

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation the Effectiveness of Counseling based on EX-PLISSIT model on Sexual Self-Concept and Marital Satisfaction in Infertile Women

Protocol summary

Study aim

Determining the effect of EX-PLISSIT-based counseling on sexual self-concept and marital satisfaction of women referring to urban infertility centers.

Design

A Clinical trial with control group, with parallel group design, A blind side, randomized

Settings and conduct

Location of Hazrat Maryam Infertility Center in Sari

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Couples who live together during the research; have a high school education and more; at least 6 months and at most 10 years have passed since the diagnosis of infertility. Non-inclusion Criteria: occurrence of any severe psychological stress such as accident or loss of a loved one during the past 3 months; underlying medical conditions.

Intervention groups

Intervention group: Infertile women who received two 45-minute counseling sessions with one week interval in a safe and comfortable environment based on the PLISSIT-EX model. Control group: Infertile women who were not consulted and completed the questionnaires in only three steps. The sessions were held for control group on request after the end of the study.

Main outcome variables

Marital satisfaction; sexual self-concept

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042976N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **retrospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Arezou khodaiyan Krim

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-02-09, 1397/11/20

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2019-07-23, 1398/05/01

Scientific title

Evaluation the Effectiveness of Counseling based on EX-PLISSIT model on Sexual Self-Concept and Marital Satisfaction in Infertile Women

Public title

The Effect of Counseling based on EX-PLISSIT model on Sexual Self-Concept and Marital Satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Couples living together during research (no barriers to the presence of a spouse at home, such as having a job in a city other than the spouse's residence). Having high school education and more (due to the complexity of the self-concept questionnaire) At least 6 months and up to 10 years have passed since their infertility was diagnosed Have no children (primary infertility)

Exclusion criteria:

Any severe psychological stress such as an accident or the loss of a loved one over the past 3 months
Underlying medical conditions such as heart disease, gastrointestinal or respiratory disease, epilepsy, high blood pressure, diabetes, rheumatoid arthritis, or depression (self-reported) Addiction of each couple to drugs and alcohol (based on self-expression) Known sexual dysfunction, including vaginismus, premature ejaculation (based on self-expression)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in this study will be assigned to two groups by block randomization method (blocks of size 4). The blocks are as follows: Test group: A, Control group: B. 1- AA BB 2- AB AB 3- AB BA 4- BB AA 5- BA BA 6- BA AB After creating the different states of the blocks of size 4, We produce random numbers 1 to 6 using a regular hexagon. This process will be repeated 24 times. For the selection of a random number, a block of size 4 will be selected, accordingly 2 people will be in the test group and 2 people will be in the control group. At each stage of the study, the number of people assigned to the test and control group is the same.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants were kept blind and after completing the first stage questionnaire, they would be informed which of the test or control groups they were in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gorgan University of Medical Sciences

Street address

Shast Kola

City

Gorgan

Province

Golestan

Postal code

4663255

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.GOUMS.REC.1397.199

Health conditions studied

1

Description of health condition studied

Sexual self-concept and marital satisfaction

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Sexual self-concept score on the Snell questionnaire

Timepoint

Before the start of the intervention, one week later and one month after the start of the intervention

Method of measurement

Snell Persian sexual self-concept questionnaires

2

Description

Marital Satisfaction Score in Lee Questionnaire

Timepoint

Before the start of the intervention, one week later and one month after the start of the intervention

Method of measurement

Lee's Persian Marital Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: infertile women receiving counseling. The counseling intervention group was based on the PLISSIT-EX model, during which two one-hour weekly visits were held at Hazrat Maryam Infertility Center. Individual counseling was without the presence of a spouse, and during these sessions, the patient was first told about his or her problems by creating a safe, trustworthy, and non-judgmental environment. The patient was then allowed to talk about his or her marital satisfaction and sexual problems. In the next step, the researcher provided limited information directly related to the client's sexuality and concerns, and provided the patient with information about the anatomy and physiology of the female sexual organ, the stages of the sexual cycle, and sexual function. At the end, the client was offered a specific and problem-solving proposal, and during each step there was feedback to increase self-awareness, and the review process was guided by reviewing, exchanging views and opinions, and discussing patient learning and understanding during counseling.

Category

Other

2

Description

Control group: Infertile women who completed only the questionnaires in three stages and no advice was given to them until the end of the project. At the end of the project, the control group was asked to hold counseling sessions if they wished, and only two people were willing to hold counseling sessions, which were also consulted.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Maryam Infertility Center

Full name of responsible person

Arezo khodaiyan karim

Street address

Moalem

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Arezo Khodaiyan Karim

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable