Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness survey of holistic-oriented psychological intervention on stress of infertility, quality of life, psychological health, marital adjustment and rate of infertility in infertile women undergoing ART in Kermanshah

Protocol summary

Summary

The purpose of this study is to determine of the effectiveness of holistic-oriented psychological intervention on stress of infertility, quality of life, psychological health, marital adjustment and rate of fertility in infertile women undergoing ART in Kermanshah. This study is a semi-experimental study with two groups; intervention (n=60) and control (n=60). The study population is infertile women referred to Kermanshah Motazedi hospital and the sample size is 120 women. Inclusion criteria are; age between 20-45 years and moderate to severe depression or stress score in DASS-21 scale. Exclusion criteria are; no responding ovaries to treatment and have secondary infertility. Experimental group receive holistic- oriented psychological intervention in 10 sessions (2 hours in week). Control group receive no kind of intervention. Primary outcomes are; increase quality of life and psychological health in infertile women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061322680N1**
Registration date: **2015-08-13, 1394/05/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-13, 1394/05/22

Registrant information

Name

Monir Hossinie

Name of organization / entity

Kermanshah University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness survey of holistic-oriented psychological intervention on stress of infertility, quality of life, psychological health, marital adjustment and rate of infertility in infertile women undergoing ART in Kermanshah

Public title

The effectiveness survey of holistic-oriented psychological intervention on stress of infertility, quality of life, psychological health, marital adjustment and rate of infertility in infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: at least guidance school educated; age between 20-45 years; primary infertility; not have somatic and psychiatric diseases; using the ART (IVF, ICSI) treatment; moderate to severe depression or stress scores in DASS-21 scale. Exclusion criteria: no responding ovaries to treatment; somatic or psychiatric problems; have secondary infertility.

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: **120**

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

Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd

City

Kermanshah

Postal code

Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

KUMS.REC.1394.20

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

infertility stress

Timepoint

Before-after and one month after intervention

Method of measurement

inFertility problem inventory(FPI)

2

Description

quality of life

Timepoint

befor- after and a month after intervention

Method of measurement

quality of life questionnaire Fertiqol

3

Description

Dyadic adjustment

Timepoint

Before-after and one month after intervention

Method of measurement

Dyadic adjustment scale (DAS)

Secondary outcomes

1

Description

pragnancy rate

Timepoint

Two weeks after embryo transfer

Method of measurement

BHCG test

Intervention groups

1

Description

intervention group:Holistic-oriented Psychological intervention, duration: 10 sessions. any session 2 hours. skills training; stress management, effective communication couples, controlling anger, mindfulness

Category

Behavior

2

Description

control group: receive no kind of treatments

Category

Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah Infertility Treatment center, Motazedi Hospital
Full name of responsible person
Dr. Nasrin Jalilian
Street address
Kermanshah Infertility Treatment centre, Motazedi Hospital, Ferdosi Square, Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Science
Full name of responsible person
Dr. Reza Khodarahmie
Street address
Shahid Beheshti Blvd
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Science
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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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