Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Khouzestan

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

Street address
Imam Khomeini hospital, Azadegan road, Ahvaz, Khozestan

City
Ahvaz

Province
Khouzestan

Postal code
6193673111

Phone
+98 61 3222 2922

Email
masoumehsadat.hosseini@yahoo.com

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

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

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3333 3477

Email
masoumehsadat.hosseini@yahoo.com

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

Street address
Faculty of Midwifery and Nursing, Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8331

Email
masoumehsadat.hosseini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Kadighe Hekmat

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Faculty of Midwifery and Nursing, Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8331

Email
Hekmat1346@gmail.com

Person responsible for updating data

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

Street address
Faculty of Midwifery and Nursing, Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khozestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8331

Email
masoumehsadat.hosseini@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
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