

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of invitro fertilization (IVF) mothers' preparation for maternal role playing on maternal self-esteem and stress

Protocol summary

Summary

Considering the challenging nature of mothering for the first time and especially using assisted reproductive techniques, a Randomized Controlled Clinical Trial study will be conducted on pregnant mothers using IVF fertility assisted reproductive technique with the gestational age between 12 weeks to end of 20 weeks, with a history of at least 2 years of primary infertility and without a history of mental diseases, with the aim to determine the effect of preparation of fertilized mothers through intrauterine fertilization on maternal self-esteem and stress in Royan Research Institute. 60 people of these mothers who have the conditions for inclusion in the study will be selected by available sampling method and will be randomly placed in to two test and control groups , a mother' preparation program for the test group will be implemented with maternal care content in pregnancy (nutrition, sleeping and rest, exercise and body condition correction), mother's stress control ways, education about the stages of growing and development of the fetus and baby, attachment to the fetus, preparation for delivery and care for the baby, relationship with husband during pregnancy and after delivery, care taking of her during pregnancy and after delivery in 4 sessions in 2-hours for 4 weeks . At first, information collecting tools including demographic questionnaire, Pregnancy's Worries and Stress Questionnaire, and Maternal Self-Report Inventory for maternal self-esteem are provided to the mothers of the two groups and they are asked to complete the questionnaires after obtaining informed consent,. The mothers' preparation program of the test group will be implemented. Information of two groups will be re-collected in the fourth week and one month after completing the initial questionnaires. The educational content will be given to mothers of the control group as educational pamphlets after completing the final questionnaires. Finally, the data are analyzed using SPSS version 21, and descriptive and inferential statistics will

be used according to the goals of the research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061734592N1**

Registration date: **2017-07-09, 1396/04/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-09, 1396/04/18

Registrant information

Name

Atefe Salimi Akin Abadi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 4474 1308

Email address

atefe-salimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of invitro fertilization (IVF) mothers'preparation for maternal role playing on maternal self-steem and stress

Public title
The effect of invitro fertilization (IVF) mothers' preparation on maternal self-steem and stress

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria for the study: fertile women treated with assisted reproductive techniques in vitro fertilization (IVF), gestational age between 12 weeks to the end of 20 weeks, history of least 2 years of infertility and no history of mental illness. Exclusion criteria from the study: mothers fertilized with other methods of assisted reproductive technology, secondary infertility, gestational age less than 12 weeks and more than 20 weeks,history of infertility less than 2 years, a history of mental illness, mothers who have Preterm delivery

Age
No age limit

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

Shahid Beheshti University of Medical Sciences, school of nursing and midwifery

Street address

school of nursing and midwifery, Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to

Rajaei Heart Hospital, Tehran, Iran

City
Tehran

Postal code
1985717443

Approval date
2016-10-24, 1395/08/03

Ethics committee reference number
IR.SBMU.PHNM.1395.534

Health conditions studied

1

Description of health condition studied

invitro fertilization (IVF) mothers

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes

1

Description

Maternal Self Steem

Timepoint

Before the intervention, immediately after the intervention, one month after the intervention.

Method of measurement

Maternal Self-Report Inventory-Short Version

2

Description

Maternal stress

Timepoint

Before the intervention, immediately after the intervention, one month after the intervention.

Method of measurement

Inventory of stress and worry of pregnancy

Secondary outcomes

empty

Intervention groups

1

Description

The content of the mother's preparation program to play mothering role in optimal way and investigating its effect on maternal stress and self-esteem, will include maternal care during pregnancy (nutrition, sleeping rate and rest, exercise and body condition correction), ways to control of mother's stress, training on the stages of development and growing of the fetus and the baby, attachment to the fetus, preparation for delivery and caretaking baby, relationship with the husband during pregnancy and after delivery, self-care during pregnancy and after

delivery. Additionally, the evaluation needs form of educations for pregnancy period will be given to mothers by the researcher to review and resolve other educational needs of mothers. This content will be given to mothers after a complete overview of valid articles and resources, in addition to attending training in preparation sessions in the form of educational pamphlets. The number of sessions will be 4 sessions of 2 hours for 4 weeks in this study due to the effectiveness of the number of mother's preparation sessions on mother's stress in the paper by Pouafshar et al. (2005), with the title of the effect of delivery preparation training on stress during pregnancy and delivery in first pregnant women referring to social security clinics in Mashhad. At first, information collecting tools including demographic questionnaire, Pregnancy's Worries and Stress Questionnaire, and Maternal Self-Report Inventory for maternal self-esteem are provided to the mothers of the two groups and they are asked to complete the questionnaires after obtaining informed consent. The contents regarding the goals of the preparation program, maternal care during pregnancy (nutrition, sleeping rate and rest, exercise and physical situation correction) control the mother's stress and relaxation will be thought at the first session of the preparation program, relaxation will be exercised at the end of the session slowly and mothers are asked to write down the frequency of relaxation, the purpose of writing the frequency of relaxation performed by the mother is to increase attention and to remind this matter to mother at home. The second session will include the presentation of contents about fetus growing and development, attachment to the fetus, and education of fetus attachment enhancement behaviors. At the end of the session, mothers will be asked to write the times of talking with the fetus, calling the fetus and touching the abdomen to feel the emotions of the fetus's motions, the purpose of writing the frequency of doing attachment behaviors by mother is to increase attention and to remind this matter to the mother at home. Educational contents for the third session include explanations about the preparation for delivery, baby take caring, infant's developmental stages and attachment to the baby, the sense of completeness of the mother is facilitated by learning how to care for the infant and how to understand his/her reactions and respond appropriately to them, such as calming down the infant in crying time. At the fourth session, contents will be provided about relationship with husband during pregnancy and after delivery, self-take caring during pregnancy and after delivery. Sessions will be face-to-face education in groups of up to 5-6 people using PowerPoint, speech and questions and answers, and educational pamphlets will be given to mothers. The probable questions of the mothers will be answered at the end of each session. Information from the mothers of the test group will be collected and compared immediately after the end of the fourth session and four weeks after the intervention. The samples are free in responsive to the questionnaire and the information is recorded and kept confidential. The researcher will be available at the time of completing the tools to answer any probable questions.

Category

Other

2

Description

The samples are contacted by the phone and made an appointment with them after assigning 30 mothers to the control group. At first, information collecting tools including demographic questionnaire, Pregnancy's Worries and Stress Questionnaire, and Maternal Self-Report Inventory for maternal self-esteem are provided to the mothers of the two groups and they were asked to complete the questionnaires after obtaining informed consent. Information from the mothers of the test group will be collected and compared again immediately after the end of the fourth session and four weeks after the completing the primary questionnaire. It should be noted that in order to observe ethics in the research, educational content will be given to mothers of the control group as educational pamphlets after completing the final questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Dr Mahrokh Dolatian

Street address

School of Nursing and Midwifery, Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaei Heart Hospital, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Nursing and Midwifery

Proportion provided by this source

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***2****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

t 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source**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**

School of Nursing and Midwifery

Full name of responsible person

Atefe Salimi Akin Abadi

Position

ms student

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

School of Nursing and Midwifery, Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 88 6553 6671

Fax**Email**atefe-salimi@sbmu.ac.ir
atefe.salimi@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Nursing and Midwifery

Full name of responsible person

Atefe Salimi Akin Abadi

Position

ms student

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

School of Nursing and Midwifery, Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran

City

Tehran

Postal code

1985717443

Phone

+98 88 6553 6671

Fax**Email**atefe-salimi@sbmu.ac.ir
atefe.salimi@yahoo.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

School of Nursing and Midwifery

Full name of responsible person

Atefe Salimi Akin Abadi

Position

MS student

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

School of Nursing and Midwifery, Vali-Asr Avenue, Cross of Vali-Asr and Neiaiesh Highway, Opposite to Rajaee Heart Hospital, Tehran, Iran

City

Tehran

Postal code

1985717443

Phone

+98 88 6553 6671

Fax**Email**atefe-salimi@sbmu.ac.ir
atefe.salimi@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