

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of sexual counseling based on BETTER model on sexual function of infertile women.

Protocol summary

Study aim

(GENERAL OBJECTIVES): Determining the effect of sexual counseling based on BETTER model on sexual function of infertile women. (SPECIFIC OBJECTIVES): 1- Determination and comparison of the mean of sexual function score in infertile women before and two months after the intervention in the intervention group. 2. Determination and comparison of mean sexual function score in infertile women before and two months after intervention in control group. 3. Determination and comparison of mean sexual performance score in infertile women before and two months after intervention in two intervention and control groups. 4. Determining the relationship between marital satisfaction and sexual function.

Design

Randomized, controlled clinical trial, in parallel with a control group

Settings and conduct

This study was performed on 80 infertile women who referred to the Infertility Center of Karaj and infertility center of Taleghani Hospital in Tehran. Samples are randomly distributed from each center (40 people per center) based on entrance criteria and randomly assigned to each intervention and control group.

Participants/Inclusion and exclusion criteria

Age between 20 - 45 years Married and living with a spouse At least 6 months have passed since infertility diagnosis Primary infertility Do not have a adopted child Iranian nationality Spoken in farsi having at least middle School degree Having at least one sexual problem based on a short screening form

Intervention groups

40 infertile women entered the study according to entry criteria. For each person, two sexual counseling sessions will be held on a weekly basis. Each counseling session will take about 60-90 minutes. Data were collected before and two months after the intervention with demographic forms, the female sexual function index and Enrich marital satisfaction questionnaire.

Main outcome variables

sexual function

General information

Reason for update

Provide project's results.

Acronym

IRCT registration information

IRCT registration number: **IRCT20161230031662N8**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **prospective**

Last update: **2021-05-21, 1400/02/31**

Update count: **1**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

raziehlotfi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

2019-08-27, 1398/06/05

Actual recruitment end date

2019-12-28, 1398/10/07

Trial completion date

2019-12-28, 1398/10/07

Scientific title

The effect of sexual counseling based on BETTER model on sexual function of infertile women.

Public title

The effect of sexual counseling on sexual function of infertile women.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 - 45 years Married and living with a spouse At least 6 months have passed since infertility diagnosis Primary infertility Do not have a adopted child Iranian nationality Spoken in farsi having at least middle School degree Having at least one sexual problem based on a short screening form

Exclusion criteria:

menopause pregnancy medical conditions such as; diabetes, cardio-vascular diseases, hypertension... Using drugs effective on sexual function, known mental disorders Alcohol and drug abusing Husband's sexual dysfunction Participating in similar educational classes in the past 6 months Loss a close relative in the past 3 months

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization Individual randomization Online randomization Allocation concealment: Using opaque envelopes

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 Alborz University of Medical Sciences

Street address

North Taleghani- Azimiyeh

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.ABZUMS.REC.1397.216

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention, two months after intervention

Method of measurement

Female Sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 40 infertile women entered the study according to entry criteria. For each person, two sexual counseling sessions will be held on a weekly basis. Each counseling session will take about 60-90 minutes. Data were collected before and two months after the intervention with demographic forms, the female sexual function index and Enrich marital satisfaction questionnaire.

Category

Behavior

2

Description

Control group: 40 infertile women entered the study according to entry criteria. This tutorial will be given to this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouyesh infertility treatment center

Full name of responsible person

Maryam mohammadzadeh F

Street address

north Taleghani

City

Karaj

Province

Alborz

Postal code

3155784390

Phone

+98 26 3250 6247

Email

info@rouyeshfertility.com

2

Recruitment center

Name of recruitment center

Taleghani infertility treatment center

Full name of responsible person

Maryam mohammadzadeh F

Street address

Yaman street-Velenjak

City

tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 9982

Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

عظیمیه، طالقانی شمالی

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3464 4255

Email

dr.noorisepehr@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Alborz University of Medical Sciences

Full name of responsible person

maryam mohammadzadeh F

Position

BsC in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Medicine, University of Medical Sciences
Campus, University of Art, End of West Bou Ali Street,
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City

karaj

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences
Full name of responsible person
Razieh Lotfi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
1st Street Golestan, Eshteraki Boulevard, Baghestan,
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Person responsible for updating data

Contact

Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
maryam mohammadzadeh F
Position
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Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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karaj

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Email
marmarmzf@yahoo.com

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

Total potential data can be shared after unidentifiable people

When the data will become available and for how long

Data will be in access 6 months after publishing the results.

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

scientific studies

From where data/document is obtainable

Using Email Address:marmarmzf@gmail.com

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

Up to a week after sending the email address

Comments