

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

The effect of couple-group reality therapy on perceived stress and stigma of infertility, marital intimacy, and financial conflict management of infertile couples undergoing treatment at Royan Research Institute

Protocol summary

Study aim

Investigating the effect of couple-group reality therapy on reducing perceived stress and infertility stigma, increasing marital intimacy, and improving financial conflict management in infertile couples undergoing treatment at the Royan Research Institute

Design

A randomized, controlled clinical trial on eight couples.

Settings and conduct

going through the legal procedures and after obtaining the consent of the applicant couples and the groups, the intervention of the present study will be carried out on the experimental group and the control group will not receive any intervention. Pre-test: before the start of the sessions Post-test: 2 months after the post-test 8 sessions, each session 90 minutes Focus on communication, problem solving and financial decision-making Training in stress management skills, sharing experiences and reducing stigma

Participants/Inclusion and exclusion criteria

- Infertility diagnosis and treatment at Royan Research Institute
- At least one year has passed since the infertility diagnosis and both couples are aware of their status
- Age between 25 and 45 years
- Iranian nationality
- Resident in Tehran
- Willingness to participate in couple and group sessions
- 5 years have passed since their marriage.

Intervention groups

1: Introduction, goals and pre-test questionnaire 2: Identifying couples' problems and feelings (WDEP) technique 3: Responsibility training and positive feedback practice. 4: Identifying ineffective behaviors and practicing role-playing 5: Goal-oriented planning with the SMART technique. 6: Stress management and dealing with social stigma 7: Practicing communication skills and resolving financial conflict 8: Reviewing achievements and consolidating changes

Main outcome variables

Reality of couples-group therapy: perceived stress and stigma of infertility, marital intimacy, and financial conflicts.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260628069991N1**

Registration date: **2026-07-13, 1405/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-13, 1405/04/22**

Update count: **0**

Registration date

2026-07-13, 1405/04/22

Registrant information

Name

Saede Bahramzadeh someh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

s.bahramzadeh.4460@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of couple-group reality therapy on perceived stress and stigma of infertility, marital intimacy, and financial conflict management of infertile couples undergoing treatment at Royan Research Institute

Public title
The effect of couple-group reality therapy on perceived stress and stigma of infertility, marital intimacy, and financial conflict management of infertile couples undergoing treatment

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 ● Infertility diagnosis and treatment at Royan Research Institute● At least one year has passed since the infertility diagnosis and both couples are aware of their status● Age between 25 and 45 years● Iranian nationality● Resident in Tehran● Willingness to participate in couple and group sessions● 5 years have passed since their marriage
Exclusion criteria:
 ● Dropping out of treatment or not attending at least 80% of sessions● Having a child or adopted child● Having a history of remarriage● Receiving previous psychological interventions in the area of the components of the present study● Having chronic mental disorders

Age
From **25 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Faculty of Medicine - Tehran Islamic Azad University of Medical Sciences

Street address

Tehran, Dr. Shariati St., Qolhek Intersection, Amir Paborja St., Aineh Blvd., corner of Gol Yakh St., Headquarters Building of Tehran Islamic Azad University of Medical Sciences.

City

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Province

Tehran

Postal code

1949635881

Approval date

2026-06-08, 1405/03/18

Ethics committee reference number

IR.IAU.TMU.REC.1405.093

Health conditions studied

1

Description of health condition studied

Mental health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people with infertility stress

Timepoint

Measuring infertility stress before and after reality therapy intervention

Method of measurement

Infertility Stress: Fertility Problem Inventory (Newton et al., 1999)

2

Description

People with Perceived Stigma of Infertility

Timepoint

Measuring the perceived stigma of infertility before and after the reality therapy intervention

Method of measurement

Perceived Stigma of Infertility: Scale (Fu & Hekaran, 2015) Infertility Stigma Scale

3

Description

Managing financial conflicts

Timepoint

Measuring financial conflicts before and after reality therapy intervention

Method of measurement

Financial Conflict Management: Soleimani Marital Conflict Questionnaire (2013)

4

Description

Measuring marital intimacy

Timepoint

Measuring marital intimacy before and after reality therapy intervention

Method of measurement

Marital intimacy: Mink-Bagaruzi questionnaire, 2001),

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Infertile couples undergoing treatment at Royan Research Institute

Category

Behavior

2

Description

Control group: Infertile couples undergoing treatment at Royan Research Institute

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Research Institute

Full name of responsible person

Reza Omani Samani

Street address

Shahid Soleimani Highway, Bani Hashem Street, Bani Hashem Square, East Hafez Street, Royan Alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

The researcher herself

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Saideh Bahramzadeh Soumeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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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