Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of implementing Levantal's self-regulation model on sexual function and satisfaction of women with diabetes in Qazvin city.

Protocol summary

Study aim
Determining the effect of implementation of Levantal's self-regulation model on sexual performance and sexual satisfaction of women with diabetes

Design
Clinical trial with control group, with parallel groups, without blinding, randomized, on 90 patients. Random allocation sequence generation software was used to determine the allocation sequence using the quadruple block method

Settings and conduct
Obtaining approval from the ethics committee of Qazvin University of Medical Sciences, registering the project in RCT. Selection of samples from women with diabetes (type 1 and 2) referring to the diabetes clinic (with entry requirements) in Qazvin city. After obtaining informed consent, completing the questionnaires in both groups. Randomization will be done into two intervention groups (counseling with Leventhal's self-regulation method) and control group (no intervention). In the test group, the intervention based on the Levantal self-regulation model was conducted individually in three sessions and the follow-up one and two and three months after the intervention, recompletion of the questionnaire on the perception of the disease, sexual performance and sexual satisfaction in both groups.

Participants/Inclusion and exclusion criteria
The individual's desire to participate in the study, age 15-49 years, living in Qazvin Be married and have sex At least reading and writing, the ability to communicate verbally, suffering from type 1 or type 2 diabetes, at least 6 months have passed since the diagnosis of diabetes not pregnant Any physical and mental illness in a person or his wife, marital problems, and the use of drugs effective on sexual performance or sexual satisfaction Participation in other training sessions

Intervention groups
Levantal self-adjustment method counseling

Main outcome variables
Sexual performance, sexual satisfactiondiabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221114056495N1**
Registration date: **2023-02-10, 1401/11/21**
Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**
Update count: **0**

Registration date
2023-02-10, 1401/11/21

Registrant information

Name
Leila Ghorbani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-25, 1401/12/06

Expected recruitment end date
2023-08-28, 1402/06/06

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of implementing Levantal's self-regulation model on sexual function and satisfaction of women with diabetes in Qazvin city.

Public title
Investigating the effect of implementing Levantal's self-regulation model on sexual function and satisfaction of women with diabetes in Qazvin city.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Age 15-49 years Living in Qazvin province At the time of study, be married and have sex Minimum literacy Ability to verbally communicate and answer questionnaire questions Having type 1 or type 2 diabetes according to expert opinion and laboratory factors (recorded in the medical record) not pregnant At least 6 months have passed since the diagnosis of diabetes
Exclusion criteria:
Any physical illness with a doctor's approval in the person or partner that affects their sexual function or sexual satisfaction Taking any type of medicine that (according to the patient) is effective on the patient's sexual function. Participation in other sexual education or counseling sessions during the last month or at the beginning of the study The existence of marital problems that affect people's sexual relations. Patients with severe psychiatric disorders that require drug therapy (clinical and semi-clinical disorders)
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
For random allocation, given that there is an intervention method (consulting with the self-regulation method of Levantal) and two control and intervention groups, random allocation sequence generation software will be used to determine the allocation sequence using the quadruple block method. The four-block method is used to prevent significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization, and at certain points the number of participants in each group is equal. By using the randomization block balanced method, they will be placed in two test and control groups with blocks of four. In this way, by choosing 20 blocks out of 6 possible blocks from the quadruple combination of two test and control groups, the selection process is defined by default and the patients will be assigned to two groups respectively. 1-AABB/ 2-ABBA/ 3-BAAB/ 4-ABAB/ 5-BABA/ 6-BBAA
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
After the registration of the eligible people in the study, after obtaining informed consent from the participants, the questionnaires will be provided to them, and explanations will be given regarding how to complete the questionnaire, emphasizing the confidentiality of the information. Each person will receive five questionnaires, which include demographic and fertility questionnaires; sexual performance questionnaire; Sexual satisfaction questionnaire, IPQ (Illness Perception Questionnaire) and diabetes severity index will be completed in both groups. relevant questionnaires; It will be completed by face-to-face interview.- To randomize the sample, a simple random block method with 4 blocks will be used. The participants of the research will be randomly divided into two intervention groups (consulting with Leventhal's self-regulation method) and the control group (without intervention). In the test group, the intervention based on Leventhal's self-regulation model will be implemented individually in three sessions. After the completion of the intervention, one month, two months and three months after the intervention, the questionnaire of understanding of the disease, sexual performance and sexual satisfaction will be completed again in both groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of ghazvin University of Medical Sciences
Street address
No. 59, No. 48, Imamzade Ebrahim St., Qom
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Qazvin
Postal code
3717689483
Approval date
2023-02-05, 1401/11/16

Ethics committee reference number
IR.QUMS.REC.1401.296

Health conditions studied

1

Description of health condition studied
Investigating the effect of implementing Levantal's self-regulation model on sexual function and satisfaction of women with diabetes in Qazvin city
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual performance and sexual satisfaction
Timepoint
Before the start of the intervention, after that one month, two months and three months after the intervention
Method of measurement
Demographic and Fertility Questionnaire, Sexual Function Questionnaire (FSFI), Sexual Satisfaction Questionnaire (SSS-W), Disease Perception Questionnaire (IPQ-R) and Diabetes Severity Index (DCSI)

Secondary outcomes

1

Description
Determining and comparing the level of understanding of the disease in women with diabetes in the control and test groups before and after the intervention
Timepoint
Before the intervention, one month, two months and three months after the intervention
Method of measurement
Illness perception will be measured with the Illness Perception Questionnaire (IPQ-R).

Intervention groups

1

Description
Intervention group: in the test group, in addition to receiving the usual care and training, their counseling needs are first determined and a counseling program is designed based on that. The educational content is based on the stages of Loenthal's self-regulation theory, before the intervention, questionnaires on demographic characteristics, sexual performance, sexual satisfaction, and understanding of the disease will be completed. Then the researcher will start the disease understanding intervention during three sessions of 60 to 90 minutes in three consecutive weeks face to face and individually in a private place. will be completed
Category
Other

2

Description
Control group: The control group only received the usual training and care that was given to the patients by the nurse, doctor, nutritionist and other members of the care team in the clinic according to the previous routine. In this group, questionnaires of demographic characteristics, sexual function and sexual satisfaction, understanding of the disease will be completed at the beginning of the study, one month, two months, and three months later.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital ، Mohammadzadeh Clinic
Full name of responsible person
Dr. Sima Hashemipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Full name of responsible person
Leila Ghorbani
Position
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the publication

of the article results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If the results of this study show the effectiveness of the method, this counseling method can be used to improve sexual performance and increase sexual satisfaction of diabetic women.

From where data/document is obtainable

Valid databases

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

1- After obtaining approval from the Ethics Committee of Qazvin University of Medical Sciences, registering the project in the National System of Clinical Trials and obtaining the necessary permits, the diabetes clinic located in Qazvin city is referred to. 2- The samples will be selected from women with diabetes (type 1 and 2) referring to the diabetes clinic in Qazvin city. 3- In these centers, people with conditions to enter the study are identified and they are invited to participate in the study 4- About the importance and objectives of the research, information, having the freedom to participate in the study, is explained to the people who have the conditions to enter the study, and in line with the ethical principles of research, they are assured that their information will remain confidential. The questionnaires will be anonymous and only coded. After taking a written consent form and obtaining permission, the samples are included in the study. Also, the researcher undertakes that the subjects can withdraw from the study whenever they wish and will be explained to the participants about receiving services by participating or not participating in the study and to some extent about how to do the work. 5- After the registration of the eligible people in the study, after obtaining informed consent from the participants, the questionnaires will be provided to them and the explanation about how to complete the questionnaire will be done with emphasis on the confidentiality of the information. Each person will receive five questionnaires, which include demographic and fertility questionnaires; sexual performance questionnaire; Sexual satisfaction questionnaire, IPQ (Illness Perception Questionnaire) and diabetes severity index will be completed in both groups. relevant questionnaires; It will be completed by face-to-face interview. 6- To randomize the sample, a simple random block method with 4 blocks will be used. The participants of the research will be randomly divided into two intervention groups (consulting with Leventhal's self-regulation method) and the control group (without intervention). In the test group, the intervention based on Leventhal's self-regulation model will be implemented individually in three sessions. After the completion of the intervention, one month, two months and three months after the intervention, the questionnaire of understanding of the disease, sexual performance and sexual satisfaction will be completed again in both groups. 7- Analysis of findings: after the end of the data collection process, the analysis of findings will be done with statistical software.

Comments