Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of group training based on schema therapy on hope and anxiety in women with infertility undergoing in vitro fertilization treatment

Protocol summary

Study aim
Determining the Effect of Schema Therapy-Based Group Training on Hope and Anxiety in Infertile Women Undergoing In Vitro Fertilization (IVF)

Design
Participants recruited consecutively & after informed consent, randomly allocated to the intervention & control groups by a random number table. The sample size: 18 participants per group(min attrition rate of 10%).

Settings and conduct
Shahid Akbarabadi Educational and Medical Center/ The schema therapy(ST) based educational intervention, Jeffrey Young's approach, selected & implemented. The sessions conducted in a structured manner using cognitive, experiential & behavioral techniques. Twelve 90 minute sessions delivered in person & through a virtual platform. The control group will receive the routine care and provided with ST based educational package after completion of the study. Assessments: before, immediately after the twelfth session & 4 weeks after completion of the intervention.

Participants/Inclusion and exclusion criteria
Minimum literacy (reading and writing skills) required to complete questionnaires Confirmed infertility and selection for in vitro fertilization (IVF) by a fertility specialist At least one year elapsed since the infertility diagnosis Age 18–40 years Absence of other physical or psychological disorders (based on self-report or medical records) No use of alcohol, narcotics, or psychotropic substances No use of psychiatric medications No stressful life events in the past six months No participation in infertility-related quality-of-life enhancement programs in the past six months First-time in vitro fertilization (IVF)

Intervention groups
All married Iranian women of reproductive age with infertility who are undergoing in vitro fertilization (IVF)

Main outcome variables
Hope & Anxiety

General information

Reason for update

Acronym
IVF

IRCT registration information
IRCT registration number: **IRCT20260721070287N1**
Registration date: **2026-10-18, 1405/07/26**
Registration timing: **prospective**

Last update: **2026-10-18, 1405/07/26**
Update count: **0**

Registration date
2026-10-18, 1405/07/26

Registrant information

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Fatemeh Mirzakhani Eshlaghi Mirzakhani Eshlaghi

Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-24, 1405/08/02

Expected recruitment end date
2026-12-23, 1405/10/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of group training based on schema therapy on hope and anxiety in women with infertility undergoing in vitro fertilization treatment

Public title
Investigating the effect of group training based on schema therapy on hope and anxiety in women with infertility undergoing in vitro fertilization treatment
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1/Ability to read and write sufficiently to complete the study questionnaires.2/Confirmed diagnosis of infertility and selection for in vitro fertilization (IVF) by an infertility specialist.3/At least one year has elapsed since the diagnosis of infertility.4/ Age between 18 and 40 years.5/ No other physical or psychological disorders, based on self-report or documented medical records.6/No history of alcohol, illicit drug, or psychoactive substance use.7/Not currently using psychiatric medications.8/No experience of major stressful life events during the previous six months.9/No participation in infertility-related quality-of-life enhancement or psychological intervention programs during the previous six months.10/Undergoing the first IVF cycle.
Exclusion criteria:
Failure to attend at least two educational intervention sessions.a. Diagnosis of or development of a medical illness during the intervention period.b. Occurrence of major stressful events or unexpected acute life events (e.g., the death of a close family member) at any stage of the study, as determined by participants' self-report.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants who meet the inclusion criteria and are selected by the infertility specialist to undergo in vitro fertilization (IVF) after clinical evaluation will be randomly allocated to the intervention or control group using a random numbers table, following the provision of written informed consent. Sampling Method: Continuous Sampling will be conducted continuously. Participants will be assigned to either the intervention or control group using a table of random numbers. To this end, eligible individuals who have provided informed consent will be numbered from 1 to 18. From these, 18 numbers will be randomly selected and assigned to the intervention group, while the remaining 18 numbers will be assigned to the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
The present study is a controlled interventional (quasi-experimental) study designed to evaluate the effect of group schema therapy–based education on hope and anxiety among infertile women undergoing in vitro fertilization (IVF). Participants will be consecutively recruited from infertile women attending the Infertility Clinic of Shahid Akbarabadi Educational Hospital who meet the eligibility criteria. After providing written informed consent, participants will be randomly allocated to either the intervention or control group using a random numbers table.This clinic was selected as the study setting due to the accessibility of the target population and its willingness to collaborate with the research team. The sample size was calculated based on the estimated effect size reported in similar studies. Allowing for a minimum attrition rate of 10%, a total of 18 participants will be enrolled in each group.The educational intervention is based on Jeffrey Young's schema therapy approach, which was selected because of its emphasis on identifying and modifying early maladaptive schemas and their influence on cognitive, emotional, and behavioral patterns. The intervention will be delivered through structured educational sessions using cognitive, experiential, and behavioral techniques.The intervention will consist of twelve 90-minute sessions delivered both face-to-face and online. The educational content is based on the principles of schema therapy, adapted using evidence from studies conducted among infertile women, and supplemented with structured homework assignments. Participants in the control group will receive the routine care provided by the infertility center and, after completion of the study, will be provided with the schema therapy–based educational package.Outcome assessments will be performed at three time points: at baseline (before the intervention), immediately after completion of the twelfth intervention session, and four weeks after the end of the intervention. The primary outcome measures include hope, assessed using the Snyder Hope Scale, anxiety, assessed using the Beck Anxiety Inventory (BAI), and early maladaptive schemas, assessed using the Young Schema Questionnaire (YSQ).Data will be analyzed using SPSS software version 24. Between-group comparisons will be conducted using the independent-samples t-test, repeated-measures analysis, or analysis of covariance (ANCOVA), as appropriate. Potential confounding variables, including age, duration of infertility, cause of infertility (male or female factor), and type of infertility (primary or secondary), will be controlled for in the analyses. A two-sided p-value of less

than 0.05 will be considered statistically significant.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Shahran 2nd Roundabout, Siadat Alley
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1478816656
Approval date
2026-08-31, 1405/06/09
Ethics committee reference number
IR.IUMS.NURSE.REC.1405..27

Health conditions studied

1

Description of health condition studied
infertility
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean hope score on the Snyder scale, mean anxiety score on the Beck inventory, and mean schema score on the Young questionnaire.
Timepoint
Before and immediately after the completion of 12 sessions, and 4 weeks after the intervention ended.
Method of measurement
Young's Schema Questionnaire, Schneider's Hope Questionnaire, and Beck's Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Schema therapy-based educational intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-Abadi Educational and Medical Center
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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
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The protocol stipulates that the confidential data remains with the principal investigator; it may only be released upon a formal request and with the university's authorization, and will not be published as public data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available