Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness psychotherapy on psychological well-being and quality of life of infertile women

Protocol summary

Summary

Objectives: The aim of the study is to assess the effect of mindfulness psychotherapy on psychological well-being Design: Randomized Controlled Trial Setting and conduct: 60 infertile women who will referred to Infertility Research Center Fatemeh Zahra (SA) Babol will be allocated in four groups based on Solomon trial (n = 15 experiments with pre-test, 15 tests without pre-test, 15 control subjects without pre-test, 15 control with pre-test). Participants: Inclusion criteria are the distance of eight weeks from beginning of using assisted reproduction of microinjection method and no attending in relaxation psychological intervention. Women who use other methods of infertility such as intrauterine insemination will be excluded the study. Interventions: Experimental group will attended in 8 weeks group mindfulness psychotherapy sessions. Control group do not received any interventions. Participants will complete Ryfe Well-being questionnaire and Quality of life before and after the intervention. Main outcome: Psychological well-being and quality of life.

General information

Acronym

Mindfulness and infertility

IRCT registration information

IRCT registration number: **IRCT2017021132321N2**
Registration date: **2017-06-03, 1396/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name

Seyed Mohammad KalantarKoshe

Name of organization / entity

Allameh Tabatabaei University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2015-07-07, 1394/04/16

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness psychotherapy on psychological well-being and quality of life of infertile women

Public title

The effect of mindfulness on psychological well-being and quality of life of infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having ability of reading and writing; The distance of eight weeks from beginning of using assisted reproduction of Microinjection method; without attending relaxation meetings or other psychological interventions; desire to participate in the study and

giving informed consent. Exclusion criteria: Infertile women who use other methods of infertility such as intrauterine insemination.

Age
From **17 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Allameh Tabatabaei university

Street address
Tehran, Olympic square,Olympic village, Allameh Tabatabaei university

City
Tehran city

Postal code
1489684511

Approval date
2014-11-14, 1393/08/23

Ethics committee reference number
1153126

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Psychological well-being

Timepoint
Before and after completion of the intervention

Method of measurement
Psychological well-being questionnaire Ryff

Secondary outcomes

1

Description
Quality of life

Timepoint
Before the intervention and after intervention

Method of measurement
Quality of life questionnaire short form of 26 questions

Intervention groups

1

Description
Intervention group: The meetings based Kabat-Zinn mindfulness-based psychotherapyon 8 session 120-minute once a week, in two groups of 15 people will be held. The subject with participating in sessions based on Kabat-Zinn mindfulness-based psychotherapy will be able through practicing mindfulness relieved from automatic negative that are released during disturbing events such as infertility. And in one of the intervention groups before and after the intervention in both groups completed the questionnaire.

Category
Behavior

2

Description
Control group: In one of the control groups before the intervention and control groups completed questionnaires immediately after the intervention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility and Reproductive Health Research Center Fatemeh Zahra (SA) Babol

Full name of responsible person
Dr. Mahbobe Faramarzi

Street address
Street martyr Salehi, after Mohammad Hassan Khan

Bridge, Tork mahale village

City

Babol city

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Tabatabaei University

Full name of responsible person

Seyed Mohammad Kalantar Koshe

Street address

Olympic Square, Olympic Village, Village and Hemmat Blvd.

City

Tehran

Grant name

8830000

Grant code / Reference number

2324922

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Allameh Tabatabaei University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Tahere Rahmani Fard

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty