

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of counseling based on acceptance and commitment consulting on perceived stress, number of oocytes retrieved and pregnancy rates in infertile women undergoing IVF treatments

#### Protocol summary

##### Study aim

Determination effect of counseling based on acceptance and commitment consulting on perceived stress, number of oocytes retrieved and pregnancy rates in infertile women undergoing IVF treatments

##### Design

Two-group randomized clinical trial on 76 women eligible for randomized study through [www.randomization.com](http://www.randomization.com)

##### Settings and conduct

Samples will be selected from among infertile women who are eligible to enter the intervention. Then, for random assignment of samples to the intervention and control groups, the permutation block method will be used, which this method uses random software.

Allocation Software is performed and randomly places one person in the intervention group and one person in the control group., In Milad Infertility Center, Mashhad

##### Participants/Inclusion and exclusion criteria

Diagnosis of primary infertility, age between 20 and 40 years, the couple has no children or adopted children, is being treated for IVF for the first time, has a normal view of ovarian base on ultrasound to start treatment, has a normal spermogram, has a smartphone.

##### Intervention groups

The intervention group will conduct six sessions of 45-60 minutes, individually, in person and the rest of the sessions in absentia every six days. The control group receives only the usual services of the center.

##### Main outcome variables

Stress, number of eggs taken and pregnancy rate

#### General information

##### Reason for update

##### Acronym

ACT

##### IRCT registration information

IRCT registration number: **IRCT20210510051249N1**

Registration date: **2021-08-25, 1400/06/03**

Registration timing: **prospective**

Last update: **2021-08-25, 1400/06/03**

Update count: **0**

##### Registration date

2021-08-25, 1400/06/03

##### Registrant information

###### Name

Toktam sadat Taheri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3859 1511

###### Email address

taherits971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-06, 1400/06/15

##### Expected recruitment end date

2022-01-20, 1400/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of counseling based on acceptance and commitment consulting on perceived stress, number of oocytes retrieved and pregnancy rates in infertile women

undergoing IVF treatments

### Public title

The effect of counseling on perceived stress, number of oocytes retrieved and pregnancy rates

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Diagnosis of primary infertility, Iranian and resident of Mashhad, ability to speak and write in Persian, no known medical diseases, age between 20 to 40 years, couple have no children or adopted children, no mental illness, IVF treatment for For the first time, in the basic ultrasound (day 2 to 3 of the cycle) the ovary has a normal appearance to start treatment, the spermogram is normal, the husband has no other spouse, no smoking and alcohol consumption, BMI is below 30, IVF candidate, has Smartphone and consent to participate in the study

#### Exclusion criteria:

Intend to use embryos and donated eggs or surrogates

### Age

From **20 years** old to **40 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **76**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Sampling is available by simple random assignment. After determining the sample size, through a table of random numbers using the statistical software Random allocation software, the numbers are divided into two groups of sequences marked with the letters A and B. The sequence stored in sealed envelopes that the researcher uses when selecting a research unit to send individuals to two groups that meet the inclusion criteria.

### 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 Mashhad University of Medical

Sciences and Health Services

### Street address

Opposite to University Street 18, University Street, Mashhad University of Medical Sciences, Khorasan Razavi, Iran

### City

Mashhad

### Province

Razavi Khorasan

### Postal code

9188667656

### Approval date

2021-06-15, 1400/03/25

### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.032

## Health conditions studied

### 1

#### Description of health condition studied

The effect of counseling based on acceptance and commitment consulting on perceived stress number of oocytes retrieved and pregnancy rates in infertile women undergoing IVF treatments

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Stress score

#### Timepoint

The beginning of the study (before the intervention) and the trigger day (two weeks after the last consultation) and two weeks after the embryo transfer

#### Method of measurement

Newton Infertility Stress Questionnaires

## Secondary outcomes

### 1

#### Description

Follicle number

#### Timepoint

Number of ovarian follicles at trigger time with HCG

#### Method of measurement

With ultrasound by a gynecologist

### 2

#### Description

pregnancy rates

#### Timepoint

Two weeks after embryo transfer

#### Method of measurement

blood test

## Intervention groups

### 1

#### Description

The intervention group will receive six sessions of 45-60 minutes, counseling based on acceptance and commitment individually, the first session of day 2 to 3 of the first cycle (after basic ultrasound) in person and the rest of the sessions in absentia every six days ( Day 8-14-20-26 The first cycle and the last session will be run on days 2 to 3 of the next virtual cycle

#### Category

Behavior

### 2

#### Description

Control group: In the first session, the control group completes the questionnaires and provides the routine services of the center, which include explanations about IVF treatment and possible complications and costs for treatment, to decide on treatment. On day 2-3 of the cycle, measures including basic ultrasound and initial tests are requested and then 21 units of subcutaneous ampoules of Cinnafact are prescribed daily for 0.5 units, and they are taught how to use infertility drugs and the time of their next visit. Second, HMG 150-300 units are added daily depending on the ovarian reserve under the supervision of an infertility specialist and 6 days after the onset of ovarian stimulation, folliculography is performed every two to three days, until at least 3 dominant 17 mm follicles are observed. HCG is triggered and ovulation will occur 36 hours later.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Milad Infertility Clinic, Mashhad

##### Full name of responsible person

Nahid jahani shorab

##### Street address

School of Nursing and Midwifery, Ibn Sina St., Doctora Intersection, Daneshgah St., Mashhad, Khorasan Razavi, Iran

##### City

mashhad

##### Province

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##### Postal code

9137913199

##### Phone

+98 51 3859 1511

##### Fax

+98 51 3859 7313

##### Email

jahanishn@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Darabi Mahboob

##### Street address

Opposite to University Street 18, University Street Mashhad University of Medical Sciences, Khorasan Razavi, Iran

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##### Email

Bahreynimh@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Toktam taheri

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

University Street, Ph.D. Crossroads, School of Nursing and Midwifery

##### City

Mashhad

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Razavi Khorasan  
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9189835486  
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taherits971@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Nahid Jahani Shorab  
**Position**  
Master  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery  
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## Person responsible for updating data

### Contact

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

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**Latest degree**  
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**Other areas of specialty/work**  
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taherits971@mums.ac.ir

## 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