# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 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 Jahad 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:**
geting 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 commitee 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 questionaire

## 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

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**Province**
Ghoum

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Shahroud University of Medical Sciences

**Full name of responsible person**
Mohammad Hasan Emamian

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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**
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

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## Person responsible for updating data

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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