

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effectiveness of Mindful Self compassion training to Symptoms of Psychopathology and Increased Life expectancy in Infertile Women Undergoing IVF

Protocol summary

Study aim

Determining the effectiveness of mindfulness self-compassion treatment program on psychopathology symptoms and increasing life expectancy in infertile women undergoing IVF treatment.

Design

The placebo group sessions will consist of eight ninety-minute sessions

Settings and conduct

For the intervention group, group therapy sessions related to self-compassion and conscious attention, including eight ninety-minute sessions, are conducted, and for the control group, eight ninety-minute sessions are discussed about IVF. In the first session and before the start of the session the pre-test and at the end of the last session, the post-test will be done in both groups. The follow-up meeting will be held in the same place after two months. At the end of the sessions, a list of the important contents of each session and homework for practice will be presented to the patients in the form of brochures. Treatment sessions will be held at Shiraz Infertility Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum education at diploma level one year has passed since the definite diagnosis of infertility Not suffering from debilitating chronic physical diseases Absence of psychiatric disorders Exclusion criteria: Having two absentee session Getting any kind of disease while doing the research participating in an educational or other therapeutic workshop Not wanting to continue cooperation during meetings

Intervention groups

Mindful self-compassion group therapy sessions will consist of eight ninety-minute sessions

Main outcome variables

Revised scale of the 90 symptom inventory Hope questionnaire of Schneider

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053093N3**

Registration date: **2022-07-31, 1401/05/09**

Registration timing: **retrospective**

Last update: **2022-07-31, 1401/05/09**

Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Kimia Sahraian

Name of organization / entity

Eghlid Higher Education Center

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3886

Email address

leilarazeghian1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-30, 1400/10/09

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

2022-01-01, 1400/10/11

Actual recruitment end date

2022-04-29, 1401/02/09

Trial completion date

2022-09-08, 1401/06/17

Scientific title

Effectiveness of Mindful Self compassion training to Symptoms of Psychopathology and Increased Life expectancy in Infertile Women Undergoing IVF

Public title

Effectiveness of Mindful Self compassion training in Infertile Women Undergoing IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum education at diploma level one year has passed since the definite diagnosis of infertility Not suffering from debilitating chronic physical diseases Absence of psychiatric disorders

Exclusion criteria:

Having two absentee sessions Getting any kind of disease while doing the research Participating in an educational or other therapeutic workshop Not wanting to continue cooperation during meetings

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants do not know which group they are in. The data analyser does not know which group it is analysing. The number of people in the intervention and treatment groups is the same (we have 15 patients in each group for the treatment group). The duration for both intervention and control groups is 8 sessions and each session is 90 minutes. The number of sessions is equal, so the patient is blind to the type of treatment. Data analysis is given only data and does not know what treatment was done for either group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Kilometer 13 of Shiraz-Isfahan highway, Ostad Mohrhari Hospital

City

Shiraz

Province

Fars

Postal code

71441-13331

Approval date

2021-07-02, 1400/04/11

Ethics committee reference number

IR.SUMS..REC.1400.311

Health conditions studied

1

Description of health condition studied

Infertility in females

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified N97.9

Primary outcomes

1

Description

Psychopathology score

Timepoint

Before starting the study and after completing the study

Method of measurement

Revised scale of the 90 symptom inventory It is a common self-report instrument for measuring psychopathology. The 90 items of this scale describe the symptoms that psychiatric patients experience and report.

2

Description

amount of hope

Timepoint

Before starting the study and after completing the study

Method of measurement

hope questionnaire of Schneider The 12-factor hope scale is designed for ages 15 and up. You get the person's general hope score, which ranges from 8 to 32.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group consists of 15 patients. Eight sessions of MSC therapy will be performed, each session lasting for 90 minutes. The intervention will be performed according to a practical guide adapted from Neff's protocol and modified for group use. Necessary feedback will be provided and patients will be asked to actively attend and comment on the sessions and discuss their experiences related to the topic of each session. Also, at the end of each session, the contents of that session were summarized. Pre test consists of (SCL-90-R) and Snyder's Hope Questionnaire and is done before the start of the first session and at the end of the last session. Session 1: Group members will get to know the goals of the treatment program and each other. They will be taught the meanings of concepts such as self-compassion, mindfulness, self-kindness, common human experience. Session 2: Attention will be introduced theoretically and practically, and how the mind can naturally, when at rest, look for problems in the past or future. Session 3: People learn to love and be kind. Session 4: The main goal is to practice kind phrases with their own compassion dimension, and distinguish self-compassion from the inner critic. Session 5: The goal is to discover the core values that give meaning to our lives. Session 6: People are taught how to label a difficult emotion and then express the emotion as a bodily sensation. Session 7: People are taught to use compassionate expressions to endure the pain of problematic relationships. Session 8: It is said that the human mind has a negative bias. Examining physical threats or emotional integrity can be useful for survival.

Category

Treatment - Other

2

Description

Control group: This group consists of 15 patients. During eight 90-minute sessions, people are talked about the IVF method. Pre test consists of (SCL-90-R) and Snyder's Hope Questionnaire and is done before the start of the first session and at the end of the last session.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Infertility Center

Full name of responsible person

Leila Razeghian Jahromi

Street address

Kilometer 13 of Shiraz-Isfahan highway, Ostad Mohrhari Hospital

City

Shiraz

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Postal code

71441-13331

Phone

+98 71 3260 5701

Email

leilarazeghian1366@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Street 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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant Proffesor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila RazeghianJahromi

Position

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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 further 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

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

No - There is not a plan to make this available