

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effectiveness of Mindfulness integrated cognitive behavior therapy on psychological symptoms, quality of life and Marital Satisfaction in infertile women undergoing IVF treatment

Protocol summary

Psychological symptoms, quality of life, marital satisfaction

Study aim

Determination of the effect of MICBT

Design

A clinical trial with a parallel control group, single-blind, randomized, phase 3 groups on 44 patients, for randomization from www.

<http://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; one year applying for IVF infertility; treatment no history of experience in Cognitive-behavioral therapies and mindfulness; at least age 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

Treatment groups: 3 groups of 5 people and a group of 7 people for whom 8 sessions of MICBT treatment will be offered. also for the control group will be 4 sessions of developmental psychology.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220116053733N1**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **prospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

seyed hossein لاری معصومی

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3285 1504

Email address

masoumi-sh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of Mindfulness integrated cognitive behavior therapy on psychological symptoms, quality of life and Marital Satisfaction in infertile women undergoing IVF treatment

Public title
The effectiveness of Mindfulness integrated cognitive behavior therapy on psychological symptoms, quality of life and Marital Satisfaction

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Have a history of infertility for at least one year one year applying for IVF infertility treatment no history of experience in Cognitive-behavioral therapies and mindfulness at least age 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:
Physical inability to perform exercises Use of drugs and other addictive substances

Age
From **25 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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)
Single blinded

Blinding description

Consequences are with self-report tools so there is no need to blind the evaluator. The data is entered into SPSS software by the evaluator and by changing the names of the groups, the analyst will not be informed about the assigned treatment. After collecting the data, the names of the groups will be changed by the researcher.

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

Qutb Ravandi

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2022-01-03, 1400/10/13

Ethics committee reference number

IR.KAUMS.REC.1400.055

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Score of psychological symptoms in the short form questionnaire of psychological symptoms

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

Global Health Quality of Life Questionnaire score

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

Global Health Quality of Life Questionnaire

3

Description

Marital Satisfaction Score in Enrich Marital Satisfaction Questionnaire

Timepoint

Measurement of marital satisfaction before the intervention eight weeks after the intervention and two months after the intervention

Method of measurement

Enrich Marital Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Structured 8-session treatment that is held according to the protocol for 90 minutes a week and teaches clients to internalize their attention in order to regulate their emotions and attention, and then externalize their regulated emotions and attention to manage their problems and use.

Category

Behavior

2

Description

Control group: In order to comply with ethical considerations, 4 sessions of developmental psychology training will be provided.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Shahid Beheshti Hospital, Kashan

Full name of responsible person

Dr. Fatemeh Forouzanfard

Street address

Kashan University of Medical Sciences, Qutb Ravandi,

Shahid Beheshti Hospital

City

Kashan

Province

Isfahan

Postal code

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

Hamid Reza Banafshe

Street address

Kashan University of Medical Sciences, Qutb Ravandi

City

Kashan

Province

Isfahan

Postal code

87159-81151

Phone

+98 31 5554 2999

Fax

+98 31 5557 5057

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

Abdollah OMIDI

Position

Profesor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Kashan University of Medical Sciences, Qutb Ravandi

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

Abomidi20@yahoo.com

Web page address

<http://Kaums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyed Hossein Masoumi Lari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Kashan University of Medical Sciences, Qutb Ravandi

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

hmasoumi.psy@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Seyed Hossein Masoumi Lari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Kashan University of Medical Sciences, Qutb Ravandi

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

hmasoumi.psy@yahoo.com

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 researchers of the project should be mentioned in the Thanksgiving section. No one has the right to use the data for non-human consumption, 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 Hossein Masoumi Lari Kashan University of Medical Sciences School of Medicine
hmasoumi.psy@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