

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Investigation the effectiveness and non-effectiveness of McMaster-based intervention models on family function in infertile couples

#### Protocol summary

##### Summary

This study will be done with aim to investigate the effectiveness and non-effectiveness of McMaster-based intervention models on family function in infertile couples. This is not blind clinical trial. The study population will be consisted of all infertile couples undergoing IUI (Intrauterine insemination) referred to the Moatazedi Infertility Center of Kermanshah city that 40 eligible infertile women will be selected in available method and randomly will be assigned in to tow experimental and control groups. Baseline McMaster family functioning (FAD) questionnaire will be provided to both groups. Intervention group four 60-90 minutes training sessions will receive McMaster family functioning Training (including group discussions, lectures and use of educational booklets) weekly during a month. The control group will not receive any training. A month after the end of the study Family functioning Questionnaire will be provided to both groups and both groups will be compared. Inclusion criteria: Diagnosis of infertility with the approval of Obstetricians and Gynecologists of center; Lack of hard physical illness; No known psychiatric problems based on patient records; Lack of drug addiction; Least guidance level; Living in Kermanshah. Exclusion criteria: Dissatisfaction to the continuation of cooperation in research; Partially completed questionnaires and the absence of more than one session in the training program.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017053014333N76**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-06-11, 1396/03/21

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2017-06-15, 1396/03/25

##### Expected recruitment end date

2017-08-16, 1396/05/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation the effectiveness and non-effectiveness of McMaster-based intervention models on family function in infertile couples

##### Public title

Investigation the effectiveness of family function intervention training in infertile couples

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Diagnosis of infertility with the approval of Obstetricians and Gynecologists of center; Lack of hard physical illness; No known psychiatric problems based on patient records; Lack of drug addiction; Least guidance level; Living in Kermanshah  
Exclusion criteria: Dissatisfaction to the continuation of cooperation in research; Partially completed questionnaires and the absence of more than one session in the training program.

### **Age**

From **20 years** old to **43 years** old

### **Gender**

Male

### **Phase**

1-2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Randomly by tossing coin

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

##### **Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### **City**

Kermanshah

##### **Postal code**

#### **Approval date**

2017-05-17, 1396/02/27

#### **Ethics committee reference number**

kums.rec.1396.82

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Infertility

#### **ICD-10 code**

N97

#### **ICD-10 code description**

Female infertility

## **Primary outcomes**

### 1

#### **Description**

Family function

#### **Timepoint**

Baseline and one month after the end of the study

#### **Method of measurement**

According to McMaster Family Questionnaire (FAD)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group four 60-90 minutes training sessions will receive McMaster family functioning Training(including group discussions, lectures and use of educational booklets) weekly during a month.

#### **Category**

Behavior

### 2

#### **Description**

The control group will not receive any training

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Infertility Clinic Hospital Moatazedi

##### **Full name of responsible person**

Farkhondeh Ashtarian

##### **Street address**

Ferdowsi Square

##### **City**

Kermanshh

## **Sponsors / Funding sources**

### 1

Sponsor

**Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Koroush Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

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

Yes

**Title of funding source**

Vice chancellor for research, Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farkhondeh Ashtarian

**Position**

MA Student of consultation in midwifery

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

School of Nursing & Midwifery, First of Dolatabad Boulevard, Eisar Square

**City**

Kermanshah

**Postal code****Phone**

+98 83 3827 9394

**Fax****Email**

f.ashtarian@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Marzieh Kaboudi

**Position**

Ph.D. in Reproductive Health

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farkhondeh Ashtarian

**Position**

MA Student of consultation in midwifery

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**Postal code****Phone**

+98 83 3827 9394

**Fax****Email**

f.ashtarian@yahoo.com

**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*