

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of supportive counseling on self-esteem and self-efficacy of infertile women after IVF failure

Protocol summary

Study aim

The effect of supportive counseling on self-esteem and self efficacy of infertile women after IVF failure

Design

Clinical trial with control group with parallel groups, without blinding, randomized, on 70 patients, rand software was used for randomization

Settings and conduct

Phone call with infertile women ,a negative pregnancy test after using the first IVF In Milad Infertility Center, Mashhad

Participants/Inclusion and exclusion criteria

Diagnosis of primary infertility, Iranian and resident of Mashhad, no known medical disease, negative pregnancy test after using the first IVF Has a smartphone, consent to participate in the study

Intervention groups

Support intervention counseling group in 4 sessions (two face-to-face sessions and one virtual face-to-face session) each session for 45 to 60 minutes and a week with the content of the first session (face-to-face) reassuring and explaining (establishing a positive relationship, resolving misunderstandings and doubts Patient and pointing out potential abilities and potentials and reducing stress by clarifying and providing information and explanation on the topic under discussion (Jabkson relaxation training),Second and third sessions (individual-virtual): guidance, encouragement and persuasion (online virtual individual counseling with the content of the first session feedback, explanation of various assisted reproductive methods, treatment protocols, experience of successful mothers, providing success statistics of reproductive assistive methods), fourth session (Individual-face-to-face): Vacation (practicing the techniques of revealing and releasing emotion, psychological support by active and empathetic listening, and a positive and unconditional outlook on life) is offered

Main outcome variables

The main outcomes are the self-esteem score and the infertility self-efficacy score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210407050883N1**

Registration date: **2021-05-25, 1400/03/04**

Registration timing: **prospective**

Last update: **2021-05-25, 1400/03/04**

Update count: **0**

Registration date

2021-05-25, 1400/03/04

Registrant information

Name

Manijeh Shafaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

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shafaghim2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive counseling on self-esteem and self-efficacy of infertile women after IVF failure

Public title

The effect of supportive counseling on self-esteem and self-efficacy of infertile women after IVF failure

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of primary infertility Negative pregnancy test following failure of the first IVf Iranian and resident of Mashhad ability to speak and write in Persian No known medical conditions do not smoke or drink alcohol Has a smartphone or any electronic device with the ability to connect to the Internet Satisfaction to participate in the study Do not have a mental illness

Exclusion criteria:

Occurrence of stressful events during the study Not attending one of the counseling sessions, participating in other training and counseling sessions while studying

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization
Randomization tool: statistical software(Random allocation software) How to make a random sequence: They are selected as available and are randomly placed in each of the groups using a simple random sequence.
Hide allocation: using randomly sealed opaque envelopes with random sequence

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This analysis is only performed on patients who have completed all stages of counseling correctly - generalizing the results to the community should be done with caution.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences and Health Services

Street address

Khorasan Razavi - Mashhad - University Street - in front of University Alley 18 - Mashhad University of Medical Sciences - Vice Chancellor for Research and Technology

City

Mashhad

Province

Razavi Khorasan

Postal code

9188667656

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.010

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

It is not a disease

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Infertility self-efficacy

Timepoint

At the beginning of the study and 4 weeks after the intervention

Method of measurement

Infertility self-efficacy questionnaire

2**Description**

Self-esteem

Timepoint

At the beginning of the study and 4 weeks after the intervention

Method of measurement

Eysenck Self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": Support counseling in 4 sessions (28), two face-to-face sessions and two face-to-face sessions - virtual and each session for 45 to 60 minutes and each week with the content of the first session (individual-face-to-face): reassuring and explanation (establishing a positive relationship, resolving Patient misunderstandings and doubts and pointing out potential abilities and potentials and reducing stress by clarifying and providing information and explanation on the subject under discussion, Jacobsen relaxation training). Second and third sessions (individual-virtual): guidance, encouragement and persuasion (online virtual individual counseling with the content of the first session feedback, explanation of various assisted reproductive methods, treatment protocols, experience of successful mothers, providing success statistics of reproductive assistive methods), fourth session (Individual-face-to-face): Vacation (practicing the techniques of revealing and discharging emotions, psychological support by active and empathetic listening, and a positive and unconditional outlook on life) is provided.

Category

Behavior

2

Description

"Control group": in the first session coordinated by the clients at the Infertility Center, the Demographic Characteristics Questionnaire, Eysenck Self-Esteem Questionnaire and Cousinio (2006) Infertility Self-Efficacy Questionnaire were completed and routine care provided at Milad Infertility Center was included. With how to continue treatment is assisted reproduction

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Clinic Mashhad

Full name of responsible person

Dr. Fatemeh Zahra Karimi

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East Razi Street

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hussein Bahraini

Street address

Khorasan Razavi - Mashhad - University St. - Ghorashi Building of the Presidential Building of Khorasan Razavi University of Medical Sciences and Health Services

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Manijeh Shafaghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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)

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

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