Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of supportive counseling on resilience in infertile women after failure of in vitro fertilization(IVF)

Protocol summary

Study aim

The main goal: to determine the effect of supportive counseling on the resilience of infertile women after the failure of in vitro fertilization.

Design

A two-group clinical trial will be conducted on 60 infertile women immediately after the failure of in vitro fertilization. Research units will be randomly assigned to intervention and control groups.

Settings and conduct

This two-group clinical trial study will be conducted on 60 infertile women immediately after the failure of in vitro fertilization at the Milad Infertility Center in Mashhad. Research units will be randomly assigned to intervention and control groups. In the intervention group, in addition to the center's routine care, they will receive 4 individual support counseling sessions with an interval of 1 week. Data collection tools include the demographic profile questionnaire, the Connor and Davidson resilience questionnaire, and the DASS-21 stress-anxiety-depression questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Iranian Ability to read and write No known medical disease No known mental illness Diagnosis of primary infertility based on the information in the patient's file Negative pregnancy test after in vitro fertilization Consent to participate in the study No severe depression stress or anxiety according to the DASS-21 scale Not having adopted children Monogamous partner Non-entry criteria: Absence of stressful incidents during study Participating in any of the counseling sessions or not answering the questionnaires Not placing the resilience score in the last decile (i.e. score 90 and above)

Intervention groups

supportive counseling by a midwife (45 to 60 minutes) will be done in person and individually during 4 weekly sessions.

Main outcome variables

Determining the effect of supportive counseling on the resilience of infertile women after in vitro fertilization failure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057809N1**
Registration date: **2023-06-04, 1402/03/14**
Registration timing: **prospective**

Last update: **2023-06-04, 1402/03/14**
Update count: **0**

Registration date

2023-06-04, 1402/03/14

Registrant information

Name

Aida Kabirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3767 9033

Email address

kabiriana992@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-13, 1402/03/23

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive counseling on resilience in infertile women after failure of in vitro fertilization(IVF)

Public title

The effect of supportive counseling on resilience in infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian Ability to read and write No known medical disease No known mental illness Diagnosis of primary infertility based on the information in the patient's file Negative pregnancy test after in vitro fertilization Consent to participate in the study No severe depression, stress or anxiety according to the DASS-21 scale Not having adopted children Monogamous partner

Exclusion criteria:

Absence of stressful incidents during study Participating in any of the counseling sessions or not answering the questionnaires Failure to place the resilience score in the last decile (i.e. score 90 and above).

Age

No age limit

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

Random assignment of eligible women to the two groups of supportive counseling and control will be simple randomly using a random sequence created by the random number table at randomization.com. It is written in small letters and kept in a sealed envelope. When each person is selected, the envelope door is opened and the person enters supportive counseling or controlgroup according to the code

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

Mashhad University of Medical Sciences

Street address

Khorasan Razavi - Mashhad - University Street - across from 18 University Street - Mashhad University of Medical Sciences - Research and Technology Vice-Chancellor of the University

City

Mashhad

Province

Razavi Khorasan

Postal code

9188667656

Approval date

2023-04-09, 1402/01/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.001

Health conditions studied

1

Description of health condition studied

Resilience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Resilience of infertility

Timepoint

Before, immediately after and 4 weeks after the end of the intervention.

Method of measurement

Connor and Davidson Resilience Questionnaire

Secondary outcomes

1

Description

Stress, anxiety, depression

Timepoint

Before, immediately after and 4 weeks after the end of the intervention

Method of measurement

DASS 21 stress-anxiety-depression questionnaire

Intervention groups

1

Description

Intervention group: supportive counseling by a midwife (45 to 60 minutes) will be done in person and individually during 4 weekly sessions. The stages of supportive counseling include creating a therapeutic alliance, clinical interview and talking about in vitro fertilization, the rate of failure and its effectiveness (first session), implementing the principle of reassurance, removing misunderstandings and doubts of the patient and pointing out his abilities and potentials, guiding, encouraging and persuasion (second and third sessions), Jobson's relaxation technique training and release for emotional discharge (fourth session).

Category

Behavior

2

Description

Control group: In the first session, the control group will complete the demographic characteristics questionnaire and the resilience questionnaire, and the center's routine care, which includes phone calls and explanations related to the continuation of assisted reproductive treatment, will be provided.

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

Razi Sharghi Street

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1355691359

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Web page address

http://www.goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Bahreini

Street address

Khorasan Razavi - Mashhad - University St. - Qurashi Building, Khorasan Razavi University of Medical Sciences and Healthcare 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

Aida kabirian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Full name of responsible person
Aida kabirian

Position
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Latest degree
Bachelor

Other areas of specialty/work
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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