

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of sexual function and satisfaction of infertile women candidate for egg donation in two groups of control and intervention (Sexual counseling, EXPLISSIT method).

Protocol summary

Study aim

The compare of the sexual function and satisfaction of infertile women, candidates for egg donation in the two group of control and intervention, before, three and eight weeks after the intervention.

Design

A parallel randomized controlled clinical trial on 56 infertile female candidates for egg donation, with sexual dysfunction who are divided in two equal groups of intervention (A) and control(B), by randomized blockade based on 4 blocks.

Settings and conduct

Satisfaction and sexual dysfunction play an important role in the quality of life of many infertile patients and their husbands.This study will be performed on 56 infertile women who are candidates for egg donation with sexual dysfunction at Imam Khomeini Hospital. The samples are randomly divided into four equal groups intervention(A) and control (B). In the intervention group, in addition to routine infertility treatments, the educational intervention will be in the form of individual counseling during four to seven sixty-minute sessions over two months and the control group will receive only routine infertility treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Infertile women candidate for egg donation at fertility age, having sexual dysfunction and absence of physical and mental illness in self and her husband. exclusion criteria:The presence of any known physical or mental illness in the individual or her husband.

Intervention groups

Intervention group: Infertile women candidates for egg donation with sexual dysfunction, in addition to routine infertility treatments, individual intervention training in 4-7 session for 60 minutes during two months. Control group: Infertile women who are candidates for egg

donation with sexual dysfunction, will receive only routine treatments and will not receive any educational intervention.

Main outcome variables

Sexual function Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045607N1**

Registration date: **2019-12-10, 1398/09/19**

Registration timing: **prospective**

Last update: **2019-12-10, 1398/09/19**

Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name

Maryam Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sexual function and satisfaction of infertile women candidate for egg donation in two groups of control and intervention (Sexual counseling, EXPLISSIT method).

Public title

Effect of sexual counseling on sexual function and satisfaction in infertile candidates for egg donation.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

reproductive age Infertile woman that the need of egg donation for fertility confirms by an infertility specialist stable life with her husband (not on the verge of divorce). Sexual dysfunction, score of 26.5 and lower in the female sexual function index questionnaire Lack of sexual problem or debilitating illness in husband Lack of known mental illness and use of Psychiatric drugs drugs (all patients receive psychiatric consultation). Lack of herbal and hormonal drugs or drugs that affect sexual function, according to the patient statement Access to her for at least the next three months

Exclusion criteria:

Occurrence of any known physical or mental on patient or her husband irregular attending to counseling sessions The occurrence of pregnancy during the study

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: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

56 infertile women who are candidates for egg donation are randomly divided into four equal groups (intervention) and control (B). As all possible modes are considered to be the letters A and B in quadruple blocks having a total of six modes, these six modes are numbered 1 through 6 and the number of blocks required is 4 The basis of the sample number will be determined. So we will have 14 blocks of four. Then the number of random blocks are arranged on the basis of random number table. For example, according to ABBA / ABAB the fourth person falls into the intervention group or A.

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

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Vice-Chancellor, 6th, No. 226, Qods St. Central Building, Keshavarz Blvd., Tehran, Iran

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Tehran

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Postal code

1416753955

Approval date

2018-07-04, 1397/04/13

Ethics committee reference number

IR.TUMS.FNM.REC.1397.040

Health conditions studied**1****Description of health condition studied**

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Sexual function

Timepoint

Before the Intervention, three and eight weeks after the intervention

Method of measurement

Female Sexual Function Index (FSFI) Questionnaire

2**Description**

Sexual satisfaction

Timepoint

Before the Intervention, three and eight weeks after the

intervention

Method of measurement

Index of sexual Satisfaction(ISS) Questionnaire

Secondary outcomes

1

Description

Depression, Anxiety,Stress

Timepoint

Before the Intervention, three and eight weeks after the intervention

Method of measurement

Depression- Anxiety- Stress Scale questionnaire

Intervention groups

1

Description

Intervention group: In addition to routine infertility treatments, sex counseling sessions for this group are based on the EX-PLISSIT model (opportunity to express sexual questions and concerns at each stage of education) for each patient individually in 4-7 sessions of 60 to 90 minutes. It will be held weekly in the infertility clinic of Imam Khomeini Hospital in Tehran.

Category

Behavior

2

Description

Control group: The control group will receive no intervention during the study, and only routine infertility treatments will be provided.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility clinic in imam hospital

Full name of responsible person

Maryam Bagheri

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Infertility clinic, imam hospital, keshvarz Blv

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Sponsors / Funding sources

1

Sponsor

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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

Maryam bagheri

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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