Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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

Street address
East Razi Street

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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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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