

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of group counseling 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 counseling 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. These 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

Seyyede Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0150

Email address

zahra.masoomi@umsha.ac.ir

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 counseling 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

Email
zahramid2001@yahoo.com
Web page address

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

Street address

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

Hamedan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Masoomi

Position

Assistant professor

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Hamadan University
of Medical Sciences, Shahid Fahmideh Avenue,
Hamedan, Iran

City

Hamedan

Postal code

6516845977

Phone

+98 81 3838 0150

Fax

+98 81 3838 0447

Person responsible for scientific 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

Street address

School of Nursing and Midwifery, Hamedan University
of Medical Sciences, Shahid Fahmideh Avenue,
Hamedan, Iran

City

Hamedan

Postal code

6516845977

Phone

+98 81383880818

Fax

Email

zahramid2001@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Kalhori

Position

MSc student of counselling in midwifery

Other areas of specialty/work

Street address

School of nursing and midwifery, Hamedan university
of medical sciences, Shahid Fahmideh Avenue,
Hamedan, Iran

City

Hamedan

Postal code

6517808836

Phone

+98 81 3838 0150

Fax

Email

fkalhori55@gmail.com

Web page address

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