

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effects of relaxation technique on stress in infertile women who refer to the Esfahan infertility clinic.

#### Protocol summary

##### Summary

The purpose of this study was determination of relaxation effect on stress score in the infertile women and pregnancy test as outcome of their treatment. The inclusion criteria included women who were diagnosed with firstly infertility and aged 18 to 35 years. Exclusion criteria included women who were diagnosed with secondary infertility and their aged under 18 and upper 35 years. The study included 76 infertile women that for infertility treatment (IVF, ICSI) was referred to the Isfahan Infertility clinic. At first, the stress score was determined in both groups, by Newton's infertility stress questionnaire. Stress score was evaluated in participants and then relaxation technique was administered in the intervention group. This technique performed in 12 sessions. All questionnaires were completed under supervision of the researcher after embryo transfer to the uterus (after 2 weeks) and before pregnancy test administering.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014021516581N1**

Registration date: **2014-03-03, 1392/12/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-03-03, 1392/12/12

##### Registrant information

##### Name

Sara Abedian

##### Name of organization / entity

Islamic Azad University of Semnan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 1445 0345

##### Email address

s.abedian@semnan.iau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Science

##### Expected recruitment start date

2010-02-20, 1388/12/01

##### Expected recruitment end date

2010-06-20, 1389/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of relaxation technique on stress in infertile women who refer to the Esfahan infertility clinic.

##### Public title

The effects of relaxation technique on infertility stress

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria :women who have a diagnosis of firstly infertility;women who age in the realm of 18 to 35 years;women who according to case health care, using the ART(IVF OR ICSI) for them;women who due to illness like depression and psychological. . . Under medical treatment;women who were not called a child. Exclusion criteria : women who have a diagnosis of secondary infertility;women who age under18 and after 35 years;women who according to case health care not using the ART(IVF OR ICSI) for them;women who due to

illness like depression and psychological. . . not Under medical treatment;women who were called a child.

### Age

From **18 years** old to **35 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **76**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Science

##### Street address

Isfahan University of Medical Science,St. Hezar

Jerib,Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2010-02-06, 1388/11/17

#### Ethics committee reference number

388553

## Health conditions studied

### 1

#### Description of health condition studied

Infertility

#### ICD-10 code

N97

#### ICD-10 code description

Female Infertility

## Primary outcomes

### 1

#### Description

stress score

#### Timepoint

before and after study

#### Method of measurement

Newton infertility stress questionnaire

## Secondary outcomes

### 1

#### Description

pregnancy outcome

#### Timepoint

after study

#### Method of measurement

pregnancy test

## Intervention groups

### 1

#### Description

In the intervention group, in addition to IVF or ICSI treatments , relaxation techniques for 12 sessions ( 6 sessions before transferring the embryo into the uterus and 6 sessions later) was implemented. For the implementation of this technique, the participants lying down on side , legs slightly bent, the muscles contraction not entered into any combination. Jacobson and Benson technique was used for reduce stress physical and mental. Jacobson techniques or progressive muscle relaxation , as muscle contraction and release of muscles took it . In this way the muscles divided into eight parts and techniques during an active contraction of the muscle for 5 seconds and then release of muscle for 30 seconds stress. The contraction and release of muscles were as follows Right leg; left leg; Right Hand; Left Hand; Abdomen and Lumbar; chest and shoulder; Head and Scalp. Benson technique , concentration to the entry and exit of air to the lungs and the creation of mental imagery. On arrival at the center of the samples , a questionnaire based on stress evaluation , was completed under the supervision of a researcher . These women in seventh day of their menstrual cycle were referred for ultrasound, infertility clinic , the questionnaires were completed at the same time . Relaxation technique for intervention group as a day of eighth, tenth , twelfth , fourteenth , sixteenth and seventeenth cycle will be performed by the researcher .in similar circumstances the previous meetings technique by listening to a CD or tape do. All questionnaires were completed under supervision of the researcher after embryo transfer to the uterus (after 2 weeks) and before pregnancy test administering.

#### Category

Behavior

## 2

### Description

In the control group treated by IVF or ICSI treatment for patients who were supposed to be the case, the researcher is not doing any additional intervention for these patients.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Infertility Clinic

##### Full name of responsible person

Sayed Mahdi Ahmadi(Proficient of Obstetrics,Gynecology and Infertility)

##### Street address

Isfahan Infertility Clinic,St. Moshtagh,Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Isfahan University of Medical Science

##### Full name of responsible person

Maryam Kianpour

##### Street address

School of Nursing and Midwifery, Isfahan University of Medical Science ,St. Hezarjerib, Isfahan

##### City

Isfahan

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Isfahan 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

Islamic Azad University of Semnan

#### Full name of responsible person

Sara Abedian

#### Position

MA, Faculty member of Midwifery Group

#### Other areas of specialty/work

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s.abedian@semnan.iau.ac.ir,abedian\_sara@yahoo.com

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## Person responsible for scientific inquiries

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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*