

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 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 Fertiqlol

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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Full name of responsible person

Monir Hossinie

Position

PhD Student

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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