

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of collaborative infertility counseling on perceived stress and coping strategies in infertile women undergoing IVF

#### Protocol summary

##### Summary

This study was designed to examine the effect of collaborative infertility counseling on infertility perceived stress and coping strategies in infertile women undergoing In Vitro Fertilization in 2010 in Mashhad, Iran. In this clinical trial 60 women with primary infertility selected from Montaserieh Research Center and were randomly allocated to intervention (29) and control (31) groups. Women in intervention group were counseled in five meetings with the participation of midwife, gynecologist and clinical psychologist. Control group were counseled routinely. Perceived infertility-related stress and coping strategies were measured using Newton Fertility Problem Inventory and Folkman & Lazarus Ways of Coping questionnaire at the beginning and embryo transfer day. Results show that collaborative infertility counseling can decrease infertile women's perceived infertility-related stress. Thus it could be suggested as one of the stress management strategies in infertile women undergoing IVF.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110267915N1**

Registration date: **2014-07-25, 1393/05/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-25, 1393/05/03

##### Registrant information

##### Name

Mahbobeh rasolzadeh Bidgoly

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 315554002125

##### Email address

mehr232007@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2009-10-23, 1388/08/01

##### Expected recruitment end date

2010-03-20, 1388/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of collaborative infertility counseling on perceived stress and coping strategies in infertile women undergoing IVF

##### Public title

The effect of collaborative counseling on psychological subsequent in infertile women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: persian ethnicity; 20-45 aged; literate; have primary infertility; no recipient of donated oocyte or gestational carrier, no have adapted child; no smoker, drug and alcohol abuser; not have somatic or psychiatric problems; in basic sonogram ovaries was normal for beginning of treatment Exclusion criteria: not responding to treatment; not completing the treatment period for

any reason; did not participate in counseling sessions regularly and did not done assignment

### 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: **60**

### 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

Mashhad University of Medical Sciences

##### Street address

Ghorashy building, Daneshgah street, Mashhad

##### City

Mashhad

##### Postal code

91375-345

##### Approval date

2009-07-21, 1388/04/30

##### Ethics committee reference number

511/1388

## Health conditions studied

### 1

#### Description of health condition studied

Primary Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female Infertility

## Primary outcomes

### 1

#### Description

Infertility persieved stress

#### Timepoint

Pretest (beginning of cycle) and posttest (after embryo transfer)

#### Method of measurement

Fertility Problem Inventory

### 2

#### Description

Coping strategies

#### Timepoint

Pretest (beginning of cycle) and posttest (after embryo transfer)

#### Method of measurement

Ways of Coping Scale- Revised (WOC-R)

## Secondary outcomes

### 1

#### Description

Marital Satisfaction

#### Timepoint

Pretest (beginning of cycle) and posttest (after embryo transfer)

#### Method of measurement

Index of Marital Satisfaction

### 2

#### Description

General Health

#### Timepoint

Pretest and posttest

#### Method of measurement

General Health Questionnaire-28

### 3

#### Description

Treatment success

#### Timepoint

posttest

#### Method of measurement

Pregnancy Test

## Intervention groups

### 1

#### Description

Women in intervention group were counseled individually in 5 meetings with the participation of MSc in midwife, gynecologist and MSc in clinical psychologist.

Intervention lasted almost 2 months (the time it take to complete a cycle of In Vitro Fertilization). The time of meeting was arranged as follow without incurring additional visit to subjects: 1. It was conducted by researchers on days 2 and 3 of cycle. 2. Around days 19

to 20 cycle that (after the sonography) was provided by psychologist and midwife. 3. The second day of the next cycle (approximately 10 days after the second session) and was conducted by psychologist and midwife. 4. 6-8 days of cycle (approximately one week after the third session) that was held by the midwife. 5. were conducted by gynecologist at 14 day of cycle.

**Category**

Behavior

**2****Description**

Control group received standard center care

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Montaserieh Infertility Research Center

**Full name of responsible person**

Mahbobeh Rasolzadeh Bidgoly

**Street address****City**

Mashhad

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Doctor Mohammad Ramezany

**Street address**

Ghorashy building, Daneshgah street, Mashhad

**City**

Mashhad

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

Yes

**Title of funding source**

Mashhad 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**

Kashan University of Medical Sciences.Kashan.I.R.Iran

**Full name of responsible person**

Mahbobeh Rasolzadeh Bidboly

**Position**

MSC, Faculty Membership

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

Department of Midwifery, Nursing Midwifery Faculty,  
Kashan University of Medical Sciences, Qotbe Ravandi  
Blvd, Kashan, Iran

**City**

Kashan

**Postal code****Phone**

+98 31 5554 2125

**Fax****Email**

Rasolzadeh-ma@kaums.ac.ir,

Mehr232007@yahoo.com

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

Kashan University of Medical Sciences

**Full name of responsible person**

Mahbobeh Rasolzadeh Bidgoly

**Position**

Msc

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

Department of Midwifery, Nursing Midwifery Faculty,  
Kashan University of Medical Sciences, Qotbe Ravandi  
Blvd, kashan, Iran

**City**

Kashan

**Postal code****Phone**

+98 315554002125

**Fax****Email**

Mehr232007@yahoo.com; Rasolzadeh-

ma@kaums.ac.ir

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

Kashan University of Medical Sciences

**Full name of responsible person**

Mahbobeh Rasolzadeh Bidgoly

**Position**

MSC

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

Department of Midwifery, Nursing Midwifery Faculty,  
Kashan University of Medical Sciences, Qotbe Ravandi  
Blvd, Kashan, Iran

**City**

Kashan

**Postal code**

**Phone**

+98 315554002125

**Fax**

**Email**

Rasolzadeh-ma@kaums.ac.ir;

Mehr232007@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*