

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of expressive writing intervention (EWI) on depression, stress, anxiety and quality of life of infertile women

Protocol summary

Study aim

Determining the effect of written expression on depression, stress, anxiety and quality of life of infertile women

Design

Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct

Participants will complete the demographic information questionnaire, DASS-21 and World Health Organization quality of life questionnaire on the first day of menstruation at the Milad infertility center. In the second week and at the time of the start of the Don Regulation, the participants have to do daily written assignments. Three weeks after the last writing session, participants will complete the DASS-21 questionnaire. Finally, 6 weeks after completing the intervention (in the 8th week after starting the treatment) and before the pregnancy test, the participants will complete the DASS-21 questionnaire and the quality of life.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least two years of infertility history, primary or secondary infertility for any reason, undergoing IVF or ICSI treatment, being Iranian and living in Mashhad, age range 18-40 years. Exclusion criteria: Having a previous mental illness, experiencing a stressful event in the last three months, suffering from depression, stress and severe anxiety, a candidate for genetic diagnosis before implantation, a candidate for using donation methods, participating in a similar study in a previous IVF cycle, addiction to Tobacco and alcohol

Intervention groups

The intervention method consists of three 20-minute written assignments that are carried out in a 3-days period. The intervention group writes about involuntary childlessness and infertility treatment, and the control group writes about their daily activities.

Main outcome variables

Depression, stress, anxiety, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221108056434N1**

Registration date: **2022-12-27, 1401/10/06**

Registration timing: **prospective**

Last update: **2022-12-27, 1401/10/06**

Update count: **0**

Registration date

2022-12-27, 1401/10/06

Registrant information

Name

Samira Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-05-19, 1402/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of expressive writing intervention (EWI) on depression, stress, anxiety and quality of life of infertile women		Other design features	
Public title	he effect of written expression on infertile women	Secondary Ids	empty
Purpose	Education/Guidance	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Having at least two years of infertility history At least middle school education Being the husband's only wife Living with a spouse Primary or secondary infertility of any cause Women undergoing IVF or ICSI treatment Being Iranian and living in the city of Mashhad Age range 18-40 years Exclusion criteria: Existence of previous mental illness Experiencing a stressful event in the past three months Suffering from severe depression, stress and anxiety candidate for pre-implantation genetic diagnosis (PGD) Candidate for using donated egg, donated embryo and surrogate uterus Participation in the same study in the previous IVF cycle Smoking and alcohol addiction	1	
Age	From 18 years old to 40 years old	Ethics committee	
Gender	Female	Name of ethics committee	Ethics Committee of Gonabad University of Medical Sciences
Phase	N/A	Street address	Side of the Asian Road - Gonabad University of Medical Sciences
Groups that have been masked	- Participant - Data analyser	City	Gonabad
Sample size	Target sample size: 124	Province	Razavi Khorasan
Randomization (investigator's opinion)	Randomized	Postal code	9691793718
Randomization description	In order to randomly assign the samples to each of the 2 intervention and control groups, blocks of 4 variables are used. In this way, six possible states of blocks (BBAA, BABA, ABBA, BAAB, AABB, ABAB) are listed and a number from one to six is assigned to each block. Then randomly and through lottery, a number between one and six is selected and then people are assigned to the test (B) and control (A) groups based on the block corresponding to the selected number. This work continues until the sample volume is completed.	Approval date	2022-10-09, 1401/07/17
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.GMU.REC.1401.085
Blinding description	Both the intervention and control groups participate in a writing intervention, but they are not aware of the content of the written expression of the other group, and only the researchers themselves were aware of the content recommended for writing, and the participants and the data analyst were not.	Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	depression
		ICD-10 code	F32.8
		ICD-10 code description	Other depressive episodes
		2	
		Description of health condition studied	Stress
		ICD-10 code	F43.0
		ICD-10 code description	Acute stress reaction
		3	
		Description of health condition studied	anxiety
		ICD-10 code	F41.1
		ICD-10 code description	Generalized anxiety disorder
		Primary outcomes	
		1	
		Description	

depression
Timepoint
Before the intervention, 3 and 6 weeks after the intervention
Method of measurement
Dass-21 questionnaire

2
Description
stress
Timepoint
Before the intervention, 3 and 6 weeks after the intervention
Method of measurement
Dass-21 questionnaire

3
Description
Anxiety
Timepoint
Before the intervention, 3 and 6 weeks after the intervention
Method of measurement
Dass-21 questionnaire

4
Description
Quality of life
Timepoint
Before the intervention, 6 weeks after the intervention
Method of measurement
WHOQOL-BREF questionnaire

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: The intervention consists of three written assignments for 20 minutes that are carried out in a period of 3 days. The intervention group is taught to write about involuntary infertility and IVF/ICSI treatment for infertility.
Category
Behavior

2
Description
Control group: The intervention consists of three written assignments for 20 minutes that are carried out in a period of 3 days. The control group is instructed to write about their daily activities for the previous day, the last five days, and finally the planned activities for the next five days.
Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital - Milad Infertility Center of Mashhad

Full name of responsible person

Smira Nasri

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On the side of Asian Road, Gonabad University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Leila Sadeghi Moghadam

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Web page address

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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

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
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Position
Associate professor of reproductive health
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The information of the contributors is confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available