

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Aug 2026

Investigating the effect of Couple Coping Enhancement Training on marital stress of infertile couples

Protocol summary

Study aim

Main Objective of the Project: To determine the effect of couples' coping enhancement training on the marital stress of infertile couples in the control and intervention groups, before and after the intervention.

Design

A randomized, controlled clinical trial with factorial groups, without blinding, on 92 couples.

Settings and conduct

This research is a randomized controlled trial with a concurrent control group, involving infertile couples who will attend the infertility treatment center at Velayat Hospital in Qazvin (Iranian calendar) for infertility treatment and meet the study inclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile couples with high or moderate levels of marital stress. Exclusion criteria: Less than 12 months of trying to conceive.

Intervention groups

Type of Intervention: Couples Coping Enhancement Training. Mode of Delivery: Couple-centered, delivered via social media platforms accessible to the couples. Number of Sessions: 8 sessions, each lasting 40 to 60 minutes. Control Group: Routine care. No intervention will be performed for this group. At the end of the study, the prepared files will be provided to them, and if necessary, a counseling session will be organized for them.

Main outcome variables

Main Objective of the Project: To determine the effect of couples' coping enhancement training on the marital stress of infertile couples in the control and intervention groups, before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260217068897N1**

Registration date: **2026-05-17, 1405/02/27**

Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**

Update count: **0**

Registration date

2026-05-17, 1405/02/27

Registrant information

Name

Elham Ghajar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3255 7100

Email address

e.ghajar@qums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Couple Coping Enhancement Training on marital stress of infertile couples

Public title

Investigating the effect of Couple Coping Enhancement

Training on marital stress of infertile couples

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 At least 12 months of attempts to conceive, regardless of female or male cause of infertility A score higher than 34 on the Marital Stress Scale, indicating moderate to high stress Confirmed diagnosis of infertility by a specialist at the clinic Informed consent from each spouse individually Ability to read and use questionnaires
Exclusion criteria:
 Having psychotic disorders (psychosis), depression, anxiety disorders, and bipolar disorders, as self-reported by the individual History of adverse events in the past 6 months, such as the bereavement of a close relative.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **184**

Randomization (investigator's opinion)
Randomized

Randomization description
 We will use block randomization with blocks of four. Random allocation sequences will be generated using software for random sequence generation. Block randomization ensures that an equal number of participants are enrolled in the intervention and control groups at regular, sequential intervals. Participants will be evenly distributed between the intervention and control groups using the randomized block method. The selection process for the intervention and control groups will be pre-determined, and participants will be allocated sequentially to the two groups. A random sequence generation website (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) will be used. (CCTT/CTTC/TCCT/CTCT/TCTC/TTC)

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 Qazvin University of Medical Sciences

Street address
 Qazvin, Shahid Salmani Street, North Navab Street, Office Complex, Building No. 1 of Qazvin University of Medical Sciences Headquarters

City
Qazvin

Province
Qazvin

Postal code
3419915315

Approval date
2026-01-24, 1404/11/04

Ethics committee reference number
IR.QUMS.REC.1404.431

Health conditions studied

1

Description of health condition studied
 Strengthening marital coping for infertile couples

ICD-10 code

ICD-10 code description

2

Description of health condition studied
 Marital stress of infertile couples

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
 Couples with high and moderate marital stress

Timepoint
 Before the intervention - one and three months after the completion of the intervention

Method of measurement
 Stockholm Marital Stress Questionnaire

Secondary outcomes

1

Description
 Marital coping score of infertile couples

Timepoint
 Before the intervention - one and three months after the completion of the intervention

Method of measurement
 Bodenman Couple Coping Scale

2

Description
 Couples' infertility stress score

Timepoint

Before the intervention - one and three months after the completion of the intervention

Method of measurement
Newton Infertility Stress Scale

Intervention groups

1

Description

Intervention group: The couples' coping reinforcement training program, based on the Bodenman and Shantinath guidelines, will be presented in eight 40-60 minute couple-centered sessions on social media platforms accessible to couples.

Category

Behavior

2

Description

Control group: The care is routine and no intervention will be performed for them. At the end of the study, the prepared files will be provided to them and, if needed, a counseling session will be held for them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Elham Ghajar

Street address

Velayat Educational and Medical Center, Taiwan Square, 22th Brahman Boulevard, Elahieh Alley, Minoudar Street

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2

Recruitment center

Name of recruitment center

Qazvin University Jihad Organization

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Elham Ghajar

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House Number 12, First door, Beginning of Moseyb Moradi Street, Nokhbegan Blvd, Qazvin

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Elham Ghajar

Position

Master's Degree Student in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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