

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of cognitive behavioral therapy and pharmacotherapy on infertility stress: A randomized controlled trial

Protocol summary

Summary

Comparison of the effects of cognitive behavioral therapy and pharmacotherapy on infertility Background: Infertility has been described as creating a form of stress that can give increase to a variety of psychological problems. Both psychotherapy and pharmacotherapy are effective treatments for infertility stress. The aim of this study was to compare the effectiveness of cognitive behavioral therapy with fluoxetine in the decreasing of infertility stress in infertile women. Materials and Methods: In a randomized controlled clinical trial, 89 infertile women with mild to moderate depression (Beck scores 10-47) were recruited into three groups; cognitive behavior therapy (CBT), antidepressant therapy, and a control group. Twenty-nine participants in the CBT method received gradual relaxation training, restructuring, and eliminating of negative automatic thoughts and dysfunctional attitudes to infertility for 10 sessions. Thirty participants in the pharmacotherapy group took 20 mg fluoxetine daily for 90 days. Thirty control subjects did not receive any intervention. All participants completed fertility problem inventory (FPI) and the Beck Depression Inventory (BDI) at the beginning and end of the study. X 2 test, paired t-test, ANOVA and Tukey test were used to analyze the data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061710048N1**
Registration date: **2012-06-20, 1391/03/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-20, 1391/03/31

Registrant information

Name

Hajar Pasha

Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Science

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2007-12-21, 1386/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of cognitive behavioral therapy and pharmacotherapy on infertility stress: A randomized controlled trial

Public title

Comparison of the effects of cognitive behavioral therapy and pharmacotherapy on infertility stress

Purpose

Supportive

Inclusion/Exclusion criteria

Women with these characteristics were invited to this study: age younger than 45 years old; education more than five years; infertility more than two years, having at

least one IVF; not undergoing fertility treatment until 3 months afterward; not currently practicing any relaxation techniques; not participating in any support group; not currently taking any psychotherapy; not currently undergoing any assisted reproductive therapy.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **89**

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**

Babol University of Medical Sciences Ethics Committee

Street address

Babol University of Medical Sciences

City

Babol

Postal code

-

Approval date

2007-02-24, 1385/12/05

Ethics committee reference number

6133/30

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

Infertility stress

ICD-10 code

F40-48

ICD-10 code description

Neurotic, stress-related and somatoform disorders

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

Evaluation of fertility problem in infertile women(fertility stress Inventory), depression before intervention

Timepoint

Before intervention

Method of measurement

Infertility Stress Inventory, Beck Depression Inventory

Secondary outcomes**1****Description**

Evaluation of fertility problem in infertile women(fertility stress) , depression after intervention

Timepoint

3 month after intervention

Method of measurement

Infertility Stress Inventory ,Beck Depression Inventory

Intervention groups**1****Description**

Participants in the CBT group were engaged in a 10-week, two-hour group cognitive behavior therapy program. Progressive muscle relaxation was added to sessions 5-10. Groups consisted of 8-12 members and the therapist was an expert psychologist who trained for the CBT program. Therapy was conducted at the Psychiatry Department of the Babol University of Medical Sciences. The first three sessions provided patients with a general orientation to cognitive therapy and the causes of infertility. A gynecologist participated in the first three sessions for 30 minutes and explained the cause of infertility for each patient. Cognitive interventions have been based on the premise that both negative automatic thoughts and dysfunctional attitudes to social concerns, sexual concerns, marital concerns, rejection of childfree lifestyle, and need for parenthood more require restructure. The following three sessions (sessions 4-6) included the identification and challenging of core dysfunctional or irrational beliefs that underlie automatic negative thoughts about the infertility. Finally, sessions 7-10 taught participants varying techniques (e.g. countering, self-reward) for maintaining the change of their dysfunctional beliefs about infertility. In addition to the above program, sessions 5-10 taught participants progressive muscle relaxation in a group setting. For home practicing, subjects read a relaxation book and listened to a 20-minute pre-recorded CD two times daily over a period of 5 weeks. Cognitive sessions were conducted based on Beck Depression Inventory and tension releasing sessions were conducted based on Relaxation Inventory of Jacobson.

Category

Behavior

2

Description

The pharmacotherapy group took a capsule of fluoxetine (20 mg) daily for 90 days. After the interview, the subjects took 30 capsules from the midwives of the center and return monthly to get their drug

Category

Treatment - Drugs

3

Description

The control group didn't undergo any drug or psychological intervention. They completed two questionnaires at the beginning of the study and 3 months after the interview

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Alzahra fertility & infertility Health Research Center, Babol University of Medical Sciences

Full name of responsible person

Hajar Pasha

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mostafazadeh

Street address

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Grant name

مورخ 19/10/1385

Grant code / Reference number

201191025

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mahbobeh Faramarzi

Position

Psychologist, PhD

Other areas of specialty/work

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Msc

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در قسمت اسپانسر نام خود را مرقوم نفرمایید. لطفا نام و مشخصات و آدرس و تلفن معاون پژوهشی موسسه ای که بودجه تحقیق را فراهم کرده یا دانشگاهی که تحقیق در آن اتفاق افتاده است را وارد کنید.

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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