Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of Mindfulness- Based Cognitive Therapy on Worry ,State anexity and Ambiguity Tolerance in infertil 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 anexity of infertile women undergoing IVF treatment 3-Determining the effectiveness of mindfulness-based cognitive therapy on the Ameiguity 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 examinad.

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

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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 anexity and Ambiguity Tolerance in infertil women under IVF

Public title
Mindfulness On Worry, State anexity ,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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Razavi Khorasan
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9135913556
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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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Researchkish3@gmail.com
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
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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