Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 8persons 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 recieve routin 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 routin 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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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
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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.
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Person responsible for updating data

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Email
mohammadzadehmm3@mums.ac.ir
Web page address
https://nurse.mums.ac.ir/

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