The effects of relaxation technique on stress in infertile women who reffere 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

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 reffere 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

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
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

Street address
Islamic Azad University of Semnan, 5 kilometer Damghan, Semnan

City
Semnan

Postal code

Phone
+98 23 1335 4040

Fax

Email
s.abedian@semnan.iau.ac.ir, abedian_sara@yahoo.com

Web page address

Person responsible for updating data

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

Street address
Islamic Azad University of Semnan, 5 kilometer Damghan, Semnan

City
Semnan

Postal code

Phone
00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty