

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing effect of relaxation and expressive writing intervention on depression, anxiety, stress and success of treatment in infertile women undergoing assisted reproductive technology treatment (ART).

Protocol summary

Study aim

Determining and comparing the effect of relaxation and expressive writing on depression, anxiety, stress and success of treatment of women undergoing assisted reproductive techniques.

Design

andomised, superiority, parallel group trial
Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

This study is a randomized clinical trial study in which samples are assigned to three groups of relaxation, written expression and randomized control through 6 blocks. At the beginning of the study, the demographic information form and the DASS-42 questionnaire will be completed by the samples in all three groups. For relaxation intervention, various studies have stated the number of sessions and the duration of relaxation from 12 sessions of 15 to 30 minutes to several sessions of 8 weeks. For written expression intervention, in different studies, the number of sessions and the duration of the intervention were stated as 3 sessions in 3 consecutive days for each session of 20 to 30 minutes. At the end of the follow-up, the success of the treatment will be measured by measuring the BHCG titer.

Participants/Inclusion and exclusion criteria

Age 20-40 years and no use of anti-anxiety and sedative drugs and no previous history of sedation and written expression, no physical, mental problems and medical diseases other than infertility, recorded in the file

Intervention groups

Relaxation and expressive writing groups

Main outcome variables

Infertility treatment success

General information

Reason for update

Acronym

ART

IRCT registration information

IRCT registration number: **IRCT20110629006917N5**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Leila Amini

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 3316 6574

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of relaxation and expressive writing intervention on depression, anxiety, stress and success of treatment in infertile women undergoing assisted reproductive technology treatment (ART).

Public title

Comparing effect of relaxation and expressive writing intervention on depression, anxiety, stress and success of treatment in infertile women undergoing assisted reproductive technology treatment (ART).

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

- Being of Iranian origin
Literacy
Being in the age range of 40-20 years
Candidate for IVF and ICSI treatment
Access and ability to use social networks such as WhatsApp

Exclusion criteria:

Uterine and endometriosis causes of infertility
anti-anxiety and sedative drugs use
previous history of relaxation and expressive writing
PGD candidate having an adopted child
physical, mental or medical problems other than infertility that recorded in the file-

AgeFrom **20 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **12**

In this study, the participants are infertile women who refer to the infertility clinic of Shahid Akbarabadi (infertility confirmation was done by a gynecologist and is recorded in the patient file) are eligible for study and have including criteria

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size of the present study, which is 90, will be done through blocking. To form a block, an equal number is assigned to each group so that the block reaches the desired size. List of all possible blocks with size 6 (multiplier of the number of study groups) using MATLAB and Excel software, duplicate blocks are removed and then assigned to the blocks, numbers 1 to 90 according to the total volume of moisture, which is 90's. And using a random table of numbers, 15 blocks of 6 are selected. Entry into each of the groups of relaxation, expressive writing and control (assignment of names A, B, C to the groups is also done randomly) is done by selective blocks and arrangement inside the block, respectively.

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**

Iran University of Medical Sciences (Biomedical Research Ethics Committee)

Street address

Hemmat Highway, next to Milad tower, IUMS

City

Tehran

Province

Tehran

Postal code**Approval date**

2020-02-29, 1398/12/10

Ethics committee reference number

IR.IUMS.REC.1399.716

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

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

Treatment Success

Timepoint

Days of 0, Puncture and a day before pregnancy test

Method of measurement

Questionnaires

Secondary outcomes**1****Description**

no

Timepoint

-
Method of measurement
-

Intervention groups

1

Description

Intervention group: Benson Relaxation

Category

Rehabilitation

2

Description

Intervention group: Expressive writing

Category

Rehabilitation

3

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Akbar-Abadi Hospital

Full name of responsible person

Zahra Najd Gholami

Street address

Molavi Ave, Before Molavi Cross, Bagh Ferdose
Station

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1168743514

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

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Iran University of Medical Sciences, Shahid Hemmat
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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Zahra Najd Gholami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Leila Amini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

student

Latest degree

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Other areas of specialty/work

Midwifery

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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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available