Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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)

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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
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Mashhad
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Mohammad Reza Darabi Mahboob

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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
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

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Person responsible for scientific inquiries

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Master
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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