Clinical Trial Protocol
Iranian Registry of Clinical Trials
13 Aug 2020

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 age 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
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 Sciences, 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**

**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
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 (Professor 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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Phone
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