

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

Sari

Province

Mazandaran

Postal code

4843163181

Phone

+98 11 3333 3334

Fax

+98 11 3336 7342

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

City

Sari

Province

Mazandaran

Postal code

4843163181

Phone

+98 11 3336 7342

Email

z.hamzehgardeshi@mazums.ac.ir

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
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Street,
Amir Mazandarani Street Sari Mazandaran Iran,
Islamic Republic Of
City
sari
Province
Mazandaran
Postal code
4843163181
Phone
+98 48 4316 3181
Fax
+98 11 3337 8915
Email
z.hamzehgardeshi@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Zeinab HamzehGardeshi
Position
Associate professo
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Street,
Amir Mazandarani Street Sari Mazandaran , Iran
City

sari
Province
Mazandaran
Postal code
48431-63181
Phone
+98 11 3379 5550
Email
hamzehgardeshi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Zeinab HamzehGardeshi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Nasibeh Nursing and Midwifery Faculty, Vesal Street,
Amir Mazandarani Street Sari Mazandaran
City
Sari
Province
Mazandaran
Postal code
48431-63181
Phone
011-33795555-01133115500
Email
z.hamzehgardeshi@mazums.ac.ir

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