Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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, sexo-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
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Iran (Islamic Republic of)
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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 Raziyeh Masoomi

Street address

Qotbe Ravadi bulvar., Kashan

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Isfehan

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r_masoumi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Raziye Maasoumi

Street address

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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

Raziyeh Maasoumi

Position

Assisstant Proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Sexology, Sexual and Reproductive Health

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

Full name of responsible person
Raziyeh Maasoumi

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Latest degree
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