Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

effect of the PLISSIT model on the sexual quality of life in infertile women with sexual dysfunction

Protocol summary

Study aim
Determining the effect of counseling based on the PLISSIT model on the quality of sexual life of infertile women with sexual dysfunction

Design
A clinical trial with a control group, with parallel groups, one-sided blind, randomized, 41 samples for each of the test and control groups.

Settings and conduct
The research environment is the Fertility and Infertility Center of Hazrat Maryam Isfahan. Eligible individuals to enter the study who have sexual dysfunction based on FSFI questionnaire will enter the study. These people will be placed in two test and control groups using a table of random numbers. The participants will not know whether they are in the control group or the test group. The SQOLF questionnaire is completed in both groups before the intervention. In the test group, the sexual counseling will be conducted individually based on the PLISSIT model , which will be 4 weekly counseling sessions or more depending on the needs of the participants with 45-60 time. For the control group, an individual counseling session will be held for one hour, and counseling in this group will not be based on a specific model. 4 weeks after the intervention, the FSFI and SQOLF questioner will be completed again in both groups

Participants/Inclusion and exclusion criteria
Age from 18 to 45 , the treatment in the stage before ART, having sexual dysfunction based on the FSFI questionnaire, Not suffering from mental and physical diseases and not taking drugs that affect sexual function

Intervention groups
In the test group, the sexual counseling will be held individually based on the PLISSIT model, which will be 4 weekly counseling sessions or more depending on the needs of the participants with 45-60 time.

Main outcome variables
Counseling based on the plissit model, Quality of sexual life, Sexual function index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230205057328N1**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

Registration date
2023-02-14, 1401/11/25

Registrant information

Name
Reyhane Amini

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 5442 0731

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reyhane.aminiiiiii@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-14, 1401/11/25

Expected recruitment end date
2023-07-16, 1402/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

effect of the PLISSIT model on the sexual quality of life in infertile women with sexual dysfunction

Public title
effect of the PLISSIT model on the sexual quality of life in infertile women with sexual dysfunction

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be Iranian Age range from 18 to 45 years Having at least reading and writing literacy The treatment process of infertile women should be in the stage before assisted reproductive treatments having sexual dysfunction based on the score obtained from the standard FSFI questionnaire (score less than 28 from the FSFI questionnaire)

Exclusion criteria:
Husband suffering from erectile dysfunction and premature ejaculation suffering from known mental and physical diseases affecting sexual function such as diabetes, hypertension, rheumatoid arthritis, depression, etc. based on the documents included in the patient's file taking drugs that affect sexual function, such as cardiac drugs and beta blockers, H2 blockers, antidepressants, anticholinergics, and continuous use of antihistamines based on the patient's statements or the documents included in the patient's file history of participation in training classes or counseling sessions focused on sexual performance

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **82**

Randomization (investigator's opinion)
Randomized

Randomization description
For random allocation, using the table of random numbers, people will be placed in two groups, test and control, in such a way that if they receive an even number from this table, they will be placed in the test group, and if they receive an odd number, they will be placed in the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants will be placed in the test and control groups based on the random number table. In the test group, there will be 4 weekly counseling sessions based on the PLISSIT model. The control group will receive one hour of individual sex counseling. After 4 weeks, both groups will complete the FSFI and SQOLF questionnaires. During this period, the participants are not aware that they are in the control group or the test group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medica

Street address
Isfahan University of Medical Sciences, Hazar Jarib Street, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2023-01-28, 1401/11/08

Ethics committee reference number
IR.MUI.NUREMA.REC.1401.148

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

2

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Sexual quality of life

Timepoint
Before the intervention and 4 weeks after the intervention

Method of measurement

Sexual quality of life -female questionnaire

2

Description
Sexual function index
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Female sexual function index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Individual sexual counseling based on the 4 steps of the PLISSIT model in the form of 4 weekly counseling sessions or more depending on the needs of the participants with a time of 45-60 minutes.
Category
Treatment - Other

2

Description
Control group: Individual counseling session for one hour without using counseling models
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Maryam fertility and Infertility Center,
Full name of responsible person
Mahboube Taebi
Street address
Motahari St., Shahid Beheshti Hospital, Hazrat Maryam Fertility Center
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Gholamreza Asgari
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reyhaneh Amini
Position
Master student of midwifery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available