

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of mindfulness-based cognitive therapy via whats app social media on sexual function and sexual distress in women with diabetes

Protocol summary

sexual function, sexual distress, mindfulness-based
Cognitive therapy

Study aim

1- Investigating the effect of mindfulness- based cognitive therapy via Whats App social media platform on sexual function and sexual distress in women with diabetes

Design

The clinical trial has a randomized control group, an intervention and a control group of 36 people each, randomization by 4 blocks method.

Settings and conduct

The place of the study is Qazvin comprehensive health centers, the sample of the research is diabetic women referring to the health centers who meet the conditions for entering the study. The participants are randomly assigned to two control and intervention groups. . In the control group, there is no intervention, and in the intervention group, the method of (MBCT) is used. The program will be presented by the researcher as an 8-session program during 8 weeks (the first week in person and the next 7 weeks on WhatsApp platform). Meetings will be held individually. Contents and assignments will be presented to the people of the intervention group on a weekly basis through social media (WhatsApp). The way to follow up the samples in 4 steps is to fill the questionnaire in the first session (pre-test), the last session (post-test), one month after the last session and 3 months after the last training session.

Participants/Inclusion and exclusion criteria

Entry conditions: definitely suffering from diabetes, willing to participate in the study, suffering from sexual dysfunction
Conditions of non-entry: unwillingness to participate in the study, suffering from gestational diabetes and breastfeeding

Intervention groups

Participants are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the method of mindfulness based cognitive therapy (MBCT) is used.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220726055556N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

mina fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-12, 1401/05/21

Expected recruitment end date

2022-12-12, 1401/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness-based cognitive therapy via
whats app social media on sexual function and sexual
distress in women with diabetes

Public title

The effect of mindfulness-based cognitive therapy via
whats app social media on sexual function and sexual
distress in women with diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

being married Definite diabetes with a doctor's diagnosis
- Being 15 to 49 years old Having sexual dysfunction
based on the FSFI questionnaire Access to social media
such as internet and smartphone At least 3 months have
passed since having sex with your spouse Willingness to
participate in the study

Exclusion criteria:

Having any symptoms of diseases such as depression,
panic attacks, delusions, hallucinations and any other
type of mental illness based on the person's self-report.
Unwillingness to continue participating in the study
Taking drugs that affect sexual performance, such as
psychotropic drugs Known physical, mental, sexual
disorders in the spouse Gestational diabetes and
breastfeeding diabetes

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **72****Randomization (investigator's opinion)**

Randomized

Randomization description

: For random allocation, considering that we have two
intervention and control groups, we will use a block of 4.
In order to determine the allocation sequence using the 4
block method, random allocation sequence generation
software will be used. In order to hide the sequence of
allocation, the papers identifying the group of people are
placed inside the envelopes in the opaque package and
coded in the same order. In this case, a questionnaire
with the same code will be completed for the person who
receives the code 1 intervention

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Working group/committee of ethics in research of
Qazvin University of Medical Sciences

Street address

Qazvin, North Nawab St., Shahid Salmani Alley,
Administration Complex, Headquarters Building of
Qazvin University of Medical Sciences

City

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Province

Qazvin

Postal code

5316848893

Approval date

2022-07-23, 1401/05/01

Ethics committee reference number

IR.QUMS.REC.1401.117

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

diabetes

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sexual performance score in women's sexual
performance questionnai

Timepoint

The beginning of the study (pre-test), the end of the
study (post-test), 1 month and 3 months after the last
session.

Method of measurement

Women's sexual performance index - shortened form

2**Description**

Sexual distress score based on revised sexual distress
questionnaire

Timepoint

The beginning of the study (pre-test), the end of the
study (post-test), 1 month and 3 months after the last
session.

Method of measurement

Revised Sexual Distress Questionnaire

3

Description

Mindfulness score based on mindfulness questionnaire

Timepoint

The beginning of the study (pre-test), the end of the study (post-test), 1 month and 3 months after the last session.

Method of measurement

Mindfulness questionnaire (awareness of conscious attention)

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Diabetic women with sexual dysfunction receiving mindfulness-based cognitive therapy . Mindfulness-based cognitive therapy (MBCT) is an approach to psychotherapy that uses cognitive behavioral therapy (CBT) methods along with mindfulness meditation practices and similar psychological strategies. In MBCT, mindfulness is based on 4 principles including Body awareness (body position and body movement/activity), body sensations (including those related to emotions), mental states (including emotional states) and mental content (thoughts, images) are taught. Internet-based cognitive behavioral therapy has recently been introduced as a new method for treating sexual problems. This treatment uses traditional cognitive and behavioral therapy methods to treat sexual problems based on increasing comfort, privacy and anonymity of people. In this study, the participants who meet the study entry criteria are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the method of cognitive therapy based on mindfulness (MBCT) is used. Before starting the treatment program, the training certificate of the MBCT course will be received and attached to the study, then the cognitive therapy program based on mindfulness for sexual function in the form of an 8-session program during 8 weeks (the first week in person and the next 7 weeks on WhatsApp) by The researcher will be presented. Meetings will be held individually. Contents and assignments will be presented to the people of the intervention group on a weekly basis through social media (WhatsApp). After presenting any new content, the researcher will inform the participants by SMS. It will be considered that the participants, whenever they have

a problem in doing the assignments, have more interaction with the researcher in person or virtually to ensure the correctness of the assignments. How to follow up the samples in 4 steps by filling out the questionnaire The first session (pre-test), the last session (post-test), one month after the last session and 3 months after the last training session.

Category

Treatment - Other

2

Description

Control group: Diabetic women without receiving cognitive therapy based on mindfulness

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bolandian Health Center of Qazvin

Full name of responsible person

Dr. Alireza Mehralian

Street address

Qazvin, Shahid Babaei Blvd., Dentist Street

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Dr. Abutaleb Simiari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi Mirhashmi

Street address

Shahid Salmani Alley, Shahid Salmani Alley, Qazvin,
Qazvin University of Medical Sciences Headquarters
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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mina Fathi

Position

University student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available