

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the quality of life of infertile women in two groups without receiving education and with presenting education based on mindfulness-based stress reduction program

Protocol summary

Study aim

The efficacy of education based on mindfulness-based stress reduction program on the quality of life of infertile women

Design

In this research, 36 infertile women refer to infertility center of Ahvaz Imam Khomeini hospital will be chosen. Cases will be allocated to two equal groups of intervention and control according to block randomization method.

Settings and conduct

This interventional study will be conducted on infertility center of of Ahvaz Imam Khomeini hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ability to participate in treatment sessions; primary infertility more than 3 years; being able to read and write; having poor quality of life score (50 or less) in pretest. Exclusion criteria: having physical inability for doing treatment techniques; having history of doing treatment techniques during 6 months ago; having substance abuse and drug and alcohol addiction; use of anti-psychotic drugs.

Intervention groups

Cases will be allocated to two equal groups of intervention and control according to block randomization method. Then for group education, intervention group will be divided to 3 groups with 6 cases in each group and group education will be provided based on mindfulness-based stress reduction program by researcher in 8 sessions with 2 hours duration weekly. In control group, cases will not receive any specific education. However, education will be presented to all cases in control group at the end of the study.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180307038993N1**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **prospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Masoumeh Sadat Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5326 7297

Email address

hosseini.m.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the quality of life of infertile women in two groups without receiving education and with presenting education based on mindfulness-based stress reduction program

Public title

The efficacy of education based on mindfulness-based stress reduction program on the quality of life of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to participate in treatment sessions Primary infertility more than 3 years Being able to read and write Having poor quality of life score (50 or less) in pretest

Exclusion criteria:

Having physical inability for doing treatment techniques Having history of doing treatment techniques during 6 months ago Having substance abuse and drug and alcohol addiction Use of anti-psychotic drugs

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Cases will be allocated to two equal groups of intervention and control according to block randomization method.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2018-01-23, 1396/11/03

Ethics committee reference number

IR.AJUMS.REC.1396.907

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Quality of life

Timepoint

Before, immediately after and one month after intervention

Method of measurement

Short form of quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For group education, intervention group will be divided to 3 groups with 6 cases in each group and education will be provided by researcher based on mindfulness-based stress reduction program in 8 sessions with 2 hours duration weekly.

Category

Lifestyle

2

Description

Control group: In control group, cases will not receive specific education. However, education will be presented to all cases in control group at the end of the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center of Ahvaz Imam Khomeini hospital

Full name of responsible person

Masoumeh Sadat Hosseini

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Imam Khomeini hospital, Azadegan road, Ahvaz, Khozestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Behzad Sharif Makhmalzadeh

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Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Ahvaz Jundishapur 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Masoumeh Sadat Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Faculty member

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Master

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Person responsible for updating data

Contact

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Position

Student

Latest degree

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of patients demographical data and main outcomes will be shared.

When the data will become available and for how long

Six months after data publishing

To whom data/document is available

Data will be available only for researchers working on academic and university associations.

Under which criteria data/document could be used

Mention of study name and authors name

From where data/document is obtainable

Masoumeh Sadat Hosseini: School of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

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

At last one month after request

Comments