inability to continue participating in the study for any reason (need for special care, immigration, death)
Failure to participate in all meetings

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to select the sample, after preparing a list of type 2 diabetes patients who referred to the diabetes clinic of Shahid Rajaei Alborz Hospital, they will be contacted. Then, 60 people who wish to participate in the research will be selected using available sampling and will be included in the study based on the criteria for entering the research. And they will be randomly assigned to two groups of psycho-spiritual approach and control, each of which will have 30 participants. In order to randomize the samples, the block randomization method, which is a limited randomization method related to studies with groups with the same sample size, will be used. Also, in this study, according to the sample size, two blocks of 30 will be considered. In order to implement this method, jerrydallal.com/random/assign.htm will be used. And on

the mentioned site, the title of the two groups (psycho-spiritual intervention and control), the number of blocks, and the volume of each block will be mentioned. Then, according to the randomization obtained from the site and the last three numbers of the patients' files, randomization will be done. In this way, in the face of the obtained randomizations, we will write down the last three numbers of the patients' files in order from the least to the most, and according to that, the patients in each of the control groups and the psycho-spiritual approach They will be.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a blinded clinical trial. Therefore, blinding will be implemented in the evaluators who will analyze the study data. For this purpose, the questionnaires that will be completed by the researchers in all three groups, in the form of a contract between the researchers. Also, it will be specified with one of the English letters above it, which questionnaire was completed by the participants of which of the study groups; However, the evaluators of the data analysis will not be aware of the English letter of agreement between the researchers assigned to each group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Alborz University of Medical Sciences

Street address

Ethics committee office, Second floor, Safarian alley, 45 meters to Golshahr

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-08-12, 1401/05/21

Ethics committee reference number

IR.ABZUMS.REC.1401.119

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

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Sexual performance scores on Female Sexual Function Index

Timepoint

Measurement of women's sexual performance scores at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

Female Sexual Function Index

2

Description

Sleep quality scores in the Pittsburgh Sleep Quality Index

Timepoint

Measurement of sleep quality score at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

Pittsburgh Sleep Quality Index

3

Description

Depression scores in Beck depression Inventory

Timepoint

Measurement of depression score at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

Beck Depression Inventory

4

Description

Patient's treatment compliance

Timepoint

Measurement of treatment compliance score at the beginning of the study, 10 weeks later, 22 weeks later

Method of measurement

Morisky Medication Adherence Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It will be formed in the intervention group in order to create group coordination in WhatsApp. Group meetings will be held in groups of 30 people. In order to implement the psycho-spiritual approach in the

intervention group, 10 sessions of 45-90 minutes each week will be held by a psychologist and a psycho-nurse with experience in the field of psycho-spiritual approach and with the coordination of patients in a group. Considering that the conditions of diabetic patients are special, it is difficult for them to participate in face-to-face classes. Therefore, they may not be able to participate in the class in person. In addition, if they gather in one place for training, some diseases may be transmitted and become a problem. Therefore, according to the mentioned cases, it was preferred that the training be virtual, but still, a decision will be made according to the conditions of the patients in this field. The spiritual approach is written by using the content of the chapter on spiritual methods to relieve the pain of patients from the book of spiritual care. Dr. Mino Asadzandi, a member of the academic faculty of the Baqiyatullah University of Medical Sciences and the Medicine and Religion Research Center, will be implemented. Also, the psychological approach will be implemented using the content of the group psychotherapy book (theoretical and practical basics) by Yalom and Lashech translated by Mahshid Yasai. The first session is for familiarization and introduction, sessions 2 to 4 are designed for a spiritual approach, and sessions 5 to 10 will be designed for a psychological approach.

Category

Treatment - Other

2

Description

Control group: The control group will receive usual care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Karaj educational and therapeutic center

Full name of responsible person

Fatemeh Abdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Alborz University of Medical Sciences (ABZUMS),
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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

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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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
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data, such as information related to the main outcome and general demographic information can be shared.
When the data will become available and for how long
The access period starts 3 months after the results are published
To whom data/document is available
Doctors, nurses, midwives, researchers working in

universities and medical centers and hospitals, clinical psychologists
Under which criteria data/document could be used
In order to use it for scientific purposes and by mentioning the source used and requesting the journal in which the article will be published
From where data/document is obtainable
Communication through e-mail (if possible to share information from a legal and ethical point of view, such as sharing the primary outcome of the study) To receive information, contact the following email address: fatemeh.abdi87@yahoo.com In the case of sending letter with regard to the current study, the following postal address of the corresponding author is available: School of nursing, Eshteraki street, Takhti Park, Baghestan BLVD
What processes are involved for a request to access data/document
Finding the responsible author's email, stating the reason, complying with ethical and legal issues; In this case, a quick response will be given to the requester.
Comments