

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effectiveness of Mindfulness- Based Cognitive Therapy on Worry ,State anxiety and Ambiguity Tolerance in infertile women under IVF

Protocol summary

Study aim

1-Determining the effectiveness of mindfulness-based cognitive therapy on the 2-Determining the effectiveness of mindfulness-based cognitive therapy on the state anxiety of infertile women undergoing IVF treatment 3- Determining the effectiveness of mindfulness-based cognitive therapy on the Ambiguity Tolerance of infertile women undergoing IVF treatment

Design

The sample size was determined based on previous similar studies using Treatment Center in Mashhad were selected by targeted sampling method and randomly tested and controlled in two groups of 20 people. .

Settings and conduct

Center in Mashhad. protocol, the control group does not receive any intervention and training. Before and after the intervention, the anxiety, state anxiety and unbearable anxiety questionnaires for both the experimental and control groups are completed. Will be

Participants/Inclusion and exclusion criteria

- Entry requirements: having a history of infertility, IVF diagnostic therapy Failure to enter: Having a specific underlying disease (hypothyroidism, diabetes, heart disease, high blood pressure, etc.) Non-IVF (and IUI) treatment methods

Intervention groups

8 2-hour training sessions a week receive a mindfulness training protocol, the control group does not receive any intervention or training. Before and after the intervention, the anxiety, state anxiety and unbearable anxiety questionnaires for both the experimental and control groups are completed. Will be

Main outcome variables

In this study, The Effect of mindfulness-based cognitive therapy on Worry, State anxiety, and Ambiguity Tolerance in infertile women undergoing IVF treatment is examined.

General information

Reason for update

Acronym

MBCT

IRCT registration information

IRCT registration number: **IRCT20200518047499N1**

Registration date: **2020-05-21, 1399/03/01**

Registration timing: **retrospective**

Last update: **2020-05-21, 1399/03/01**

Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Zohreh Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5252 6992

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-08-23, 1398/06/01

Trial completion date

2019-10-23, 1398/08/01

Scientific title

The effectiveness of Mindfulness- Based Cognitive Therapy on Worry ,State anxiety and Ambiguity Tolerance in infertile women under IVF

Public title

Mindfulness On Worry, State anxiety ,Ambiguity Tolerance

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women under IVF Treatment Having physical and mental health Higher education than guidance Awareness and willingness of people to attend meetings

Exclusion criteria:

Infertility treatment other than ivf Simultaneous infection with the underlying disease Being illiterate

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

In a simple random way, people's names were written on sheets of paper and the sheets were placed in a container. The names extracted from the container were then substituted one by one and completely randomly in the control and intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the intervention group received training, and after completing the training and post-test, both groups, For the control group, training sessions were held briefly. While both groups were unaware of the title of the group they were in

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University of Medical Sciences Ethics Committee

Street address

Enghelab Square, Shahid Chamran Boulevard

City

bandare abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.HUMS.REC.1399.090

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Worry score in Pennsylvania questionnaire, state anxiety score in Spielberger questionnaire, Ambiguity Tolerance score in Freestone unambiguity tolerance

Timepoint

Measure before starting the intervention. After the intervention, 3 months after the intervention to follow up

Method of measurement

Complete the relevant questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Awareness training protocol was taught in groups for 8 sessions of 2 hours a week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center in Mashhad

Full name of responsible person

Dr. Nayreh Khadem Ghaibi

Street address

razi street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University, Kish International Branch

Full name of responsible person

Dr. Alireza Rousta

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Web page address<https://iaukish.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, Kish International Branch

Proportion provided by this source

50

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, Kish International Branch

Full name of responsible person

hassan ahadi

Position

full Profesor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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

Failure to issue permits even anonymously to participants

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

No - There is not 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