Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the effect of relaxation on mother’s anxiety and maternal-fetal attachment in primiparous women with IVF

Protocol summary

Summary

Background and Objectives: Infertility is one of the main stressful events of life and a crisis affecting various dimensions of infertile couples’ lives. Relaxation, as a strategy, can be effective in the individuals’ resistance to stress and anxiety. Therefore, the present study aimed to assess the effect of relaxation on mother’s anxiety and maternal-fetal attachment in primiparous women who used In Vitro Fertilization (IVF) to get pregnant. Methods: In this clinical trial, 80 primiparous women who had used IVF to get pregnant were randomly divided into a control and an intervention group. The intervention group took part in four 90-minute relaxation classes in addition to receiving the routine pregnancy care. Anxiety and maternal-fetal attachment were evaluated before and one month after the intervention. Also, maternal-infantile attachment score was computed after delivery. Results: The results revealed no significant difference between the two groups regarding the mean scores of anxiety and attachment before the intervention. However, a significant difference was observed in this regard after the intervention. Conclusion: The study results showed that relaxation training was effective in reduction of anxiety and increase of maternal-fetal attachment in the women who had used IVF to get pregnant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109097497N2**
Registration date: **2014-05-19, 1393/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-19, 1393/02/29

Registrant information

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Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Shiraz Univercity of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of relaxation on mother’s anxiety and maternal-fetal attachment in primiparous women with IVF

Public title

The effect of relaxation on mother’s anxiety and maternal-fetal attachment

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria of the study were being

primiparous; having used IVF to get pregnant; being 18-40 years old; having at least middle school degree; gestational age of 32-35 weeks; not having obstetric problems; and singleton pregnancy. On the other hand, the exclusion criteria of the study were suffering from cardiovascular diseases or serious psychological disorders and having pregnancy complications such as bleeding; diabetes; hypertension; and preterm labor

Age
From **40 years** old to **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Shiraz University of Medical Sciences, Shiraz, Iran

Street address
Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz,

Postal code
7176815674

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
90-01-42-42-84

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F40-F48

ICD-10 code description
Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description
Anxiety

Timepoint
Befor intervention and one month after intervention

Method of measurement
Spielberger's scale

Secondary outcomes

1

Description
Maternal-infantile attachment

Timepoint
Befor and one month after intervention

Method of measurement
Cranly's questionnaire

Intervention groups

1

Description
Then, the mothers in the intervention group were divided into two 20-subject groups and participated in four 90-minute educational classes weekly held on Saturdays. It should be mentioned that the intervention group received relaxation training in addition to the routine pregnancy care. The intervention was performed as follows: First session: anatomical, physiological, and hormonal changes during pregnancy, sperm and ovum, stages of IVF, physiology of fetal development, signs of anxiety, effects of anxiety on pregnancy, strategies for more adaptation with changes in pregnancy including appropriate nutrition, individual health, physical health, mental health, identification of methods for improving compatibility with changes in pregnancy such as relaxation, and effects of relaxation. Second session: development of fetus in different months of pregnancy, nutrition during pregnancy, effect of healthy nutrition and pregnancy care on maternal and fetal health, effect of relaxation on reduction of anxiety, and effect of relaxation on mother and fetus' physical and mental health. Third session: Signs of risk in pregnancy and ways to cope with them, and effect of relaxation on improvement of mother's sleeping and nutrition, maternal-fetal attachment, and fetal growth. Fourth session: effect of relaxation on delivery process, necessity to perform relaxation during delivery, effect of relaxation on improvement after delivery, breastfeeding, and reduction of postpartum depression. At the end of all the educational sessions, Benson's relaxation technique was performed. This technique is quite easy and safe and the mothers were reassured regarding its safety by a gynecologist. This method is very easy to learn and does

not take more than 10-20 minutes to perform (from the tip of toes to forehead). Benson's relaxation technique can be done while lying down or sitting on the chair. In order to make sure that women did the relaxation technique at home, in addition to an educational CD, they were provided with a checklist to record their daily exercises. The mothers were required to perform the relaxation technique at least once a day. At the beginning of each educational session, the checklists were collected, the educational content of the previous session was reviewed, and the participants' questions were answered. The most important practical trainings included staying in a calm environment, mental preparation, passive attitude, staying in a comfortable status, relaxation of all body muscles from the sole of the foot towards the upper extremities (for 10-20 minutes), and slowly getting out of relaxation.

Category

Behavior

2

Description

The control group only received the routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Marzieh Akbarzadeh

Street address

Shiraz- College of midwifery

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

MarzehAkbarzadeh

Street address

Fatemeh School of Nursing and Midwifery, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences - Shiraz, Iran

Full name of responsible person

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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