Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 coopration 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

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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 is consist of 15 patients.Eight sessions of MSC therapy will be performed, each session lasting for90 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 is consist 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 is consist of 15 patients.uring eight 90-minute sessions, people are talked about the IVF method.Pre test is consist 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
Province
Fars
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
Kilometer 13 of Shiraz-Isfahan highway, Ostad Mohrhari Hospital
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Postal code
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Email
leilarazeghian@1366gmail.com
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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Leila Razeghian Jahromi

Position
Assistant Proffesor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

Contact

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Position
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Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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