Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effectiveness of the Empathy, Intimacy, and Sexual Satisfaction (EIS) Counseling Model and the Good Enough Sex (GES) Model on Sexual Function and Infertility-Related Stress in Women with Infertility

Protocol summary

Study aim
determine and compare the Effectiveness of the Empathy, Intimacy, and Sexual Satisfaction (EIS) Counseling Model and the Good Enough Sex (GES) Model on Sexual Function and Infertility-Related Stress in Women with Infertility

Design
Design: Phase 2, RCT, parallel-group Sample: 68 patients Randomization: Permuted block (size 4) Concealment: Sequentially numbered, sealed envelopes

Settings and conduct
Setting: Yazd Reproductive Sciences Institute Approvals: Ethics, University permit, IRCT registration/code Sampling: Infertile women, inclusion criteria, written consent Blinding: Single-blind (Data analyst only); participants/providers unblinded

Participants/Inclusion and exclusion criteria
Inclusion Persian literacy & internet access Primary infertility record Active sexual relationship & consent FSFI < 28 & FPI (98–167) Exclusion Systemic/psychiatric diseases or meds Substance, alcohol, or sex-enhancer use Severe marital conflict Concurrent psychological interventions

Intervention groups
Intervention: 8 weekly 90-min online sessions (Skyroom) based on EIS & GES models.

Main outcome variables
sexual function

General information

Reason for update
"Sampling and patient enrollment have been delayed until administrative and security clearance at the center is finalized."

Acronym

IRCT registration information
IRCT registration number: **IRCT20260711070129N1**
Registration date: **2026-07-30, 1405/05/08**
Registration timing: **prospective**

Last update: **2026-08-25, 1405/06/03**
Update count: **1**

Registration date
2026-07-30, 1405/05/08

Registrant information

Name
Fatemeh Adresi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3522 0837

Email address
f.adresi@stu.ssu.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effectiveness of the Empathy, Intimacy,

and Sexual Satisfaction (EIS) Counseling Model and the Good Enough Sex (GES) Model on Sexual Function and Infertility-Related Stress in Women with Infertility

Public title

Comparing the Effectiveness of the Empathy, Intimacy, and Sexual Satisfaction (EIS) Counseling Model and the Good Enough Sex (GES) Model on Sexual Function and Infertility-Related Stress in Women with Infertility

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to read and write in PersianHaving an infertility record at the infertility centerAbility to access and use the internetHaving sexual intercourse with one's spouseProviding informed consent to participate in the studyScoring below 28 on the Rosen Female Sexual Function Index (FSFI)Scoring between 98 and 167 on the FPI questionnaireDiagnosis of primary infertility

Exclusion criteria:

(1) having systemic diseases based on the medical record; (2) having mental disorders (psychosis and use of psychiatric medications based on the medical record); (3) use of alcohol, illicit drugs, psychotropic substances, or libido-enhancing medications; (4) severe marital conflict based on self-report; and (5) participating in other psychological interventions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to one of the two intervention groups using permuted block randomization with a block size of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

Random allocation will be performed with allocation concealment, employing sequentially numbered, sealed, opaque envelopes based on the block sequence.Due to the nature of the intervention, blinding of participants and care providers is not feasible; however, the data analyst will remain blinded to the group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Yazd Reproductive Sciences Institute

Street address

Reproductive Sciences Institute, Bouali St., Safaieh, Yazd, Iran

City

yazd

Province

Yazd

Postal code

۸۹۱۶۸۷۷۳۹۱

Approval date

2026-07-21, 1405/04/30

Ethics committee reference number

IR.SSU.RSI.REC.1405.011

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

sexual function

Timepoint

At baseline, week 8 (end of intervention), week 12 (follow-up)

Method of measurement

Female Sexual Function Index (FSFI) questionnaire

Secondary outcomes

1

Description

Infertility-Related Stress

Timepoint

At baseline, week 8 (end of intervention), week 12 (follow-up)

Method of measurement

FPI- Newton Infertility Stress Questionnaire

Intervention groups

1

Description

Intervention group: counseling based on the Empathy, Intimacy, and Sexual Satisfaction (EIS) model. Women in the counseling group based on the Empathy, Intimacy, and Sexual Satisfaction (EIS) model will receive 8 consecutive online sessions, held once a week for 90 minutes by the second researcher, a senior midwifery counseling student who has completed the sexual disorders course and obtained the required certificate, under the supervision of the first researcher, the supervisor (a reproductive health specialist and clinical psychologist) and the third researcher, the consultant professor (a reproductive health specialist), in the Skyroom platform.The sessions will be delivered in the form of educational videos, PowerPoint presentations, lectures, and question-and-answer sessions. At the beginning of each session, a summary of the previous session will be reviewed, and the assignments from the previous session will be evaluated by the first and second researchers to assess progress in each session.The women will be asked to participate in the counseling discussions and raise their questions. The second researcher will also ask questions related to the session topics to encourage greater participation. To facilitate learning, the relevant educational video will also be shown. At the end of each session, a summary of the main points will be presented, participants' questions will be answered, and the women will be asked to complete their homework assignments before the next session.

Category

Behavior

2

Description

Control group: counseling based on the Good Enough Sex (GES) model. Women in the counseling group based on the Good Enough Sex (GES) model will receive 8 consecutive online sessions, held once a week for 90 minutes by the second researcher, a senior midwifery counseling student who has completed the sexual disorders course and obtained the required certificate, under the supervision of the first researcher, the supervisor (a reproductive health specialist and clinical psychologist), and the third researcher, the consultant professor (a reproductive health specialist), in the Skyroom platform.The sessions will be delivered in the form of educational videos, PowerPoint presentations, lectures, and question-and-answer sessions. At the beginning of each session, a summary of the previous session will be reviewed, and the assignments from the previous session will be evaluated by the first and second researchers to assess progress in each session.The women will be asked to participate in the counseling discussions and raise their questions. The second researcher will also ask questions related to the session topics to encourage greater participation. To facilitate learning, the relevant educational video will also be shown. At the end of each session, a summary of the main points will be presented, participants' questions will be answered, and the women will be asked to complete their homework assignments before the next session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Research and Clinical Center for Infertility, Yazd

Full name of responsible person
Fatemeh Adresi

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Yazd, Safaeieh, Bou-Ali Ave, Yazd Research and Clinical Center for Infertility

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
مهران کریمی

Street address
Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

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Province
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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
Fatemeh Adresi
Position
midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact
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Latest degree
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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable

Data Dictionary

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

Title and more details about the data/document

“The de-identified individual participant data will be available upon request.”

When the data will become available and for how long

after the publication of the results

To whom data/document is available

The data will be available to researchers at academic and scientific institutions, as well as those working in the industry, upon request

Under which criteria data/document could be used

"Scientific institutions may submit their formal requests to the project's Principal Investigator via email. Data will be shared following approval from the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd. Conducting further statistical analysis on the provided data is not permitted."

From where data/document is obtainable

farajkhoda_t@yahoo.com

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

one week after receiving the applicant’s email

Comments