

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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**

before- 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Monir Hossinie

**Position**

PhD Student

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*