

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of counseling intervention by a midwife on perceived infertility-related stress and outcome of assisted reproductive technology in infertile women

Protocol summary

Summary

This study is an interventional study. Our population is infertile women referred to Imam Khomeini hospital and the mother clinic in Sari. The sample size identified after the pilot study and selected randomly, then they will be assigned randomly into two groups. The tools used in this study is, a questionnaire on demographic characteristics, general health questionnaire and Newton infertility stress questionnaire. Intervention program will be led by trained midwifery counseling and supervised graduate student research team. The intervention consisted of six two-hour sessions of group counseling services. The control group received only usual care of center. Finally, the data for statistical analysis will be entered into statistical software SPSS (version 21).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080328528N2**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

Zeinab Hamzehgardeshi

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.hamzehgardeshi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-08-20, 1395/05/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling intervention by a midwife on perceived infertility-related stress and outcome of assisted reproductive technology in infertile women

Public title

Effect of group counseling on stress reduction in infertile women undergoing assisted reproductive techniques

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: women less than 45 years, primary infertility, women treated with IVF and ICSI, Iranian nationals, having read and write ability, do not intend to use the embryo and oocyte donation or a rented uterus, don't having adopted child, not being under consulting psychologist or psychiatrist during the study or at least one month before the start of the study, no major

psychiatric disorder during the study period (detect the first visit by a psychiatrist) and non-use of psychiatric drugs, the lack of intense domestic debate in the weeks leading up to the beginning of the study, the lack of cigarettes, hookah and drink alcohol, lack of systemic diseases such as diabetes, hypertension, hyperlipidemia and diseases of the thyroid gland, based on treatment history, records and reports of the person in study, don't receiving ovulation induction treatment in other centers. Exclusion criteria included: lack of ovarian response to stimulation drugs, stops ovulation induction treatment, IVF program is canceled for any reason under medical supervision, the occurrence of bitter contention family, death of a relative or a traumatic event during treatment, the diagnosis pregnancy by blood tests during the study, received or necessity of prescribing any medication or psychotherapy counseling during the study.

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:

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**

Ethics committee of Mazandaran University of Medical science

Street address

Moalem square, Vice chancellor for research

City

Sari

Postal code

4843163181

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.MAZUMS.REC.95.2316

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

Female infertility

ICD-10 code

N97

ICD-10 code description

inability to achieve a pregnancy

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

Perceived Stress related to infertility

Timepoint

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

Method of measurement

Newton Infertility Stress Questionnaire

Secondary outcomes**1****Description**

The outcome of assisted reproduction treatment

Timepoint

Two weeks after embryo transfer

Method of measurement

Beta-HCG measurement by blood tests

2**Description**

The number of oocytes obtained

Timepoint

Puncture Day

Method of measurement

Counting oocytes by embryologists

3**Description**

The fertilization rate

Timepoint

Puncture Day

Method of measurement

View by embryologists

Intervention groups**1****Description**

The intervention consisted of six two-hour sessions of group counseling services. The first half hour the support group and continuation psychological training that focuses on stress management in infertility women. In summary the content of the sessions: the first session

learning about infertility and its causes and impact of stress on the outcome of pregnancy rate, body relaxation training, the second session includes improved control of emotions and head and face relaxation training, the third meeting included of the Communication Skills Training , the fourth session, coping skills training, the fifth session is stress management training and the sixth meeting is improving knowledge in relation to other aspects of treatment (pregnancy by a third partner).

Category

Treatment - Other

2

Description

Control group will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother Infertility clinics

Full name of responsible person

Dr. Zeinab HamzehGardesi

Street address

Nasibeh Nursing and Midwifery Faculty, Vesal street

City

Sari

2

Recruitment center

Name of recruitment center

Infertility Center of Imam Khomeini Hospital

Full name of responsible person

Dr. Zeinab HamzehGardesi

Street address

Nasibeh Nursing and Midwifery Faculty, Vesal street

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahmadali_enayati@yahoo.com

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moalem Street, Vice chancellor for research

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahmadali_enayati@yahoo.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Zeinab Hamzehgardeshi

Position

Phd

Other areas of specialty/work

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Position

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

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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