Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sexual counseling with cognitive behavioral approach on promoting sexual function of infertile women

Protocol summary

Summary

This study is a randomized controlled trial study with one intervention and one control group. The aim of the study is the assessment of the effectiveness of cognitive behavioral counseling on sexual function of infertile women. Sampling will be done using convenience sampling method, and after recruiting eighty participants, random allocation will be done into control and intervention groups without blinding through simple randomization using random number table. Infertile women in this study are 20-45 years old with a history of at least 6 months of infertility. Eight sessions of group counseling (10 -12 women in each group) will be conducted once a week. Data gathering will be done using a demographic form and FSFI questionnaire in three times; before, just after intervention, and followed 1 month later. Sexual function in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042031662N2**
Registration date: **2017-08-12, 1396/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-12, 1396/05/21

Registrant information

Name

Razieh Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3430 4433

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Alborz University of Medical Sciences

Expected recruitment start date

2017-08-08, 1396/05/17

Expected recruitment end date

2017-11-08, 1396/08/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling with cognitive behavioral approach on promoting sexual function of infertile women

Public title

The effect of sexual counseling with cognitive behavioral approach on promoting sexual function of infertile women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 20-45 years; married and having sexual practice; history of at least 6 months of infertility; not having adapted child; Iranian nationality and speaking to Farsi; education level of grade 9 and higher. Exclusion criteria: menopause; known physical or mental illness; using medications that affect sexual function; IVF; get pregnant.

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**

Randomization (investigator's opinion)

Randomized

Randomization description

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 St., Azimiyeh

City

Karaj

Postal code

Approval date

2016-06-06, 1395/03/17

Ethics committee reference number

Abzums.Rec.1395.29

Health conditions studied

1

Description of health condition studied

Sexual Function

ICD-10 code

Z70

ICD-10 code description

Counselling related to sexual attitude, behaviour and orientation

Primary outcomes

1

Description

Sexual function

Timepoint

before, just after, and 1 month after intervention

Method of measurement

FSFI questionnaure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will receive 8 sessions sexual counseling based on cognitive behavioral approach weekly. Duration of each session is 90 minutes. Titles of counseling sessions include, anatomy and physiology of sexual tract, sexual response, relaxation techniques, exploring thoughts and emotions, Kegel exercise, sexual fantasies, and sensate focus.

Category

Behavior

2

Description

Control group will not receive routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouyesh Infertility Treatment Center

Full name of responsible person

Maryam Sahraiyan

Street address

No. 151, 18th Golestan St., North Taleghani St., Azimiyeh

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Alborz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noorisepehr

Street address

North Taleghani street, Azimiyeh

City

Karaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Alborz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty