Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of group therapy based on positive psychology on anxiety and result of IVF/ICSI in infertile women candidate of IVF/ICSI

Protocol summary

Summary

The aim of this study is to evaluate the effect of group therapy based on positive psychology on patients anxiety and result of IVF/ICSI in infertile women candidate of IVF/ICSI. research community in this clinical trial is infertile women undergoing IVF/ICSI in Yas Hospital in Tehran. Forty infertile women, candidate for IVF/ICSI, who referred by her infertility doctor and their high anxiety level needed psychological intervention are studied in two groups; control and case by non-randomized division. All The patients in the control and case group sign the informed consent and then will be tested by Beck anxiety questionnaire as pre-test questionnaire, first and before the intervention. These both groups are matched according to Beck anxiety test score, age, duration of infertility. Intervention in the case group is ten sessions of group therapy based on positive psychology. Each session is ninety-minutes weakly. During this period, the control group will be placed on the waiting list. At the end of the study, the researcher must conduct these sessions for the control group, if requested. The level of anxiety in both groups will be evaluated and compared again. ovarian stimulation therapy for IVF/ICSI is done according to the patients' age and ovarian reserve. Then embryo transferred adjusting the patient's age and embryo quality. The outcome of IVF/ICSI in control and experimental groups will be investigated by pregnancy test two weeks after embryo transfer and its relation to the anxiety will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701242576N14**
Registration date: **2017-07-11, 1396/04/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-07-11, 1396/04/20

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3955

Email address

fdavaritanha@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group therapy based on positive psychology on anxiety and result of IVF/ICSI in infertile women candidate of IVF/ICSI

Public title

The effect of group psychotherapy on anxiety and result of IVF/ICSI

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women candidate of IVF/ICSI; infertile women with high anxiety who need psychological intervention. Exclusion criteria: Any history of hospitalization or drug therapy for psychological disease; interest of patient to exit from study.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Vice Chancellor for Medical Research, Tehran University of Medical Sciences, 6th floor, Central Building of Tehran University of Medical Sciences, Ghods Ave, keshavarz Blvd.

City

Tehran

Postal code

1597856511

Approval date

2017-04-23, 1396/02/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2111

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

Z35.0

ICD-10 code description

Supervision of pregnancy with history of infertility

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

before and after intervention

Method of measurement

Beck anxiety test

Secondary outcomes

1

Description

Pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

BHCG Test

Intervention groups

1

Description

Intervention on case group is a weekly ten ninety-minute sessions of group therapy based on positive psychology. first session: introduction the members to each others and training them for proper feedback. second session: training the theory of building and spread of positive emotions (step 1). third session: training the theory of building and spread of positive emotions (step 2). 4th session: cognitive challenges. 5th session: challenge of emotions. 6th session: their progress and self-esteem. 7th session: effective communication. 8th session: challenge of beliefs and values. 9th session: self-actualization as a final purpose. 10th session: wrap and finishing.

Category

Lifestyle

2

Description

There is no intervention on control group except of routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas Hospital

Full name of responsible person
Fatemeh Mehrabi

Street address
Yas Hospital, Ostad Nejatollahi Shomaly St.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Medical Research, Tehran University of Medical Sciences

Full name of responsible person
Dr. Yunesian

Street address
Vice Chancellor for Medical Research, Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blvd.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Medical Research, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Yas Hospital

Full name of responsible person
Fatemeh Mehrabi

Position
Fellowship of Infertility

Other areas of specialty/work

Street address
Yas Hospital, Ostad Nejatollahi Shomaly St.

City
Tehran

Postal code
1597856511

Phone
+98 21 4216 0000

Fax

Email
fmtums95@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yas Hospital

Full name of responsible person
Fatemeh Mehrabi

Position
Fellowship of Infertility

Other areas of specialty/work

Street address
Yas Hospital, Ostad Nejatollahi Shomaly St.

City
Tehran

Postal code
1597856511

Phone
+98 21 4216 0000

Fax

Email
fmtums95@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Yas Hospital

Full name of responsible person
Fatemeh Mehrabi

Position
Fellowship of infertility

Other areas of specialty/work

Street address
Yas Hospital, Ostad Nejatollahi Shomaly St.

City
Tehran

Postal code
1597856511

Phone
+98 21 4216 0000

Fax

Email
fmtums95@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty