

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2026

Implementing of coping strategies with infertility using couple-based approach for infertile couples

Protocol summary

Study aim

Implementing of coping strategies with infertility using couple-based approach for infertile couples

Design

The experimental study has two experimental and control groups, each of which will include 32 people. Individuals are grouped in a non-random way; people who refer on even days of the week will be in the intervention group and people who refer on odd days will be in the control group. The coping strategies program will be implemented for the intervention group.

Settings and conduct

Infertile couples referring to Shahid Beheshti Infertility Center which have inclusion criteria, are divided into two groups; case and control. The Depression Anxiety Stress Scale-21 (DASS-21) and Fertility Adjustment Scale (FAS) are completed by two groups before the intervention. The program will be implemented for the case group. The questionnaires will be completed immediately and three months after the intervention. No intervention is performed for the control group.

Participants/Inclusion and exclusion criteria

Iranian infertile couples with informed consent to enter the study - at least three months have passed since their last infertility treatment failure and have no history of mental disorders.

Intervention groups

Anxiety, depression and stress of infertile couples are measured using the Depression Anxiety Stress Scale-21 (DASS-21) and infertility adjustment using the Fertility Adjustment Scale (FAS) before implementing infertility coping strategies. Coping strategies based on interviews with infertile couples and fertility service providers are implemented for the case group. Questionnaires will be completed immediately and three months after the intervention. No intervention is performed for the control group.

Main outcome variables

Depression, stress, anxiety and infertility adjustment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045102N1**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Marziye Reisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 8636

Email address

mrz.reisi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementing of coping strategies with infertility using couple-based approach for infertile couples		Ethics committee reference number IR.MUI.NUREMA.REC.1400.019	
Public title Coping strategies with infertility in infertile couples		Health conditions studied	
Purpose Supportive		1	
Inclusion/Exclusion criteria Inclusion criteria: Infertile Iranian couples At least three months have passed since the last failure in infertility treatment. No history of hospitalization or use of medication because of mental disorders Absence of stress, anxiety and severe depression Exclusion criteria: Unwillingness to participate in study Infertile couples with history of mental disorders		Description of health condition studied mental health ICD-10 code F34 ICD-10 code description Persistent mood [affective] disorders	
Age No age limit		Primary outcomes	
Gender Both		1	
Phase N/A		Description Depression	
Groups that have been masked No information		Timepoint before the intervention, immediately after the intervention and three months after the intervention.	
Sample size Target sample size: 64		Method of measurement Depression, anxiety and stress DASS 21 Scale	
Randomization (investigator's opinion) Not randomized		2	
Randomization description		Description Anxiety	
Blinding (investigator's opinion) Not blinded		Timepoint before the intervention, immediately after the intervention and three months after the intervention.	
Blinding description		Method of measurement Depression, anxiety and stress DASS 21 Scale	
Placebo Not used		3	
Assignment Parallel		Description Stress	
Other design features		Timepoint before the intervention, immediately after the intervention and three months after the intervention.	
Secondary Ids empty		Method of measurement Depression, anxiety and stress DASS 21 Scale	
Ethics committees		4	
1		Description Adjustment to infertility	
Ethics committee Name of ethics committee Ethics committee of Isfahan University of Medical Sciences Street address Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St., Isfahan, Iran. City Isfahan Province Isfahan Postal code 81746-73461 Approval date 2021-05-08, 1400/02/18		Timepoint before the intervention, immediately after the intervention and three months after the intervention. Method of measurement Fertility Adjustment Scale	
		Secondary outcomes empty	

Intervention groups

1

Description

Intervention group: Intervention is a program that will be done with the aim of improving the structures. It should be noted that the exact content of the program will be determined after interviewing key participants (infertile couples and fertility service providers).

Category

Prevention

2

Description

Control group: The control group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti Infertility Center

Full name of responsible person

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Street address

Ostad Motahari St., Felezi Bridge., Isfahan , Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

beheshti@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

Street address

Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St., Isfahan, Iran.

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Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

mrz.reisi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Marzie Reisi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan, Iran.

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on the main consequences of depression, anxiety
and stress and fertility adjustment are generally shared

When the data will become available and for how long

Start access 6 months after printing results

To whom data/document is available

Everyone has access.

Under which criteria data/document could be used

Available for systematic review and meta-analysis.

From where data/document is obtainable

First Author and author colleagues. (Via email)

What processes are involved for a request to access data/document

By email to the first author of the article and colleagues

Comments