

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigating the effect of solution-focused counseling on sexual satisfaction and sexual quality of life in women affected by polycystic ovarian syndrome with a history of failure of assisted reproductive techniques

Protocol summary

Study aim

Investigating the effect of counseling with a solution-focused approach on the satisfaction and quality of sexual life of women with polycystic ovary syndrome with a history of failure of assisted reproductive techniques

Design

The study is semi-experimental and randomized parallel clinical trial without blinding on 60 eligible women. The available sampling method is random allocation based on online software. The intervention group includes 30 women with a solution-oriented method

Settings and conduct

Infertility Research and Treatment Center, Yazd.
Invitation to study, sample selection, random allocation and psychological intervention are carried out by the second researcher under the supervision of the first, third and fourth researchers.

Participants/Inclusion and exclusion criteria

log in: Willingness to participate in the study - At least one failure of assisted reproduction techniques in infertile women with polycystic ovary syndrome - Being Iranian -Ability to understand and speak Persian language and perform homework -Having a smart mobile phone -Having a common bed with the husband Exit: - Participating in interventional studies related to sexual health at the same time - Having a child - Using any drug or hormone affecting sexual performance within 60 days before the intervention - Existence of different types of severe mental disorders under medical treatment based on the information in the medical record or his statements - Existence of chronic diseases - Using tobacco, drugs and alcohol according to the patient - Existence of stressful events in the past 6 months

Intervention groups

8 weekly sessions of 60 minutes are held and they

receive counseling through ETA and Skyroom.

Main outcome variables

Change in mean sexual satisfaction scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057626N1**

Registration date: **2023-03-09, 1401/12/18**

Registration timing: **prospective**

Last update: **2023-03-09, 1401/12/18**

Update count: **0**

Registration date

2023-03-09, 1401/12/18

Registrant information

Name

Zeinab Moheq

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3470 4928

Email address

z.mohegh@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-08-10, 1402/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of solution-focused counseling on sexual satisfaction and sexual quality of life in women affected by polycystic ovarian syndrome with a history of failure of assisted reproductive techniques

Public title

Investigating counseling with a solution-focused approach on the satisfaction and quality of sexual life of women with polycystic ovary syndrome with a history of failure of assisted reproductive techniques

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study History of at least one failure of assisted reproductive techniques in infertile women with polycystic ovary syndrome according to the Rotterdam criteria and registered in the medical file of the Research Institute of Reproductive Sciences Being Iranian Ability to understand and speak Persian language and cooperate in doing assignments Having an Android or IOS smart phone Sharing bed with husband

Exclusion criteria:

Participating in concurrent sexual health-related intervention studies Having children Use of any drug or hormone affecting sexual performance within 60 days before the intervention Existence of various types of severe mental disorders (psychosis, schizophrenia, etc.) under medical treatment based on the information of the medical record or her statements The presence of chronic diseases such as overt diabetes, hypertension, cardiovascular disease, thyroid disease, kidney disease, etc. Use of tobacco, drugs and alcohol according to the patient Existence of stressful events during the last 6 months such as immigration, death of relatives, divorce

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The student will select the number of 60 women based on the entry and exit criteria randomly and through the online software (www.Random.org/sequences) and written informed consent will be obtained to participate in the study. Then, patients are assigned to two groups

of 30 people using a random number table, including the intervention group (consultation with a solution-oriented approach) and the control group (presentation of educational booklets). Again, the intervention group is divided into two subgroups by simple random method.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Yazd, Bahonar Square

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.SSU.REC.1401.105

Health conditions studied**1****Description of health condition studied**

Sexual satisfaction and quality counseling

ICD-10 code

Z70.0

ICD-10 code description

Counseling related to sexual attitude

Primary outcomes**1****Description**

Measuring the quality of sexual life in women with polycystic ovary syndrome using fertility failure techniques

Timepoint

In the baseline, week 8 and in follow-up at the end of the study in week 12 in both groups

Method of measurement

Secondary outcomes

1

Description

Measuring sexual life satisfaction in women with polycystic ovary syndrome with a history of failure of assisted reproductive techniques

Timepoint

In the baseline, week 8 and in the follow-up study completion in week 12

Method of measurement

Larson sexual satisfaction questionnaire

Intervention groups

1

Description

Intervention group: The intervention in the test group is counseling with a solution-oriented approach, which will be presented in 8 sessions in the Sky Room. The intervention (counseling with a solution-oriented approach 5A) is carried out by a master's student in counseling in midwifery under the supervision of a supervisor and a consultant. The content of the sessions includes introduction, introduction of group rules, measuring and evaluating the level of communication, introduction of solution-oriented treatment, melting the ice. and familiarizing the members with the goals and logic of the work (session 1), familiarizing with the basic principles of solution-oriented counseling and its application - examining the active acceptance of responsibility in a relationship - formulating problem solving circles - describing the problem objectively and away from tendencies and behaviors uncomfortable (session 2), identifying the solutions of the participants in different problem areas - familiarizing the participants with useful solutions and repeating them and abandoning inappropriate solutions - finding a positive story (session 3), making the participants committed and hopeful for Solving the problem - identifying and solving the participants' resistance - talking about the future - talking about the tasks - using the technique of scaled questions (session 4), familiarizing the members with the exceptions to the problem - strengthening and highlighting the exceptions to the problem - making the participants understand the capabilities and abilities Self (Session 5), helping the participants to identify other ways of thinking, feeling and thinking tar rather than current problematic thinking, feeling and behavior - helping participants to admire rather than criticize each other - implementing the King of Keys technique (Session 6), helping participants to imagine a desired future and a better world helping participants to Getting out of the framework of the problem and identifying objective and desirable changes, using the technique of pretend assignments (session 7), summarizing the meetings and concluding - using graded questions (session 8)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Infertility Research and Treatment Center

Full name of responsible person

Mahshid Bokaei

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Yazd - Safaiyeh - Timsar Falahi St. - Bu Ali St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

امین صالحی ابرقوئی

Street address

Alam Square, Medical Sciences Campus

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bokaei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sexual health and fertility

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All individual data of study participants can be shared after de-identification

When the data will become available and for how long

After printing the results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive it.

Under which criteria data/document could be used

Scientific useage

From where data/document is obtainable

mah_bokaie@yahoo.com

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

One week after receiving the applicant's email

Comments