

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of counseling on marital and sexual satisfaction of infertile couples: A Randomized, Controlled, Trial (RCT) study

Protocol summary

Summary

Objective: determining the effect of counseling on sexual and marital satisfaction of infertile couples Design: randomized clinical trial (RCT) study Setting: A fertility academic clinic in Tehran, Iran Patients: 100 infertile couples referring to a Reproductive Health research center Interventions: 100 infertile couples were randomly allocated into two groups of intervention (50 couples) and control (50 couples). The intervention consisted of three sessions of counseling for 90 minutes each week, and provision of pamphlets. The intervention for each couple was conducted separately. Main outcome measures: Three questionnaires consisted of demographic characteristics; sexual satisfaction and marital satisfaction were completed through interviews. The outcomes, consisting of changes in sexual satisfaction and marital satisfaction, were compared between the two groups three months after the intervention.

Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2007-02-01, 1385/11/12

Expected recruitment end date

2007-11-19, 1386/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106126777N1**

Registration date: **2011-08-14, 1390/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-14, 1390/05/23

Registrant information

Name

Minoo Pakgohar

Name of organization / entity

School of Nursing & Midwifery, Tehran University of

Scientific title

Effect of counseling on marital and sexual satisfaction of infertile couples: A Randomized, Controlled, Trial (RCT) study

Public title

Counseling on quality of marital and sexual satisfaction of infertile couples

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: infertility for 1-10 years, having no children; no previous history of assisted reproductive technologies (ART); not suffering from known mental or physical diseases; not using drugs which affect sexual function and monogamy for men. Exclusion criteria: positive pregnancy test during sampling and follow-up and attending counseling sessions outside our center

Age
From **15 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Keshavarz blvd., Ghods st.

City
Tehran

Postal code

Approval date
2006-12-26, 1385/10/05

Ethics committee reference number
5845/250

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97.9

ICD-10 code description
Female infertility, unspecified

Primary outcomes

1

Description
Sexual satisfaction

Timepoint

Pre test, 3 month after intervention

Method of measurement
Sexual satisfaction questionnaire

2

Description
Marital satisfaction

Timepoint
Pre test, 3 month after intervention

Method of measurement
Marital satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, counseling was performed through three sessions of 60-90 minutes duration and one week apart. Each session consisted of a lecture, discussion, questions and answers, and providing educational brochures and pamphlets. In the first session of intervention, definition of infertility, prevalence of infertility, etiologies, therapies and its impacts on various aspects of personal lives, particularly sexual and marital satisfaction, and their counteractive approaches were explained. The purpose of the session was providing general information about the infertility. The second discussion dealt with behaviors that create marital satisfaction. The ultimate objective was to improve marital satisfaction through teaching communicative skills. These skills, including expression of feelings and emotions, resolving differences, forgiveness, mutual respect and supportive relationship of the couple, listening actively, expressing emotions, particularly about infertility and problem-solving skills such as ability to criticize and accept criticism and establishing a supportive relationship between the couple, were taught in this session. The third session discussed the influencing factors and approaches for improving sexual satisfaction. The objective of this session was to improve sexual satisfaction through provision of necessary knowledge about male and female sexual cycles and issues such as self-esteem and self-confidence in sexual activities, and the quality and quantity of sexual intercourse. We planned the counseling sessions, while couples in intervention group had to refer to the clinic for their scheduled medical appointment. So they did not need more visit for consultation meetings.

Category
Other

2

Description

The control group only received the routine therapies and services of the fertility center. No counseling was included for this group.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-e-Asr Reproductive health research center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Research Deputy Dean

Street address

East Nosrat St, Tohid Sq

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

School of Nursing and Midwifery, Tehran 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****Contact****Name of organization / entity**

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Full name of responsible person

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Web page address**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