Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of emotional self-regulation counseling versus control group on emotion regulation skills and anxiety in infertile women undergoing in vitro fertilization (IVF) treatment: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of emotional self-regulation counseling versus control group on emotion regulation skills and anxiety in infertile women undergoing in vitro fertilization (IVF) treatment

Design
This is randomized clinical trial with a control group with parallel groups without blinding, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Fatemieh Hospital in Hamadan city, involving 66 eligible infertile women. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 20 to 40 Infertile women Mild to moderate anxiety (score 20 to 42 on the Spielberger Anxiety Risk Scale) Literacy Exclusion criteria: Mental disorder Addiction Candida treatment First time in vitro fertilization

Intervention groups
Intervention group: Routine IVF treatment plus self-regulation counseling for 60 minutes once a week for 4 weeks Control group: Routine IVF treatment

Main outcome variables
Primary outcome: Emotion score; Anxiety score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N551**
Registration date: **2025-03-07, 1403/12/17**
Registration timing: **prospective**
Last update: **2025-03-07, 1403/12/17**
Update count: **0**

Registration date
2025-03-07, 1403/12/17

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-01, 1404/03/11

Expected recruitment end date
2025-09-02, 1404/06/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of emotional self-regulation counseling versus control group on emotion regulation skills and anxiety in infertile women undergoing in vitro fertilization (IVF) treatment: a randomized clinical trial

Public title

Effect of emotional self-regulation counseling versus control group on emotion regulation skills and anxiety in infertile women undergoing in vitro fertilization (IVF) treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 20 to 40 Infertile women Mild to moderate anxiety (score 20 to 42 on the Spielberger Anxiety Risk Scale) Literacy

Exclusion criteria:
Mental disorder Addiction Candida treatment First time in vitro fertilization

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2025-03-01, 1403/12/11

Ethics committee reference number
IR.UMSHA.REC.1403.876

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
Emotion score

Timepoint
Before intervention and 4 weeks after

Method of measurement
Using the Emotion Regulation Skills Questionnaire (ERSQ)

2

Description
Anxiety score

Timepoint
Before intervention and 4 weeks after

Method of measurement
Using the Spielberger Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine IVF treatment plus self-regulation counseling for 60 minutes once a week for 4 weeks (including familiarization with the anatomy of the reproductive system and reproductive hormones, familiarization with the stages of treatment with assisted reproductive methods, possible consequences and complications of treatment, how anxiety and negative emotions affect hormonal and physiological changes in

the reproductive system, sperm and egg enhancement strategies, expression of normal emotions and problematic emotions, how to differentiate between different emotions, identification of emotions in physical and psychological states, cognitive, physiological and behavioral consequences of emotional reactions during treatment, physical, behavioral and cognitive symptoms of emotional reactions caused by thoughts to the treatment process, awareness of the relationship between emotions and behavior and thought, breaking problematic core beliefs and replacing them with new beliefs)

Category

Treatment - Other

2

Description

Control group: Routine IVF treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Fariba Soltani

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3828 3939

Email

soltanifariba484@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Soltanian

Street address

Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fariba Soltani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

soltanifariba484@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Azita Tiznobeik

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
azita.tizno@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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