

# 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

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target 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](http://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

**Street address**

Shahid Rajaei St, Hesarak

**City**

Karaj

**Province**

Alborz

**Postal code**

3197635141

**Phone**

+98 26 3457 0030

**Email**

rajaei@abzums.ac.ir

**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),  
Northern Taleghani boulevard, Taleghani square

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Phone**

+98 26 3419 7000

**Email**

info@abzums.ac.ir

**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

**Street address**

School of nursing, Eshteraki street, Baghestan BLVD,  
Karaj, Iran

**City**

Karaj

**Province**

Alborz

**Postal code**

3146883811

**Phone**

+98 26 3433 6007

**Email**

fatemeh.abdi87@yahoo.com

### Person responsible for scientific 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

**Street address**

Taleghani Boulevard, Taleghani square, Karaj, Iran

**City**

Karaj

**Province**

Alborz

**Postal code**

3146883811

**Phone**

+98 26 3419 7000

**Email**

fatemeh.abdi87@yahoo.com

### Person responsible for updating data

**Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh Abdi

**Position**

Assistant professor

**Latest degree**

Ph.D.

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**Postal code**

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**Phone**

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**Email**

fatemeh.abdi87@yahoo.com

### 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**