Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of training based on spouse's support on anxiety, perceived social support, and infertility treatment outcomes in women undergoing assisted reproductive technology

Protocol summary

Study aim
Determining the effect of training based on spouse's support on anxiety, perceived social support, and infertility treatment outcomes in women undergoing assisted reproductive technology

Design
This clinical trial with a control group will be conducted in parallel and without blinding on 86 infertile women. Samples will be taken continuously and then randomly assigned to two intervention and control groups by block of four.

Settings and conduct
This study will be conducted at Arash Hospital in Tehran. The Perceived Social Support and Anxiety Questionnaire and treatment outcomes will be completed before and after the intervention on the day of oocyte retrieval.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian nationality; ≥3 weeks before IVF/ICSI start; at least basic literacy; husband’s smartphone/internet access; cohabiting couples; primary/secondary infertility(secondary infertility with no history of live birth). Exclusion criteria: Chronic illness (e.g., diabetes, hypertension); reported mental illness in either partner; use of psychotropic/neuroactive drugs; adopted children; intention to use donor oocytes, frozen eggs, or surrogacy; IVF for sex selection; current psychological counselling; education in psychology/counselling; severe marital conflict in the week before prior to study entry. Withdrawal criteria: Stressful life event during intervention; treatment cycle cancellation (withdrawal, poor ovarian response, husband absent on retrieval day); spontaneous pregnancy; referral to psychologist during study; husband’s failure to follow virtual training.

Intervention groups
The intervention group receives support from their husbands, who are trained during 4 sessions, during the treatment.

Main outcome variables
Perceived social support, anxiety, and treatment outcomes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181207041873N5**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **prospective**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date
2025-11-26, 1404/09/05

Registrant information

Name
Seyedeh Batool Hasanpoor-Azghady

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-06, 1404/09/15

Expected recruitment end date
2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of training based on spouse's support on anxiety, perceived social support, and infertility treatment outcomes in women undergoing assisted reproductive technology

Public title

The effect of training based on spouse's support on anxiety, perceived social support, and infertility treatment outcomes in women undergoing assisted reproductive technology

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality of the couple Having at least three weeks until the start of the IVF or ICSI treatment protocol Having at least some literacy Access to a smartphone and the internet by the infertile woman's husband Couples living together Having primary or secondary infertility(secondary infertility with no history of live birth)

Exclusion criteria:

Having any chronic physical illness such as diabetes, high blood pressure Having mental illness in either partner, according to their report Taking medications that affect the nervous system or psychotropic drugs by a couple Having adopted children Having children with secondary infertility Intention to use donated oocytes Intention to use frozen eggs Intention to use a surrogacy Sex selection using IVF Each partner undergoing psychological counselling Education in psychology and counselling Intense arguments during the week leading up to the start of the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals are continuously enrolled in the study and then randomly assigned to the experimental and control groups using blocks of four. The randomisation list is generated randomly online via https://www.sealedenvelope.com (a website for generating block randomisation sequences) in a one-to-one ratio by an individual outside the research team.

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 Committees of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences Hemmat Expressway, Near Milad Tower Tehran, Iran

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Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2025-09-27, 1404/07/05

Ethics committee reference number

IR.IUMS.NURSE.REC.1404.002

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

Differences or lack of differences in perceived social support among infertile women undergoing in vitro fertilization (ivf) treatment

Timepoint

Before the intervention and after the intervention on the day of oocyte retrieval

Method of measurement

Multidimensional Perceived Social Support Scale (MSPSS)

Secondary outcomes

1

Description

Differences or lack of differences, in anxietyamong infertile women undergoing in vitro fertilization (ivf) treatment

Timepoint

Before the intervention and after the intervention on the day of oocyte retrieval

Method of measurement

State-Trait Anxiety Inventory, just state anxiety

2

Description

Difference or lack of difference in treatment outcomes in infertile women undergoing in vitro fertilization (ivf) treatment

Timepoint

After the intervention when the results are known

Method of measurement

The number of eggs is determined through microscopic examination, and the quality of the eggs and embryos, as well as the number of embryos, is assessed using a microscope and according to agreed-upon guidelines by the embryologist.

Intervention groups

1

Description

The intervention is designed to train husbands of infertile women undergoing IVF/ICSI treatment so that infertile women will be supported by their trained husbands when they begin the treatment cycle. For this purpose, the training of the husbands of the intervention group will be completed before the start of the treatment cycle of infertile women. The training will be conducted virtually by the researcher in 4 sessions of 30-45 minutes by sending educational videos on WhatsApp messenger, with the time interval between sending educational videos being every 5 days. The content of the training sessions for the husbands of the intervention group is as follows: First session: Introduction to the female reproductive system and natural fertilization, introduction to IVF and ICSI and reasons for use, drug preparation, ultrasound and egg retrieval, the husband's supportive role in these stages. Second session: Anxiety during treatment and the problems caused by it, simple anxiety reduction techniques, basic support skills to reduce women's anxiety, extensive social support (family and friends). Session 3: The importance of adequate sleep and the role of the husband in providing a comfortable environment for sleep, healthy nutrition and helping the wife in preparing and choosing the right food, light exercise and encouraging women to move with their husbands, husbands avoiding unhealthy behaviors, husbands taking care of themselves so that they can support women. Session 4: The concept of empathy and examples of it in the treatment process, active listening and examples of it in the treatment process, asking about women's thoughts and feelings, effective companionship methods during treatment, strategies for improving communication and emotional bonding. Infertile women in the intervention group will be supported by their trained husbands during the treatment cycle. The intervention group will also receive routine infertility center consultations from the treatment team, which will include explanations about the fertility treatment method and how to use infertility drugs and their side effects. Finally, they will complete two questionnaires on perceived social support and a state anxiety questionnaire on the day of egg retrieval, while waiting for their turn to undergo the egg retrieval procedure. The number and quality of embryos will also be determined on the third or fifth day after in vitro fertilization using a microscope and based on the embryologist's agreed guidelines.

Category

Lifestyle

2

Description

Control group: The control group will receive routine infertility center consultations from the treatment team, which include explanations about the fertility treatment method and how to use infertility drugs and its side effects. Like the intervention group, they will complete two perceived social support questionnaires and a state anxiety questionnaire on the day of egg retrieval, while waiting for their turn to undergo the egg retrieval procedure. The number and quality of embryos will also be determined on the third or fifth day after in vitro fertilization using a microscope and based on guidelines agreed upon by the embryologist.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Maryam Moradi

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Sponsors / Funding sources

1

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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
Iran University of Medical Sciences
Proportion provided by this source
50
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
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Full name of responsible person
Seyede Batool Hasanpoor-Azghady
Position
Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Data for researchers and people who are engaged in treatment can apply for them

Under which criteria data/document could be used
Data for researchers and people who are engaged in treatment can apply for them

From where data/document is obtainable
by Email maryammoradi1478@gmail.com

What processes are involved for a request to access data/document
by Email maryammoradi1478@gmail.com

Comments