Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of group counceling based on mindfulness on anxiety of infertile women undergoing IVF attended to center of infertility in fatemieh hospital, Hamedan, 2016

Protocol summary

Summary

(1) Objectives: The study aims at determining the effect of group counceling based on mindfulness on anxiety of infertile women undergoing IVF attended to center of infertility in fatemieh hospital in Hamedan. (2) Design: Randomized clinical trials with pretest-posttest design with a control group. (3) Setting and conduct: 90 infertile women who eligible for inclusion criteria will be recruited to this study. Thease people will randomly divided to two groups. (4) Participants including major eligibility criteria:The mild, more than average and lower than average anxiety (the score of 20 to 53 in accordance with the interpretive criteria on a scale of spielberger anxiety inventory); Age range 25-40 years; High school diploma and more; Resident of Hamedan; Not having antecedent in psychiatric hospital. (5) Intervention: The size of the sample is 90 women with primary infertility. forty five of them, as the experimental group, take part in consultation sessions, and 45 of them, as control group, without any intervention. The experimental group will take part in 8 sessions of consultation classes from the entrance of IVF treatment before the embryo transfer stage. Doing so, the women anxiety will be compared in the groups. The instruments of collecting data are a scale of Spielberger Anxiety Inventory and demographic questionnaire. (6) Primary outcome: Anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082013405N14**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counceling based on mindfulness on anxiety of infertile women undergoing IVF attended to center of infertility in fatemieh hospital, Hamedan, 2016

Public title

The effect of mindfulness-based group counseling on anxiety in women

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Age range 25-40 years; High school diploma and more; Resident of Hamedan; Not having antecedent in psychiatric hospital; Not having addiction; Not having neurologic disease or other progressive diseases; Not taking psychiatric drugs; The mild, more than average and lower than average anxiety (the score of 20 to 53 in accordance with the interpretive criteria on a scale of spielberger anxiety inventory) Exclusion criteria: Absence of more than two sessions in counseling sessions in the test group; Naturally get pregnant without assisted reproductive techniques during the course of treatment; Physical or mental illness during the study
Age
From **25 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
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
Ethic Committee of Hamedan University of Medical Sciences
Street address
Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan, Iran
City
Hamedan
Postal code
6516645977
Approval date
2016-07-02, 1395/04/12
Ethics committee reference number
IR.UMSHA.REC.1395.182

Health conditions studied

1

Description of health condition studied
Anxiety in infertile women
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention and after the intervention (in the process of embryo transfer)
Method of measurement
Spielberger anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Holding eight sessions of mindfulness-based counseling for infertile women included: Automatic guidance; Face with obstacles; Breathing Meditation practice and mindfulness of breathing; Sitting meditation; Acceptance and change and etc; Each session lasts 90 minutes
Category
Behavior

2

Description
Control group: Anxious infertile women with mild; average in low and average in high anxiety (score of 20 to 53 in accordance with the criteria for the interpretation of the questionnaire STAI)
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh hospital of Hamedan
Full name of responsible person
Fatemeh Kalhori (MSc student of Consultation in midwifery)
Street address

pasdaran Avenue, Hamedan, Iran

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ethic Committee of Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashirian

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Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan, Iran

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ethic Committee of Hamedan University of Medical Sciences

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

Hamadan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Masoomi

Position

Assistant professor

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