Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of counseling with the method of happiness training based on cognitive behavioral model on the stress of infertile women: a randomized controlled trial

Protocol summary

Study aim
Determining the effect of counseling on the stress of infertile women will be done with the method of teaching happiness program based on cognitive behavioral model

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 60 infertile women. The stratified random block method will be used for randomization

Settings and conduct
The location of the research in this study is the infertility Center of Jahad Daneshgahi in Tabriz and the time of the research is 2024. In this study, a group as an intervention group will participate in counseling sessions with the method of teaching happiness based on the cognitive behavioral model. The control group will not participate in the counseling session. Of course, both groups will receive their routine infertility treatment according to the doctor's opinion

Participants/Inclusion and exclusion criteria
Infertile women who will refer to the infertility Center of Jahad Daneshgahi in Tabriz for treatment Inclusion criteria: 1- Infertile women with at least one year of primary infertility and undergoing IVF treatment 2- Having at least basic literacy 3- Obtaining a minimum score of 184 on the Infertility Stress Questionnaire Exclusion criteria: 1- Suffering from neurological and mental illnesses according to the patient's own statement 2- Suffering from chronic illnesses (kidney and liver failure, etc.) 3- Taking psychiatric medications according to the patient's own statement 4- Referral to a psychologist within the past few months due to infertility 5- Lack of confidence in being able to attend all counseling sessions

Intervention groups
In this study, a group as an intervention group will participate in counseling sessions with the method of teaching happiness based on the cognitive behavioral model, and the control group will not participate in the counseling session.

Main outcome variables
Infertility stress score

General information

Reason for update
After approval by the Research Council of the Tabriz Faculty of Nursing and Midwifery, the sampling center has been changed from Al-Zahra Tabriz Center to the Jahad Daneshgahi Infertility Center.

Acronym

IRCT registration information
IRCT registration number: **IRCT20240809062706N1**
Registration date: **2024-08-23, 1403/06/02**
Registration timing: **prospective**

Last update: **2025-11-12, 1404/08/21**
Update count: **1**

Registration date
2024-08-23, 1403/06/02

Registrant information

Name
Khadije Hajizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3479 6770

Email address
hajizade_k@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-09-20, 1403/06/30

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with the method of happiness training based on cognitive behavioral model on the stress of infertile women: a randomized controlled trial

Public title

The effect of counseling with the method of happiness training on the stress of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women with at least one year of primary infertility and treated with IVF Having at least middle school literacy Obtaining a minimum score of 184 in the infertility stress questionnaire

Exclusion criteria:

Suffering from nervous and mental diseases according to the patient herself Suffering from chronic diseases (kidney and liver failure, etc.) Taking psychiatric drugs according to the patient's own statement Visiting a psychologist in the past few months due to infertility Uncertainty that she can participate in all counseling sessions

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **1**

Infertile women who will refer to the infertility clinic of Al-Zahra Medical Training Center in Tabriz for treatment

Randomization (investigator's opinion)

Randomized

Randomization description

The participants who completed the pre-test questionnaires were randomly selected using the website www.random.org and by blocking with blocks of four and six with an allocation ratio of 1:1. They will be assigned to two intervention groups (receiving counseling) and control group (not receiving counseling).

Blinding (investigator's opinion)

Single blinded

Blinding description

The person supervising the completion of the post-test questionnaires, the outcome evaluator, and the data analyst will be a person not involved in sampling

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2024-08-21, 1403/05/31

Ethics committee reference number

IR.TBZMED.REC.1403.404

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

F40-F48

ICD-10 code description

Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders

Primary outcomes

1

Description

Average infertility stress score

Timepoint

Before and after the intervention

Method of measurement

The Fertility problem Inventory (FPI)

Secondary outcomes

1

Description
Average infertility self-efficacy score
Timepoint
Before and after the intervention
Method of measurement
Infertility self-efficacy scale (ISE)

Intervention groups

1

Description
Intervention group: This group will participate in counseling sessions with the method of teaching happiness based on the cognitive-behavioral model during 8 sessions
Category
Treatment - Other

2

Description
Control group: No counseling session will be held for the control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
The infertility Center of Jahad Daneshgahi
Full name of responsible person
Khadijeh Hajizadeh
Street address
Jame Jam street
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Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Khosro Adibkia
Street address
Research department, third floor, central construction number 2,Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Fereshteh Shaker
Position
Student of master's degree in Counselling in Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Confidentiality of participants' information
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