Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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

Sex life quality questionnaire (Simond et al.)

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
Street address
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
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امین صالحی ابرقوئی
Street address
Alam Square, Medical Sciences Campus
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8916978477
Phone
+98 35 3149 2229
Email
abargouei@ssu.ac.ir
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

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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 usege
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