Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of sexual counseling utilizing the 'Good-Enough Sex Model' (GES) on the sexual self-care and sexual function of infertile wome

Protocol summary

Study aim
Determining the effectiveness of sexual counseling based on the Good Enough Sexual Experience model on sexual self-care and sexual function of infertile women

Design
Randomized clinical trial, including 206 people in two intervention and control groups, block random allocation method with 6 blocks as single blinding

Settings and conduct
The intervention will involve two groups at the Fatima Al-Zahra Infertility Center in Babol City: the "GES" and the control group. Blinding the participants and the researcher responsible for sampling will not be feasible. Only the data analyst will remain blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Iranian nationality; Age between 20 and 40 years; Possession of basic literacy skills; Stable marital life with a spouse and consistent sexual activity (at least over the past four weeks); a permanent marriage; Infertility; No history of genital infections; Absence of physical conditions or psychiatric disorders under medical supervision or treatment as confirmed by medical records and self-reports; No substance abuse, including alcohol, cigarettes, hookah, or illicit drugs; No use of medications that may cause sexual dysfunction (e.g., barbiturates, benzodiazepines as confirmed by medical records and self-reports; A score of 26.5 or lower on the FSFI; Not in a polygamous relationship; No plans to undergo fertility treatments within the next two months Exclusion Criteria: Pregnancy during the study; Failure to participate in completing the questionnaires; Failure to answer more than 10% of the questionnaire items; Participation in psychological interventions within the past three months; Experience of a stressful life event in the past three months

Intervention groups
Conducting sessions, according to sexual counseling based on the Good Enough Sexual Experience (GES) model

Main outcome variables
Self-care, and sexual function

General information

Reason for update
Sampling not completed

Acronym

IRCT registration information
IRCT registration number: **IRCT20250202064609N1**
Registration date: **2025-02-19, 1403/12/01**
Registration timing: **prospective**

Last update: **2026-05-25, 1405/03/04**
Update count: **1**

Registration date
2025-02-19, 1403/12/01

Registrant information

Name
Yasamin Nami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-20, 1404/03/30

Expected recruitment end date
2026-08-21, 1405/05/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of sexual counseling utilizing the 'Good-Enough Sex Model' (GES) on the sexual self-care and sexual function of infertile wome

Public title

The effectiveness of sexual counseling utilizing the 'Good-Enough Sex Model' (GES) on the sexual self-care and sexual function of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Age 20 - 40 years Possessing at least the ability to read and write and understand and answer questions Constant life with partner, having stable sexual activity (at least the last four weeks) Spouse availability, permanent marriage Infertility according to the World Health Organization definition No history of genital infections No physical problems (spinal cord injury, limb defects) No history of physical illness (diabetes, cardiovascular disease, blood pressure, thyroid disease, Addison's, Cushing's), and psychiatric disorders under medical supervision or treatment such as severe depression, psychosis, bipolar disorder based on medical records and self-reporting. No substance abuse, use of alcohol, cigarettes, hookah, and drugs. Avoid taking medications that cause sexual dysfunction, such as barbiturates, benzodiazepines (diazepam, oxazepam, chlordiazepoxide), antidepressants, and antihypertensives, according to the doctor's record. Score 26.5 or lower on the Women's Sexual Function Questionnaire(FSFI) Not being polygamous No infertility treatment for the next two months

Exclusion criteria:

Getting pregnant while studying Failure to participate in completing the questionnaire Failure to answer more than 10% of the questionnaire questions Participation in psychological interventions (participation in psychotherapy sessions, relaxation techniques, yoga) in the last 3 months Experiencing a stressful event in the last three months (death or acute illness of a close relative, major change in life situation)

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 216 participants, who were randomly divided into two groups: 108 in the intervention group and 108 in the control group. The random allocation method used was block randomization, designed by the methodologist using the SealedEnvelope.com website. The number of blocks was set at 6. According to the block randomization protocol, participants were assigned to one of the two groups—1: GES (intervention) or 2: control—in a 1:1 ratio, ensuring that the researcher could not predict which group the next participant would be assigned to. To conceal the random allocation, sealed opaque envelopes containing a random sequence were used in this study. First, 36 opaque paper envelopes were prepared (to ensure the contents remained unclear). Each random sequence was recorded on a card, and the cards were placed inside the envelopes in order. The envelopes were then sealed and placed in a box in sequential order. The random assignment was solely managed by the principal investigator, who was the only person aware of the relevant codes. The order of the envelopes corresponded to the randomization list in the box. When the interviewer confirmed a participant’s eligibility, the principal investigator provided them with the next envelope in the sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the study, blinding the participants and the researcher responsible for sampling will not be feasible. For data analysis, a methodology and biostatistics expert, who is independent of the study and unaware of all procedures conducted, will be utilized

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Babol university of Medical Sciences

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Babol University of Medical Sciences, Ganj Afroz Street, Babol, Mazandaran

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Approval date

2025-01-20, 1403/11/01

Ethics committee reference number

IR.MUBABOL.REC.1403.155

Health conditions studied

1

Description of health condition studied

Infertile women,Sex Counseling, , Sexual function ,Good Enough Sex Model, Sexual self-care, Sexual Quality of Life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function

Timepoint

before and one month after the intervention

Method of measurement

Female Sexual Function Index (FSFI): This questionnaire was designed and validated by Rosen et al. in 1997 and includes 19 closed-ended items in 6 domains: 1- Desire 2- Psychological arousal 3- Wetness 4- Orgasm 5- Satisfaction and 6- Sexual pain, which is based on a five-point Likert scale. The Persian version of the Sexual Function Index is a reliable and valid tool for assessing female sexual function. The reliability of the scale was calculated through stability analysis or internal consistency coefficient. Cronbach's alpha coefficient is ≤ 0.8, which indicates good reliability of this tool. Regarding the scoring method, according to the questionnaire designer's instructions, the scores of each domain are obtained by adding the scores of the questions in each domain and multiplying it by the number of factors. However, since the number of questions in the domains is not equal in the questionnaire, the scores of the questions in each domain are first added together to weight the domains together and then multiplied by the number of factors. The total score of the scale is obtained by adding the scores of the six domains together. In this way, the scoring is such that a higher score indicates better sexual functioning. Based on the equal weighting of the domains, the maximum score for each domain is 6 and for the entire scale is 36. A score of zero indicates that the individual has not had sexual activity for at least the past 4 weeks. The cutoff point for sexual dysfunction is 26.55 and has the highest sensitivity. A higher score indicates a higher level of sexual functioning. The validity and reliability of the FSFI questionnaire in Iranian culture has been previously evaluated by Heidari et al.

2

Description

Sexual Self-Care

Timepoint

before and one month after the intervention

Method of measurement

This questionnaire was designed by Yazdani et al., in 1401 with the aim of measuring self-reported sexual self-care in women of reproductive age. The final version of the sexual self-care questionnaire in women of reproductive age was designed with 40 items in 4 areas including: prevention of sexually transmitted diseases and genital infections, prevention of female cancers, prevention of unwanted pregnancy, and sexual promotion. The psychometric properties of this questionnaire showed that the overall validity index of the instrument was 93% and the overall validity ratio of the instrument was 96%. The relative reliability of the entire instrument was also shown by Cronbach's alpha of 94%. It has 40 questions and 4 subscales with the following questions: The first factor: prevention of sexually transmitted diseases and genital infections 14 questions: 1 to 14 The second factor: prevention of female cancers 7 questions: 15 to 21 The third factor: prevention of unwanted pregnancy 6 questions: 22 to 27 The fourth factor: promotion of sexual health 13 questions: 28 to 40 The subscale scores are interdependent and the questionnaire has a total score. The scoring of this questionnaire is based on a 5-point Likert scale, with the answer “never” being given a score of 1, “rarely” a score of 2, “sometimes” a score of 3, “often” a score of 4, and “always” a score of 5. Question numbers 25, 24, and 26 are also scored in reverse. In the first subscale, the lowest raw score is 14 and the highest raw score is 70. In the second subscale, the lowest raw score is 7 and the highest raw score is 35. In the third subscale, the lowest raw score is 6 and the highest raw score is 30. In the fourth subscale, the lowest raw score is 13 and the highest raw score is 65. The total score of the questionnaire is 200 and the minimum is 40. The higher the score, the greater the sexual self-care.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the sexual health education course and the practical training course under the supervision of a supervisor and acquiring the necessary sexual health education skills, the researcher will implement the sessions according to the sexual counseling based on the Good Enough Sexual Experience (GES) model.The Good Enough Sexual Experience (GES) model was designed by Mathers and McCarthy in 2007 and its content is a realistic view of sexual value that includes two basic issues of mutual enjoyment of sex, intimacy and love in order to obtain the highest pleasure in people based on their ability and focuses on replacing classic sexual beliefs with expectations based on pleasure and flexible sexual activity. This model teaches that sexual problems may occur periodically in people's lives and that the level of sexual pleasure is not the same throughout life and that exaggerated expectations

of ideal and perfect sex should be transformed into realistic expectations.This model includes 12 principles: 1- Explaining sex as a vital element of life 2- The importance of sex quality and sexual satisfaction in couples' sexual development 3- Setting realistic expectations of sex 4- Emphasis on physical health and healthy behavioral habits to restore sexual health 5- Behavioral education and counseling (mindfulness) 6- Equal attention to obtaining sexual pleasure and proper sexual performance 7- Counseling to overcome sexual fears and concerns and teaching flexible sexual experiences 8- Letting go of idealistic ideas about sex and setting goals in the relationship 9- Getting to know sexual arousal styles 10- Getting to know gender differences and accepting them 11- Strengthening communication skills 12- Teaching the cycle of sexual desire and counseling to personalize sexual desire which are mentioned in the section on the goals of the intervention sessions and the content of the sessions has also been compiled according to similar studies.It should be noted that the trained researcher will be supervised by the supervisor for one hour once a week for group sessions with clients and will be under his supervision and presence. The intervention will be held in groups of 6 people in 6 2-hour group sessions once a week.After the completion of each counseling and training session, the content file of the same session will be sent to the participant for repetition during the week. It is also emphasized that it should be made available to his wife as well.

Category

Behavior

2

Description

Control group: Individuals in this group will receive routine counseling from the center's staff. In order to comply with research ethics, at the end of the study, individuals in the control group will be referred to a sex clinic and provided with an educational package.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Al-Zahra Fertility and Infertility Center

Full name of responsible person

Hajar Pasha

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Babol 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

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Full name of responsible person

Hajar Pasha

Position

Associate Professor

Latest degree

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Other areas of specialty/work

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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
Due to the confidentiality of the research topic, which is related to the sexual issues of infertile women, it is not possible to provide individual data of the participants.

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