

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sexual counseling based on BETTER model on quality of sexual life in infertile women

Protocol summary

Study aim

Determining the effect of sexual counseling based on the BETTER model on the quality of infertile women's sexual life

Design

The research is a non-blind randomized clinical trial with two groups; intervention and control. Sampling will be done by random allocation using the four-way blocking method. The estimated sample size is 40 in each group. For preventing data contamination after random allocation, the even days will be considered for the test group and the odd days will be considered for the control group.

Settings and conduct

The research environment is the Infertility Clinic in Shahid Beheshti Hospital and a private gynecological clinic in Kashan, Iran. The research community will be consider all of infertile women who refer to both clinics. In the intervention group, sexual counseling based on the BETTER model will be conducted during four weekly sessions and the control group will not receive until at the end of the intervention.

Participants/Inclusion and exclusion criteria

49-15 years, permanent marriage, at least one year of primary infertility, female infertility, being sexual active, having at least level of reading and writing skills; not having known psychological and physical illnesses that affect sexual function, non-using of drugs that affect sexual function, non-using of sexual counseling before the enroll of the present study

Intervention groups

In the intervention group, an individual counseling session will be conducted by the researcher based on the BETTER model during four sessions. Duration of each session will be 60 to 75 minutes. The control group will not receive an intervention until at the end of the research. After that, based on the ethics of the research and their willingness the sexual counseling service will be presented by the researcher.

Main outcome variables

Sexual function, sexual self-efficacy, sexual-marital satisfaction

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20160808029255N3**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4214

Email address

r_masoumi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of sexual counseling based on BETTER model on quality of sexual life in infertile women

Public title
The effect of sexual counseling on quality of sexual life in infertile women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 15-49 years permanent marriage at least one year of primary infertility female infertility being sexual active having at least level of reading and writing skills
Exclusion criteria:
having well-known psychological and physical illnesses and affect sexual function such as diabetes, rheumatoid arthritis, depression , and etc. using drugs that affect sexual function such as anti lipid drugs, cimetidine, digoxin, progesterones, antidepressants using of sexual counseling from psychological services and psychiatry, and etc.

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be conducted by random allocation using four-way blocking 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 Tehran University of Medical Sciences Nursing and Midwifery Care Research Center

Street address
south Nosrat Ave., Towhid Sq., Tehran city

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
IR.TUMS.FNM.REC.1369.4662

Health conditions studied

1

Description of health condition studied
sexual function

ICD-10 code

ICD-10 code description

2

Description of health condition studied
sexual self efficacy

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Sexo-marital satisfaction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The physiological responses that a person shows to excite sexual stimulation involves four stages of sexual desire, sexual stimulation, orgasm and suppression.

Timepoint
Before the intervention, 4 and 8 weeks after the intervention

Method of measurement
The Persian version of the Female Sexual Function Index (FSFI) will be applied to evaluate sexual function.

2

Description
Sexual self-efficacy is multidimensional variable and is capable of evaluating itself effectively in achieving effective sexual function and achieving satisfactory and desirable sex.

Timepoint
Before the intervention, 4 and 8 weeks after the

intervention

Method of measurement

A researcher-made sexual self-efficacy questionnaire will be applied to evaluate sexual self-efficacy

3

Description

Sexo-marital satisfaction is the judgment of each individual about her/his sexual behavior that he considers pleasurable, as well as the individual experience of marriage that can be assessed only by any person in response to her marital satisfaction.

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Sexo-marital satisfaction subscale of Women's Sexual Quality of Life Questionnaire (SQOL-F) will be applied to evaluate sexo-marital satisfaction.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be received individual sexual counseling based on the BETTER model during four sessions. Duration of each session will be 60 to 75 minutes.

Category

Behavior

2

Description

Control group: The control group will not receive an intervention until at the end of the research. After that, based on the ethics of the research and their willingness the sexual counseling service will be presented by the researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital in the city of Kashan

Full name of responsible person

Dr Raziye Masoomi

Street address

Qotbe Ravadi bulvar., Kashan

City

Kashan

Province

Isfahan

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87159/81151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Raziye Maasoumi

Street address

East Nosrath., Towid Sq.,

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raziye Maasoumi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Raziyeh Maasoumi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Position
Assistant Professor
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Ph.D.
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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data of the study would be available after unrecognizable process of participants.

When the data will become available and for how long

6 months after publications of findings

To whom data/document is available

Data of this research would be available for academic researchers.

Under which criteria data/document could be used

Data of this study would be available for same research.

From where data/document is obtainable

Dr. Raziyeh Maasoumi email: r_masoumi@sina.tums.ac.ir

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

En Sending a request by email attendance to the office of corresponding of project presentation the reasons for similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in office of corresponding author

Comments