

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling based of PLISSIT model focused on sexual dysfunctional beliefs on sexual function and quality of sexual life of women with sexual dysfunction

Protocol summary

Study aim

Investigating the effect of counseling based on the PLISSIT model focused on sexual dysfunctional beliefs on sexual function and sexual quality of married women with sexual dysfunction

Design

After obtaining the written consent of the consultant will be conducted by the researcher. Consultation sessions consist of three 60 minute individual counseling sessions and a group meeting in groups of 5 to 8 persons with intervals of one week for the intervention group. After the end of the counseling sessions and four weeks after that and in control group that receive routine care of health center after one month, the questionnaires were completed by the research unit and collected by a researcher who did not know how to allocate the research units in the groups, and at the end, Data analysis is done by the statistician who is unaware of the allocation of individuals to the groups.

Settings and conduct

comprehensive health centers of Mashhad

Participants/Inclusion and exclusion criteria

Women with sexual dysfunction and sexual dysfunctional beliefs who have the conditions to enter the study

Intervention groups

Including 33 women attending to the comprehensive health center assigned to the intervention group and 33 women attending to the health center assigned to the control group

Main outcome variables

Sexual function, quality of sexual life

General information

Reason for update

The registered information is based on the initial proposal, which was slightly modified after

implementation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180710040407N1**

Registration date: **2018-12-15, 1397/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-22, 1400/04/31**

Update count: **1**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Malihe Mohammadzadeh moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3752 0282

Email address

mohammadzadehmm3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based of PLISSIT model focused on sexual dysfunctional beliefs on sexual function and quality of sexual life of women with sexual dysfunction

Public title
The effect of counseling based of PLISSIT model focused on sexual dysfunctional beliefs on sexual function and quality of sexual life of women with sexual dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Iranian and resident of Mashhad. At the age of fertility and above 18 years old. Having sex during the last month. The woman is living with her husband. First marriage Having sexual dysfunction according to the FSFI scale Having at least one dysfunctional sexual belief according to the SDBQ questionnaire
Exclusion criteria:
Having depression, stress, or anxiety, according to the DASS-21 scale. Having a medical or mental illness that could have an effect on sexual function Using a drug that could have an effect on sexual function. Has taken part in an educational or counseling course. Having burdensome or severe incidents in the last 6 months. being in pregnancy or lactation period (having child younger than two years old). Existence of mental or physical disability in a woman or spouse. Having infertility.

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of allocating centers to intervention and control groups is simple in lottery form.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analysis is performed by a statistician who is unaware of the allocation of individuals to groups.

Placebo
Not used

Assignment
Parallel

Other design features
in the intervention group, counseling of dysfunctional sexual beliefs is based on a PLISSIT model by a researcher whose competence has been approved by the supervisor and counselor. Meetings are held in three individual sessions and a 60 minute group session with intervals of one week based on four stages of the PLISSIT model. control group receive routine care of health center.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Mashhad University of Medical Sciences

Street address

opposite to University Street 18 .University Street -

City

Mashhad

Province

Razavi Khorasan

Postal code

051 38412081

Approval date

2018-09-18, 1397/06/27

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.052

Health conditions studied

1

Description of health condition studied

sexual dysfunction

ICD-10 code

F52.8

ICD-10 code description

Other sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

sexual function

Timepoint

The beginning of the study and after the consultation sessions and one month after the consultation sessions

Method of measurement

The Female Sexual Function Index (FSFI)

Secondary outcomes

1

Description

Quality of sexual life

Timepoint

The beginning of the study and after the consultation sessions and one month after the consultation sessions

Method of measurement

The sexual quality of life-female questionnaire (SQOL-F)

2

Description

Sexual function

Timepoint

The beginning of the study and after the consultation sessions and one

Method of measurement

FSFI questionnaire

Intervention groups

1

Description

The intervention group will receive three individual counseling sessions (60 minutes) weekly and a group counseling session (90minutes) based on on four stages of the PLISSIT model focused on sexual dysfunctional beliefs.

Category

N/A

2

Description

The control group will provided with routine services by the staff in healthcare centers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fadaeian Eslam and Kargaran centers

Full name of responsible person

Malihe Mohammadzadeh Moghadam

Street address

Between 5 and 7 .Street Fadaiyan Islam.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Deputy of Research and Technology University of Medical Sciences.Mashhad University of Medical Sciences-opposite to University Street 18- University Street - mashhad

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Email

vcresearch@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mohammadzadeh Moghadam

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Crossroad of the Doktora - School of Nursing and Midwifery-

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+98 51 3859 7313
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mohammadzadehmm3@mums.ac.ir
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<https://nurse.mums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Moradi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
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Malihe Mohammadzadeh Moghadam
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Masters student
Latest degree
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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

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

Title and more details about the data/document

The results of this study will be provided to the library of the Faculty of Nursing and Midwifery of Mashhad for the use of students and research units as well as enthusiasts as the senior dissertation on midwifery. A copy of this study was also made available to relevant authorities upon request. Publication of the results in prestigious scientific and research journals will be done in compliance with the authors' rights in all publications resulting from this research project.

When the data will become available and for how long

Probably from the Mehr 1398

To whom data/document is available

Researchers, students and research units as well as other enthusiasts

Under which criteria data/document could be used

The use of thesis in articles or any scientific article is subject to the mention of the source and in accordance with the publication regulations of Mashhad University of Medical Sciences.

From where data/document is obtainable

Library of the School of Nursing and Midwifery of Mashhad

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

Contact e-mail with supervisor and registered author

Comments