Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Fatemieh 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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+98 81 1838 0090

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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

City
Hamadan

Province
Hamadan

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

Street address

Fatemieh Hospital, Pasdaran Ave.

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6517838695

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+98 81 3828 3939

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sara.abdoli.m96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Full name of responsible person

Sara Abdoli

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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

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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