

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Aug 2026

providing and evaluation of a supportive educational intervention on treatment continuation of infertile couples

Protocol summary

Study aim

evaluating supportive intervention on attitude, treatment continuation intention and mental health of infertile couples

Design

Clinical trial with control group. No blinding, randomized, on 130 patients. A table of random numbers will be used for randomization.

Settings and conduct

This study is part of a larger study and at this stage an educational and counseling intervention will be conducted on infertile couples who have referred to the Jihad Infertility Center of Qom and do not intend to continue treatments. Samples will be randomly selected to participate in control and intervention groups. Then the designed intervention will be given to the experimental group (65 people). The control group is 65 people who will receive routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infertile women (18-42) history of at least one unsuccessful IVF / ICSI and FET cycle Having a file in the infertility center Voluntary participation and written consent. Having Iranian nationality (couple) No addiction to drugs and psychotropic drugs Fluency in Persian Exclusion criteria: get pregnant

Intervention groups

The educational and counseling intervention will be conducted on two groups (intervention and control). 4 1-hour online sessions (weekly) are provided to present the main issues of the intervention, and also some of the easier content will be presented in 6 sessions (twice a week) by forming a group in cyberspace. The content of the training sessions is based on a transtheoretical model and covers various areas such as identification and self-care about stress, depression, anxiety, social anxiety, coping skills, how to interact with others, anger management. The control group will also receive standard infertility center care.

Main outcome variables

Attitude, intention to continue treatment and mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051315N1**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Maryam Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

maryam_ghorbany89@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

providing and evaluation of a supportive educational intervention on treatment continuation of infertile couples

Public title

educational intervention for infertile couples

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile women aged 42-18 Having a file in the infertility center Voluntary participation and written consent Having Iranian nationality (for both of couples) No addiction to drugs and psychotropic drugs Fluency in Persian Perform at least one IVF / ICSI and FET cycle after the required time period to start treatment again. For this purpose, a follow-up period of at least 6 months, according to a study conducted by Moeini et al. In 2009, at Royan Infertility Center taken

Exclusion criteria:

getting pregnant

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

This randomized clinical trial will be performed at Jihad Infertility Center of Qom University . Among infertile couples who do not intend to continue infertility treatments and meet the inclusion criteria, after obtaining informed consent, samples are taken individually using a simple random method and using a random number table to participate in control group (n = 65) and intervention (n = 65). Thus, a number is first assigned to infertile couples who meet the criteria for entry into the intervention. Reading the numbers in the random table will be from bottom to top. Then even numbers will be selected to be in the intervention group and odd numbers will be selected to be in the control group. And this will continue until the required number of samples in each group is completed, and thus the researcher will not have the option to change the assignment status of individuals or predict it.

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 Shahroud University of Medical Sciences

Street address

7tir street

City

Shahroud

Province

Semnan

Postal code

3614773947

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.SHMU.REC.1397.235

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

attitude to infertility treatments

Timepoint

one month after the end of intervention

Method of measurement

Attitude Questionnaire on Infertility Treatments

2**Description**

Mental health

Timepoint

one month after the end of intervention

Method of measurement

GHQ28 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive educational counseling intervention as follows. 4 1-hour online sessions per week are provided to present the main issues of the intervention, and also some of the easier content will be presented in 6 sessions (twice a week) by forming a group in cyberspace. The content of the training sessions is based on a transtheoretical model and covers various areas such as identification and self-care about stress, depression, anxiety, social anxiety, coping skills, how to interact with others, anger management.

Category

Behavior

2

Description

Control group: participants of control group will not receive any intervention from the research team during the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jahad Infertility treatment center , Qom province

Full name of responsible person

Maryam Ghorbani

Street address

Jahad daneshgahi alley, Safashar street

City

Qom

Province

Ghoum

Postal code

3716986466

Phone

+98 25 3285 9856

Email

maryam_ghorbany89@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

Street address

7street

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

pishgiri1@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Afsaneh Keramat

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

7tir street

City

shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

keramat2222@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Afsaneh Keramat

Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
7tir street
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 5054
Email
keramat2222@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Maryam Ghorbani
Position
Student
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
7tir street

City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
009832935054
Email
maryam_ghorbany89@yahoo.com

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