# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The Effect of Counseling Based on the Sexual Health Model on Women's Sexual Well-Being after Failure of Assisted Reproductive Technology

## Protocol summary

**Study aim**

Determining the impact of counseling based on the sexual health model on women's sexual well-being after failure of assisted reproductive technology

**Design**

A randomized, controlled , parallel-group, unblinded, superiority clinical trial is conducted on 68 women after failed assisted reproductive technology. The website www.Randomization.com was used for randomization.

**Settings and conduct**

face-to-face and group sessions will be held in four 90-minute sessions weekly at Milad Infertility Center for the intervention group.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria included: women aged between 19 and 45 years old, ability to read and write, being in a monogamous marriage, having confirmed primary infertility, history of undergoing at least one of the assisted reproductive technology method, having passed at least 6 months since infertility treatment failure, not undergoing infertility treatment at present and within the past six months, not having a known physical or psychiatric illness affecting sexual life, and having had sexual intercourse within the past month; and the study exclusion criteria included: absence from more than one intervention session, occurrence of major stressful events during the study, and participating in a similar intervention.

**Intervention groups**

The intervention group will receive four 90-minute face-to-face group counseling sessions based on the sexual health model, conducted at one-week intervals, to evaluate the effect of the intervention on sexual well-being. The control group will receive routine care provided by the infertility center.

**Main outcome variables**

sexual well-being

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20251230068496N1**
Registration date: **2026-01-03, 1404/10/13**
Registration timing: **prospective**

Last update: **2026-01-03, 1404/10/13**
Update count: **0**

**Registration date**

2026-01-03, 1404/10/13

**Registrant information**

**Name**

Fateme Jahanbakhshi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 44 3367 5236

**Email address**

jahanbakhshif4022@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-02-20, 1404/12/01

**Expected recruitment end date**

2026-08-23, 1405/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Counseling Based on the Sexual Health Model on Women's Sexual Well-Being after Failure of Assisted Reproductive Technology

**Public title**

The Effect of Counseling Based on the Sexual Health Model on Women's Sexual Well-Being after Failure of Assisted Reproductive Technology

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Have informed consent to participate in the study. Be Iranian and a resident of Mashhad. Be in the age range of 19 to 45 years Be able to read and write Have a contact phone number. Have confirmed primary infertility. Be officially married. Be the only wife of their husband. Have no adopted child. Have had sexual intercourse within the last month. Failure of at least one assisted reproductive technology cycle (ZIFT, GIFT, IVF, IUI, ICSI) At least six months have passed since the last infertility treatment failure. Not undergoing infertility treatment at present and during the past six months. Not having a known physical illnesses affecting sexual life. Not having a known psychiatric disorders affecting sexual life No occurrence of major stressful life events for the couple during the past six months. Not using medications known to affect sexual life. No use of tobacco products, alcohol, or illicit drugs. No participation in sexual education or counseling sessions at present or during the past six months.

**Exclusion criteria:**

Unwillingness to continue participation in the study absence from more than one intervention session Occurrence of stressful events during the study Participation in the same intervention during the study

**Age**

From **19 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible individuals are randomly assigned to either the intervention group or the control group using simple randomization and the random number generation function available on the Randomization.com website. The allocation codes are placed inside opaque, sealed envelopes. Specifically, as each eligible participant enter the study, one of these envelopes is opened, and based on the code inside, the participant is assigned to either the 'counseling' or 'control' group. After completing the allocation of participants to the two groups, and to prevent the exchange of information between members of the different groups, the intervention is initiate.

**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**

Research Ethics Committee, Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Khorrami Educational Complex, Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2025-12-29, 1404/10/08

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1404.110

## Health conditions studied

### 1

**Description of health condition studied**

Sexual Well-Being

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Sexual Well-Being

**Timepoint**

Before, immediately after, and one month after the end of the intervention

**Method of measurement**

The Natsal Sexual Wellbeing Measure (Natsal-SW)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Participants in the intervention group will receive four 90-minute face-to-face group counseling sessions based on the Sexual Health Model at the Milad Infertility Center, conducted at one-week intervals. The counseling content will include: Session 1, establishing initial contact; assessing participants' knowledge of sexual well-being; providing opportunities to express existing concerns; discussion of the dimensions of the Sexual Health Model (including talking about sex, culture and sexual identity, sexual health care, and safe sex); and assignment of homework. Session 2, review of homework; discussion of the dimensions of the Sexual Health Model (including anatomy and sexual function, challenges, and body image); and assignment of homework. Session 3, review of homework; discussion of the dimensions of the Sexual Health Model (including positive sexuality, sexual fantasies, relationships, and intimacy); and assignment of homework. Session 4, review of homework; discussion of the spirituality dimension of the Sexual Health Model; and review of the course content, clarification of ambiguities, and evaluation of the intervention.

**Category**
Behavior

### 2

**Description**
Control group: Participants in the intervention group will receives routine care provided by Milad Infertility Center.

**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Milad Infertility Center

**Full name of responsible person**
Fatemeh Zahra Karimi

**Street address**
Milad Infertility Center, Imam Reza Hospital, Ibn Sina Street, Tagiabad Square

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Mashhad

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**Phone**
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karimifz@mums.ac.ir

**Web page address**
https://emamreza.mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Dr. Mahmud Shabestari

**Street address**
Khwarazmi Educational Complex, Ferdowsi University of Mashhad Main Campus, Adjacent to the East Gate, Azadi Square, Mashhad, Iran

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khm@mums.ac.ir

**Web page address**
https://nurse.mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Mashhad 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**
Mashhad University of Medical Sciences

**Full name of responsible person**
Fatemeh Zahra Karimi

**Position**
Associate professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Midwifery

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Azadi Square, Mashhad, Iran

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## Person responsible for scientific inquiries

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**Latest degree**
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Midwifery

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
Fateme Jahanbakhshi

**Position**
Master's student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Counselling in Midwifery

**Street address**
Baharestan Enghelab Female Dormitory, Mashhad University of Medical Sciences Campus, End of Bahonar Blvd, Vakilabad 2, Vakilabad Blvd

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JahanbakhshiF4022@mums.ac.ir

## 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**
The data used in this study include scores for sexual well-being and demographic characteristics. These data will be reported solely in numerical form and as mean scores. The identities of the participants will remain confidential and will be kept solely by the researcher.

**When the data will become available and for how long**
Access will commence alongside the publication of articles derived from the thesis

**To whom data/document is available**
Access to thesis will be available for researchers and medical science students in Mashhad, and access to related articles will be open to all researchers.

**Under which criteria data/document could be used**
Members of scientific organizations affiliated with the relevant institution may, upon request and with due respect for data ownership and explicit referencing to the original study, utilize these materials in their own research

**From where data/document is obtainable**
By email to the corresponding author of the paper.

**What processes are involved for a request to access data/document**
Upon receiving the applicant's request (including self-introduction and request details), the necessary information will be promptly reviewed and sent to the corresponding author

**Comments**