

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Formulation of a psychological empowerment package for infertile women in pre treatment stage (IVF) and comparison of its effect with dialectical behavior treatment on depression anxiety,infertility stress sexual satisfaction and hope.

Protocol summary

Study aim

Psychological Empowerment of Infertile Women and Comparison of the Effectiveness of Psychological Empowerment Therapy with Dialectical Behavior Therapy

Design

Dialectical Behavior Therapy and Psychological Empowerment group with control group, with parallel groups, randomized

Settings and conduct

This research will be a combination of qualitative and quantitative methods. In order to develop a qualitative psychological empowerment package, 83 sources will use, including articles, books, and dissertations, and will code using sterling content analysis, so continued to the point that no new information remained. To perform the quantitative method, which will include two groups of psychological empowerment training and dialectical behavioral therapy, after selecting infertile women, applicants for IVF treatment who referred to infertility centers in Isfahan will be place in two training groups with informed consent. Those will receive the necessary training at the institutes located in shahinshahr and the control group will not receive any training.

Participants/Inclusion and exclusion criteria

Entry requirements Volunteer for IVF treatment primary infertility Iranian citizenship Non-arrival conditions Being under other psychological treatments Consumption of addictive substances Unmotivated and dissatisfied

Intervention groups

Dialectical Behavioral Therapy Group is trained using the Linehan package for 8 sessions and the Empowerment Group is trained for 11 sessions; The training control group does not receive any instruction.

Main outcome variables

Depression, Anxiety, Infertility stress, Sexual Satisfaction, Hope

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200319046815N1**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Azadeh Bahrami kerchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4527 2935

Email address

a.bahrami2657@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-07, 1398/11/18

Expected recruitment end date

2020-09-01, 1399/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Ethics Committee of Islamic Azad University - Isfahan Branch (Khorasgan)
Scientific title Formulation of a psychological empowerment package for infertile women in pre treatment stage (IVF) and comparison of its effect with dialectical behavior treatment on depression anxiety,infertility stress sexual satisfaction and hope.	Street address Isfahan, East Jey Ave, Arghavaniyeh, Daneshgah Blvd, Azad university
Public title The Effectiveness of Psychological Empowerment Therapy and Dialectical Behavior Therapy on Depression, Anxiety, Infertility Stress, Sexual Satisfaction and Hope.	City Isfahan
Purpose Education/Guidance	Province Isfahan
Inclusion/Exclusion criteria Inclusion criteria: Volunteer for IVF treatment Being in the age group of 30 to 45 Primary Infertility Iranian citizenship Marriage during research Exclusion criteria: Being under other psychological treatments Acute psychiatric illness to psychiatrist diagnosis Consumption of addictive substances Unmotivated and dissatisfied	Postal code 0000000000
Age From 30 years old to 45 years old	Approval date 2019-03-12, 1397/12/21
Gender Female	Ethics committee reference number IR.IAU.KHUISF.REC.1398.085
Phase N/A	Health conditions studied
Groups that have been masked <i>No information</i>	1
Sample size Target sample size: 45	Description of health condition studied Infertility
Randomization (investigator's opinion) Randomized	ICD-10 code N97
Randomization description Accidentalization will be done on a regular basis. In this way, everyone in the community has an equal chance of being elected. First, a list of people is obtained, then a score or number is assigned to each of them, and the desired number is selected using a table of random numbers.	ICD-10 code description Female infertility
Blinding (investigator's opinion) Not blinded	2
Blinding description	Description of health condition studied Depression
Placebo Not used	ICD-10 code F32
Assignment Parallel	ICD-10 code description Major depressive disorder, single episode
Other design features	3
Secondary Ids empty	Description of health condition studied Anxiety
Ethics committees	ICD-10 code F41
1	ICD-10 code description Other anxiety disorders
Ethics committee Name of ethics committee	4
	Description of health condition studied infertility stress
	ICD-10 code F40-F48
	ICD-10 code description Stress neurotic
	5
	Description of health condition studied Sexual satisfaction
	ICD-10 code
	ICD-10 code description

6

Description of health condition studied

Hope

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression

Timepoint

7 days before training and follow-up 45 days after training

Method of measurement

Personal score on the depression scale of the DASS questionnaire

2

Description

Anxiety

Timepoint

7 days before training and follow-up 45 days after training

Method of measurement

Personal score on the anxiety scale of the DASS questionnaire

3

Description

Infertility Stress

Timepoint

7 days before training and follow-up 45 days after training

Method of measurement

Personal score in the Newton questionnaire

4

Description

Sexual Satisfaction

Timepoint

7 days before training and follow-up 45 days after training

Method of measurement

Personal score in LINDABERG and GRACY questionnaire

5

Description

Hope

Timepoint

7 days before training and follow-up 45 days after training

Method of measurement

Personal score in the Schneider questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Dialectical Behavioral Therapy Intervention Group: they will be treated for 8 sessions, 90-minute using Linehan Dialectical Behavioral Therapy package and They will receive mindfulness skills, endurance tolerance and effective interpersonal skills and the necessary psychological training in recognizing and controlling emotions. .

Category

Other

2

Description

Psychological Empowerment Intervention Group: using the psychological empowerment package developed for 11 sessions, 90 minutes, they will receive necessary psychological training in the field of cognitive distortion and the replacement of rational thoughts. , Increased self-awareness, skill of expression and management of anger and gradual muscle relaxation for eight muscle groups .

Category

Other

3

Description

Control group: This group included 15 infertile women who did not receive any training.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Fertility and Infertility Center

Full name of responsible person

Dr. Sayed Asadullah Kalantari

Street address

No. 23, BEHESHTI Ave, SALMAN FARSI Ave, BOZORGMEHR Square, ISFAHAN, IRAN.

City

ISFAHAN

Province

Isfahan

Postal code

0000000000

Phone

+98 31 3267 0030

Email

info@isf-ific.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Majid toghiani

Street address

University Boulevard, Oriental Jay Street,
Arghavaniyeh, Isfahan

City

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Province

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۳۹۹۹۸-۸۱۵۵۱

Phone

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Email

info@khuisf.ac.ir

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

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Azadeh Bahrami Kerchi

Position

coach

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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No 2, Unit 1, East 9 Ave, Ferdosi Blvd, Shahin Shahr
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Person responsible for scientific inquiries

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Full name of responsible person

Azadeh Bahrami Kerchi

Position

coach

Latest degree

Master

Other areas of specialty/work

Psychology

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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

There is no more information.

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