

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of infertility coach program on the level of perceived stress and treatment outcome of women under the treatment of assisted reproductive techniques

#### Protocol summary

##### Study aim

Determining the effectiveness of infertility instructor program on the perceived stress of women and the outcome of the treatment of women under treatment for assisted reproductive techniques

##### Design

A clinical trial with a control group with parallel, randomized groups

##### Settings and conduct

This study will be conducted in the infertile women who are candidates of and ICSI while filling in the Newton Stress questionnaire before the intervention the Stress management strategies will be educated to them in the pancher day In this study, the research environment of Imam Khomeini Hospital infertility treatment center And Maryam Sari

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women under the age of 45, primary infertility, women under IVF and ICSI treatment, reading and writing; Non-compliance criteria: Use no Cigarette, hookah and drink alcohol, having systemic diseases such as diabetes, under consulting of psychologist or psychiatrist during the study or at least one month before the start of the study, Have major psychiatric disorder during the study period (diagnose by primary visit by psychiatrist) and consumption of psychiatric drugs, Have adopted child, Do intend to use the embryo and oocyte donation or a rented uterus

##### Intervention groups

Intervention group: Visiting the patient before and after of visit in six stages of the first session of the day 2 or 3 of cycle before the baseline sonography, the second session of the day 2 or 3 of the subsequent cycles, the third session 10 days after receiving the drug, the 4 session pancake day, session 5 the day of transfer day and session 6 two weeks after transfer Control group: Routine center care

#### Main outcome variables

perceived Stress related to infertility

#### General information

##### Reason for update

Multi center sampling was updated to single center.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180811040762N1**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-15, 1398/09/24**

Update count: **1**

##### Registration date

2018-11-11, 1397/08/20

##### Registrant information

###### Name

Roghayeh Soleimani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3379 5555

###### Email address

fsoleimani1400@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of infertility coach program on the level of perceived stress and treatment outcome of women under the treatment of assisted reproductive techniques

**Public title**

Effect of infertility coach program on the level of perceived stress and treatment outcome of women under the treatment of assisted reproductive techniques

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women less than 45 years Primary infertility Women treated with IVF and ICSI (maximum 3 times) Iranian nationality Having reading and writing ability

**Exclusion criteria:**

Use no Cigarette, hookah and drink alcohol having systemic diseases such as diabetes, hypertension, hyperlipidemia and thyroid gland disease based on the treatment history, information of records and reports of the research unit under consulting of psychologist or psychiatrist during the study or at least one month before the start of the study Have major psychiatric disorder during the study period (diagnose by primary visit by psychiatrist) and consumption no psychiatric drugs Have adopted child Do intend to use the embryo and oocyte donation or a rented uterus

**Age**

From **20 years** old to **45 years** old

**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**

In the current randomized intervention, two groups with 30 patients are allocated in intervention and control groups. Devised between groups will be done through random method, in other words 60 envelopes are considered and intervention and control groups are defined with a and b letter. These envelopes will be assigned to any included individuals of study randomly and ultimately, patients will be taken in to the intervention and control groups. This calculation was performed through the G-power software

**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**

Ethics committee of Mazandaran University of Medical science

**Street address**

Moalem Street, Vice chancellor for research Sari Mazandaran Islamic Republic Of Iran

**City**

sari

**Province**

Mazandaran

**Postal code**

4843163181

**Approval date**

2018-07-11, 1397/04/20

**Ethics committee reference number**

IR.MAZUMS.REC.1397.149

**Health conditions studied****1****Description of health condition studied**

Female infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

**Primary outcomes****1****Description**

Perceived Stress related to infertility

**Timepoint**

Before the intervention, puncture day, day of embryo transfer, day of pregnancy test

**Method of measurement**

Newton Infertility Stress Questionnaire

**2****Description**

The outcome of assisted reproduction treatment

**Timepoint**

Two weeks after embryo transfer

**Method of measurement**

By using Beta-HCG measurement by blood tests

## Secondary outcomes

### 1

#### Description

The number of oocytes obtained

#### Timepoint

Immediately after intervention

#### Method of measurement

View by embryologists

### 2

#### Description

The fertilization rate

#### Timepoint

5 after the intervention

#### Method of measurement

View by embryologists

### 3

#### Description

Pregnancy outcome

#### Timepoint

Three weeks after the intervention

#### Method of measurement

Beta-HCG measurement by blood tests

## Intervention groups

### 1

#### Description

Intervention group: 1. description of genital anatomy, reproductive hormones, Also how the effect of stress and negative emotions on hormonal and physiological changes in the reproductive system Explanation of the stages of treatment with IVF. The Second session on days 19 to 20 of Cycle: Before the visit, the responding to possible questions of patient, Speak regarding the improvement of the negative emotions control Attendance at a visit, Answer to the possible patient questions of the after completing the visit, On day 2 of the next cycle (approximately 10 days after the second session): counseling on improving communication skills, Setting predetermined questions using a patient's possible worries, Attendance at a visit, After visiting about the with the counseling of medications, The fourth session on 6-8th cycle (about one week after the third meeting): Stress reduction and effective coping strategies methods. Attendance at a visit, Fifth session on removal oocyte day and around day 14: A brief explanation about oocyte oocyte removal operation, Answer to the possible patient questions of the after completing the visit, Transferring day: A brief description about the transfer operation, Answer to the possible patient questions of the after completing the visit,

#### Category

Treatment - Other

### 2

#### Description

Control group: Routine center care

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Maryam Infertility clinics

##### Full name of responsible person

Dr. Zeinab Hamzeh Gardesi

##### Street address

Maryam Infertility Treatment Center, next to Semi-Shaban Hospital, Pasdaran Boulevard, Imam Square, Sari, Mazandaran

##### City

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##### Province

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##### Phone

+98 11 3333 3334

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##### Email

z.hamzehgardeshi@mazums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr Majid Saeedi

##### Street address

Vice chancellor for research of Mazandaran University of Medical Sciences, Moalem Street, Sari, Mazandaran

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sari University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Zeinab HamzehGardeshi  
**Position**  
Associate professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available