

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of expressive writing on depression, anxiety, stress ,and sleep quality of infertile women

Protocol summary

Study aim

The effect of expressive writing on depression, anxiety, stress and sleep quality of infertile women referring to Isfahan Infertility Clinics in 2021

Design

Randomized controlled clinical trial on 102 participants (intervention group 51 and control group 51) and random allocation using opaque sealed packages.

Settings and conduct

Out of infertile women referring to Isfahan Infertility Center and Maryam Infertility Center the volunteer ones with inclusion criteria, obtaining a score of anxiety and depression above 10 from DASS-21 questionnaire, and a score above 5 from the Pittsburgh questionnaire will be entered. After random allocation to control or intervention group, depression, anxiety, stress, and sleep quality will be measured. Then the method of writing will be instructed to the participants of two groups. Just after 3 day intervention, the variables will be measured again.

Participants/Inclusion and exclusion criteria

Willing to participate in the study, Diagnosed infertility, Candidate for assisted reproductive therapy, Married, Age of 18- 45 years, Anxiety and depression, Scores above 10 and sleep quality scores above 5, Having a high school diploma or higher education, Not participating simultaneously in other research related to the treatment of anxiety/depression/sleep disorders, Not referring to a psychologist or psychiatrist during study

Intervention groups

Intervention group: In this group, samples are taught to write down their deepest feelings, worries, and thoughts about not having a child and worries related to infertility methods for 3 days, every day for 20 minutes at home. Control group: In this group, they are asked to write for 20 minutes every day for 3 days about daily events that do not involve their emotions and feelings, such as cleaning, cooking, etc.

Main outcome variables

Depression; anxiety; stress; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091001002531N6**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **prospective**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7596

Email address

dadkhah-tehrani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-03, 1400/11/14

Expected recruitment end date

2022-05-09, 1401/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of expressive writing on depression, anxiety, stress ,and sleep quality of infertile women

Public title

The effect of expressive writing on depression, anxiety, stress, and sleep quality of infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Diagnosed infertility Candidate for assisted reproductive therapy Married Anxiety and depression scores above 10 and sleep quality score above 5 Age of 18 - 45 years Having high school diploma or higher education

Exclusion criteria:

Infertile women candidate for surrogacy or ovule donation Infertile women with severe anxiety and depression scores Infertile women referring to a psychologist or psychiatrist during study Infertile women participating simultaneously in other researches related to the treatment of anxiety, depression, stress, and sleep disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher will ask the participants to take a sealed opaque package out of 102 randomly. 51 packages contain questionnaires and checklists coded 1(related to intervention group: express writing) and 51 packages contain the same questionnaires and checklists coded 2(related to control group: neutral writing). This process will continue until having 51 samples in both groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The questionnaires have code 1 or 2.The data analyzer will will not know which number relates to which group (control or intervention)

Placebo

Not used

Assignment

Parallel

Other design features

In this study, infertile women are divided into two groups of control and intervention, so two groups will be assessed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Faculty of Nursing & Midwifery, Isfahan University of Medical Science, Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.198

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

Stress

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

3

Description of health condition studied

Quality of sleep

ICD-10 code

F51.12

ICD-10 code description

Insufficient sleep syndrome

4

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression

Timepoint

Before expressive writing , Immediately after expressive writing, and 2 weeks after expressive writing.

Method of measurement

Using Depression questionnaire DASS-21

2

Description

Anxiety

Timepoint

Before expressive writing , Immediately after expressive writing, and 2 weeks after expressive writing.

Method of measurement

Using Anxiety questionnaire DASS-21

3

Description

Stress

Timepoint

Before expressive writing , Immediately after expressive writing, and 2 weeks after expressive writing.

Method of measurement

Using Stress questionnaire DASS-21

4

Description

Quality of sleep

Timepoint

Before expressive writing , Immediately after expressive writing, and 2 weeks after expressive writing.

Method of measurement

Using Sleep quality questionnaire of Pittsburg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, participants are taught to write for 3 days, every day for 20 minutes , their deepest feelings and worries and thoughts about not having a child and worries related to infertility methods. When writing, write down every word or phrase that comes to mind and do not worry about the correctness or politeness of the words and sentences, that's mean the correct spelling or spelling of the words does not matter at all and the words should be used that express their true feelings and she will be asked to write, for example, about a disturbing event in order to fix the problem.

Category

Treatment - Other

2

Description

Control group: In this group. the participants are asked to write down about everyday events that do not involve their emotions and feelings, such as cleaning, cooking... for 20 minutes every day for 3 days .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Infertility Center

Full name of responsible person

Fatemeh Sadeghi Dousari

Street address

Corner of Behesht St., Salman Farsi St. (Mustaq II), Bozorgmehr Square, Isfahan

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Web page address

2

Recruitment center

Name of recruitment center

Maryam Infertility Center

Full name of responsible person

Fatemeh sadeghi dousari

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Metal Bridge, the beginning of Motahhari , Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Mansoor Siavash

Street address

The deputy of research and technology, building 4,
Isfahan University of Medical Sciences, Hezarjerib
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https://isid.research.ac.ir/Mansoor_SiavashDastjerdi

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Tahmineh Dadkhahtehrani

Position

Instructor of Midwifery, Faculty member

Latest degree

Master

Other areas of specialty/work

Midwifery

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Other areas of specialty/work

Midwifery

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

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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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

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