

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of positive thinking counseling and cognitive restructuring versus control group on the perceived stress caused by the repeated failure of in vitro fertilization (IVF) among infertile women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of positive thinking counseling and cognitive restructuring versus control group on the perceived stress caused by the repeated failure of in vitro fertilization (IVF) among infertile women

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 60 eligible infertile women. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 45 years Perceived high stress Primary infertility A history of two failed IVFs Normal body mass index Exclusion criteria: Mental disorder History of endometriosis Addiction

Intervention groups

Intervention group: Routine treatment plus positive thinking and cognitive restructuring counseling sessions for 45 to 60 minutes twice a week for 4 weeks (including familiarity with types of female infertility, positive and negative emotions, stress and quality of life; positive effect of healthy nutrition, exercise, and meditation on reproductive health; teaching behavioral methods such as talking about stress, calming and postponing the reaction; the effect of positive emotions on the quality of married life and sexual performance of couples) Control group: Just routine treatment

Main outcome variables

Primary outcome: Perceived stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N474**

Registration date: **2023-05-15, 1402/02/25**

Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**

Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of positive thinking counseling and cognitive restructuring versus control group on the perceived stress caused by the repeated failure of in vitro fertilization (IVF) among infertile women: a randomized clinical trial

Public title

Effect of positive thinking counseling and cognitive restructuring versus control group on the perceived stress caused by the repeated failure of in vitro fertilization (IVF) among infertile women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 20 to 45 years Perceived high stress Primary infertility A history of two failed IVFs Normal body mass index

Exclusion criteria:

Mental disorder History of endometriosis Addiction

Age

From **20 years** old to **45 years** old

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

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the 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, Shahid
Fahmideh Ave

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Postal code

6517838695

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.UMSHA.REC.1402.103

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**

Perceived stress

Timepoint

Before the intervention and 4 weeks later

Method of measurement

Using Cohen's perceived stress scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Routine treatment plus positive thinking and cognitive restructuring counseling sessions for 45 to 60 minutes twice a week for 4 weeks (including familiarity with types of female infertility, positive and negative emotions, stress and quality of life; positive effect of healthy nutrition, exercise, and meditation on reproductive health; teaching behavioral methods such as talking about stress, calming and postponing the

reaction; the effect of positive emotions on the quality of married life and sexual performance of couples)
Category
Treatment - Other

2

Description
Control group: Just routine treatment plus
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Sara Abdoli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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

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
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

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