

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Look out for the secret wound: the effect of e- cognitive group therapy with emotional disclosure on infertile mental health

Protocol summary

Summary

Background: Considering the high prevalence of psychiatric disorders among infertile women, it seems that gynecologists, psychiatrists and psychologists should be more attentive to identify and treat these disorders. The aim of the study is to determine whether of E- cognitive group therapy with emotional disclosure on mental health of infertile women who receiving assisted reproduction Method: For implement this study, statistically society select. They include 800 infertile couples that visit to gynecologic Clinics, Jahrom University, for ART approach. Infertility define as at least 1 year of unprotected coitus without conception. Sampling is from women who have inclusion criteria to our study. All of the participants who have primary infertility, no somatic and psychiatric problem, jahrom residents, between 20-40 years of age, have a privet mobile, ability to reading massage and interest to participate in regular group meetings will select to research. 800 consecutive infertile women includ in hormonal therapy or other ART and who participant have including criteria randomly allocat either to receive Cognitive-Behavioral Treatment (CBT Group) or (Observation Group). CBT include the recognition of negative thinking to help the participants distinguish phobia from reality, cognitive reconstructing, thought blocking, spirituality, and the behavioral techniques included muscle relaxation exercises, imagination exercises, expressing feelings, biofeedback in 2 hour weekly to 12 session. All of participant will receive positive massage about cognitive reconstructing , change the negative thought and how to induce positive thought about their infertility and brief massage about result of session .30 late session , all of participant have emotional disclosure. Participant express positive or negative feeling about their problem and their peers feedback them. In some of session participant paint their families as art therapy to emotional disclosure. All of these painting will analyze by specialist and participant

will receive feedback from group leader about their emotional feeling individually, also all of them will present the tive and negative emotional feeling about their problem as a written task or express them into the group. In 2 additional sessions and in the first of session we will use interactive video about infertility medical approach and response to personal question about these interventional approaches by specialist. using the DASS Test and Pen worry state of inventory will use For gathering data. The aim of this study is the assessing the effect of cognitive behavioral therapy on infertile psychological distress (Anxiety- depression- stress) and infertile worry . indepednt variable into this research is cognitive behavioral therapy and dependent variable is infertile worry stste and infertile psychological distresss. Key words: Assisted reproductive therapy RT; Cognitive behavioral therapy; Psychological distress, stress; & Infertile women.

General information

Acronym

Cognitive Behavioral Therapy

IRCT registration information

IRCT registration number: **IRCT201108247407N2**

Registration date: **2011-09-14, 1390/06/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-14, 1390/06/23

Registrant information

Name

Leili Mosalanejad

Name of organization / entity

Jahrom University of Medical Sciences

Country

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Email address
mossila_1@yahoo.com

Recruitment status
Recruitment complete

Funding source
Jahrom University of Medical Sciences

Expected recruitment start date
2011-04-04, 1390/01/15

Expected recruitment end date
2011-07-06, 1390/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Look out for the secret wound:the effect of e- cognitive group therapy with emotional disclosure on infertile mental health

Public title
The impact of E-cognitive behavioral therapy on infertility

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: the participants who had primary infertility history; Jahrom residents age between 20-40 years; have a privet mobile line; ability to reading massage and interested to participate in regular group
Exclusion criteria: somatic and psychiatric problem

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **800**

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

Jahrom University of Medical Sciences

Street address

Main campus-Jahrom University of Medical Sciences-
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Postal code

74148

Approval date

2011-03-11, 1389/12/20

Ethics committee reference number

1387/د/آ

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N 97

ICD-10 code description

Female Infertility

Primary outcomes

1

Description

The impact of e cognitive beahavioral therapy with emotional self disclosure on infertile mental health

Timepoint

Before and after intervention

Method of measurement

Questionnaire and observation

Secondary outcomes

1

Description

The impact of E_CBT with emotional self disclosure on rate of pregnancy

Timepoint

Baseline, 6 and 12 months later

Method of measurement

Document

Intervention groups

1

Description

experiment group:E- Cognitive Behavioral Therapy BT with Emotional Disclosure

Category

Treatment - Other

2**Description**

control group : no any intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**Gynechology and Maternity clinic related to Jahrom
University of Medical Sciences**Full name of responsible person**

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

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Kavos solhjo

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Grant name

پژوهشی

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

Yes

Title of funding source

Jahrom 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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Position

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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