Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of mindfulness based stress reduction on psychological symptoms , quality of life and Marital Satisfaction in infertile women undergoing IVF treatment

Protocol summary

Study aim
effect of mindfulness-based stress reduction therapy on psychological symptoms, quality of life and infertile marital satisfaction under IVF treatment

Design
Clinical trial with control group, with parallel, non-blind, randomized, phase 3 groups on 44 patients, for randomization www. sealedenvelope.com/simple-randomiser/v1/lists was used

Settings and conduct
First, women who were diagnosed with infertility and met the criteria will be selected by purposive sampling from the center of Beheshti hospital in Kashan. At the first session of the researcher's visit, all the information(methods, number of the sessions, duration, etc)randomization, the confidentiality of the information and the rights of withdrawal from the research will be provided. also, their consent of participation will be obtained.Individuals will then be randomly replaced in intervention and control groups of 22 people, and both groups will be identified in terms of all factors and confounding variables. Then treatment sessions will be held for people in the medical school.

Participants/Inclusion and exclusion criteria
Have a history of infertility for at least one year Applying for IVF infertility treatment No history of experience in mindfulness treatments At least 25 years old Have the ability to read and write Marital Satisfaction score 40 and below in the Enrich Questionnaire Psychological symptoms score 44 and above in the Short Form Questionnaire Psychological symptoms

Intervention groups
The treatment groups of this study will be divided into 3 groups of 5 people and a group of 7 people and will be offered 8 sessions of stress reduction therapy based on mindfulness. Moreover,4 sessions of parenting styles will be held for control group

Main outcome variables
Psychological symptoms, quality of life and marital satisfaction of infertile women undergoing IVF treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210908052417N1**
Registration date: **2021-10-17, 1400/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-17, 1400/07/25**
Update count: **0**

Registration date
2021-10-17, 1400/07/25

Registrant information

Name
sayed abolfazl tavousi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3555 4318

Email address
tavosishahrivar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2021-11-06, 1400/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of mindfulness based stress reduction on psychological symptoms , quality of life and Marital Satisfaction in infertile women undergoing IVF treatment

Public title
The effectiveness of mindfulness based stress reduction on psychological symptoms , quality of life and Marital Satisfaction in infertile women undergoing IVF treatment
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Have a history of infertility for at least one year Applying for IVF infertility treatment No history of experience in mindfulness treatments At least 25 years old Have the ability to read and write Marital Satisfaction score 40 and below in the Enrich Questionnaire Psychological symptoms score 44 and above in the Short Form Questionnaire Psychological symptoms
Exclusion criteria:
Being absence from treatment for two sessions Use of drugs and other addictive substances Fertilization during treatment Physical inability to perform exercises
Age
From **25 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 44 (two groups of 22) and permuted block randomization method (block size=4) (11 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (44th person).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kashan University of Medical Sciences
Street address
5th of Qotb –e Ravandi Blvd.
City
kashan
Province
Isfehan
Postal code
8715988141
Approval date
2021-09-01, 1400/06/10
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1400.085

Health conditions studied

1

Description of health condition studied
infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Psychological symptoms score in the short form psychological symptoms questionnaire
Timepoint
Measurement of psychological symptoms before the intervention eight weeks after the start of the intervention and two months after the end of the intervention
Method of measurement
Short form of psychological symptoms questionnaire

2

Description
Marital Satisfaction Score in Enrich Marital Satisfaction Questionnaire
Timepoint
Measurement of marital satisfaction before the intervention eight weeks after the start of the

intervention and two months after the end of the intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire

3

Description

Quality of life score in the World Health Organization quality of life questionnaire

Timepoint

Measurement of quality of life before the intervention eight weeks after the start of the intervention and two months after the end of the intervention

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Stress reduction based on mindfulness Therapeutic intervention is 8 sessions that are performed once a week for 90 minutes, during which participants are taught that in the moment, without judgment, with full attention and awareness of the world inside and outside Communicates. This approach is achieved according to the treatment protocol of Kabat Zayn (2013).

Category

Behavior

2

Description

Control group: In the control group, in order to observe ethical considerations, 4 sessions of parenting styles training will be presented based on the book of desirable parenting styles and principles written by Hassan Maleki.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Shahid Beheshti Hospital, Kashan

Full name of responsible person

dr.Fateme Foroozanfard

Street address

Qutb Ravandi Blvd., Kashan University of Medical Sciences, Shahid Beheshti Hospital

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kashan

Province

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8715981151

Phone

+98 31 5557 5999

Email

fatemehforoozanfard@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Banafshe Hamidreza

Street address

: 5th of Qotb –e Ravandi Blvd

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Email

research@kaums.ac.ir

Web page address

http://kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Omidi Abdollah

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Tavousi Sayed abolfazl

Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Tavousi Sayed abolfazl

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like and demographic information can be shared.

When the data will become available and for how long

The access period will be available 2 years after the results are published and up to one year later.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In case of any use, the names of the project researchers should be mentioned in the Thanksgiving section. No one has the right to use the data for inhuman waste, such as cases that endanger and endanger human life. Submitting an application must be in accordance with the academic procedure and will be reviewed for up to one month. Ask the person not to have any connection with anti-humanitarian and terrorist institutions.

From where data/document is obtainable

Seyed Abolfazl Tavousi Kashan University of Medical Sciences Faculty of Medicine sa.tavosi@yahoo.com

What processes are involved for a request to access data/document

According to the circumstances, it will be reviewed and answered by the person in charge.

Comments