Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Feb 2026

Comparison the effect of sexual counseling based on two models of EX-PLISSIT and BETTER on sexual function and sexual satisfaction of women after Assisted Reproductive Treatment(ART) failure

Protocol summary

Study aim
Compare the effect of sexual counseling based on models of EX-PLISSIT and BETTER on female sexual function and satisfaction after ART failure

Design
Three group clinical trial with control group, with parallel, randomized groups, No blinding, intervention on 90 infertile women. Randomization using the Random Allocation Software.

Settings and conduct
This is a randomized quasi-experimental study in three groups. Sampling of infertile women referring to MILAD Infertility Treatment Center in Mashhad was first available by method and then infertile women will allocate in groups of intervention and control.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian and living in MASHHAD, age18-45 , at least a fifth grade education, primary infertility, failure of methods of ART, at least 6 months passed since infertility treatment failure, not being treated for infertility in past 6 months, sex at least once a week, absence of disease that affect sexual function in woman and her spouse, not taking drugs that affect sexual function by the woman and her spouse, non-addiction to tobacco and alcohol by woman and her spouse, absence of sexual dysfunction in the spouse, absence of severe depression, stress or anxiety according to the DASS-21 scale, not receiving sexual counseling for the past 6 months, having a device to use cyberspace Exclusion criteria: absence from a counseling session, reluctance to continue cooperation, occurrence of stressful events during the study

Intervention groups
In each intervention group 4 sessions of individual counseling of 60 to 90 minutes will be performed in 4 consecutive weekly sessions based on the EX_PLISSIT or BETTER model . Control group will take routine interventions.

Main outcome variables
Sexual function and sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210211050324N1**
Registration date: **2021-06-24, 1400/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-24, 1400/04/03**
Update count: **0**

Registration date
2021-06-24, 1400/04/03

Registrant information

Name
Akram Rahimi shandiz

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3842 5718

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of sexual counseling based on two models of EX-PLISSIT and BETTER on sexual function and sexual satisfaction of women after Assisted Reproductive Treatment(ART) failure

Public title
Sexual counseling based on two models of EX-PLISSIT and BETTER
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian and living in Mashhad Age of 18-45 years old Have at least a fifth grade education Diagnosis of primary infertility based on information in the patient's file Failure of one of the methods of assisted reproduction such as (IUI, ICSI, IVF, GIFT, ZIFT) At least 6 months passed since infertility treatment failure Not being treated for infertility now and for the past 6 months Having sex at least once a week Absence of disease that affect sexual function in woman and her spouse Not taking drugs that affect sexual function by the woman and her spouse Non-addiction to tobacco and alcohol by woman and her spouse Absence of sexual dysfunction in the spouse Absence of severe depression, stress or anxiety according to the DASS-21 scale Not receiving sexual counseling for the past 6 months Having a device to use cyberspace
Exclusion criteria:
Absence from a counseling session Reluctance to continue cooperation Occurrence of stressful events during the study
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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation using Random allocation software Sample of randomization sequence by randomization site 2 2 1 1 1 2 1 2 2 1 2 1 2 1 1 2 1 2 2 1 1 1 2 2 Samples are selected as available and then based on the randomly generated sequence (code 1 or 2), the women are placed in the EX-PLISSIT or BETTER group, respectively.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
So far, no counseling program has been offered and implemented in Iran for women seeking treatment failure due to ART.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical sciences
Street address
School of Nursing and Midwifery, Ibn Sina St, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2021-05-23, 1400/03/02
Ethics committee reference number
IR.MUMS.NURSE.REC.1400.011

Health conditions studied

1

Description of health condition studied
Sexual counseling
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Female sexual function
Timepoint
Before sexual counselling and 4 weeks after last counseling session
Method of measurement
Score obtained by the subject of the Female Sexual Function Index (FSFI) questionnaire. This questionnaire with 19 questions examines women's sexual function in 6 domains of desire(6 questions), arousal(4 questions), lubrication(4questions), orgasm(3 questions), pain discomfort(3 questions) and sexual satisfaction(3questions). The full-scale score is obtained by adding the six domain scores. Higher scores indicates greater sexual functioning. The overall score is a

minimum of 2 and a maximum of 6.

2

Description
women's sexual satisfaction
Timepoint
Before sexual counselling and 4 weeks after last counseling session
Method of measurement
Score obtained by the subject of the Sexual Satisfaction Scale of Women(sssw). This questionnaire contains 30 questions. Scoring is strongly agree(score 1), slightly agree(score 2), neither agree nor disagree (score 3), slightly disagree(score 4) and strongly disagree(score 5). Questions 1, 4, 5, 6, 9, 10, 11, 12 are scored in reverse. Scores of each domain are obtained from the sum of the scores of that domain. Higher scores indicates greater sexual satisfaction.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the EX-PLISSIT sex counseling group, 4 sessions of 60-90 minute individual counseling will be performed in 4 consecutive weekly sessions based on the EX-PLISSIT model. The first three stages of the model, namely the stages (Permission giving, Limited Information, Specific Suggestion) will be performed during 4 counseling sessions. Upon arrival to the fourth level (Intensive therapy) in each of the sessions, refer to the relevant specialist will be held.
Category
Prevention

2

Description
Intervention group: In the sexual counseling group based on the BETTER model, 4 sessions of individual counseling of 60 to 90 minutes will be performed in 4 consecutive weekly sessions based on the BETTER model. The sessions will be in the form of a preliminary plan, assessment of the patient's sexual status with the aim of clarifying the relationship between the disease and the client's current condition, informing the client by providing correct information and initial sexual education. Completing the counseling process in the form of sexual education and training will focus on the outcome variable of the intervention, namely sexual function and satisfaction. Finally, the consultation sessions will be summarized.
Category
Prevention

3

Description
Control group: Routine interventions will be performed in the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Infertility Center in Mashhad
Full name of responsible person
Dr. Mohammad Hossein Bahreini
Street address
Ibn Sina St, Mashhad, School of Nursing and Midwifery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
محسن تفقدی
Street address
Mashhad, Ibn Sina St, School of Nursing and Midwifery
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Grant name
Grant code / Reference number
992091
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
Akram Rahimi Shandiz

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Fatemeh Zahra Karimi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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
All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers and students of academic institutions

Under which criteria data/document could be used

With citing to the current study and without altering in data

From where data/document is obtainable

Contact the author responsible for response via Email or phone:rahimisa982@mums.ac.ir Tel:09928548691

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

The request for access to data/documents will be reviewed by the researcher team

Comments