

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 31 5442 0731

Email address

reyhane.aminiiii@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	Not used
Public title effect of the PLISSIT model on the sexual quality of life in infertile women with sexual dysfunction	Assignment Parallel
Purpose Education/Guidance	Other design features
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	Secondary Ids empty
Age From 18 years old to 45 years old	Ethics committees
Gender Female	1
Phase N/A	Ethics committee Name of ethics committee Ethics Committee of Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medical Sciences Street address Isfahan University of Medical Sciences, Hazar Jarib Street, Isfahan City Isfahan Province Isfahan Postal code 8174673461
Groups that have been masked • Participant	Approval date 2023-01-28, 1401/11/08
Sample size Target sample size: 82	Ethics committee reference number IR.MUI.NUREMA.REC.1401.148
Randomization (investigator's opinion) Randomized	Health conditions studied
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.	1
Blinding (investigator's opinion) Single blinded	Description of health condition studied Sexual dysfunction
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.	ICD-10 code F52
Placebo	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

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 groups1**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 centers1**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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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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

Latest degree

Bachelor

Other areas of specialty/work

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