

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of group counseling on stress and gender role attitude of infertile women

Protocol summary

Study aim

Determining the effect of group counseling on stress and gender role attitudes in infertile women

Design

This Clinical practice has two groups: control group and, intervention group that participants are divided by using random numbers table in two groups of 35.

Settings and conduct

Selected Infertility Centers of Alborz Province, which include 2 Infertility Centers (Roish and Ebne Sina (Kamali Branch))

Participants/Inclusion and exclusion criteria

Medical diagnosis for infertility; Iranian nationality; fluent in Persian; Infertility with female factor; at least the reading and writing skills; having a score higher than 16 from the Newton questionnaire; age18_44 years old. Exclusion criteria: having psychiatric issues; according to one's own words Infertility with male factor; not attending 5 at least 3 sessions of counseling sessions.

Intervention groups

In the intervention group, infertile women with entry criteria are referred to the selected centers of infertility in Alborez province, who will receive weekly counseling in 5 sessions (90 minutes). And the control group will not receive any advice

Main outcome variables

Stress, gender role attitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150119020719N6**

Registration date: **2018-04-14, 1397/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-14, 1397/01/25**

Update count: **0**

Registration date

2018-04-14, 1397/01/25

Registrant information

Name

Sara Esmaelzadeh Saeieh

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6007

Email address

s-esmaelzadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-03, 1396/11/14

Expected recruitment end date

2018-04-18, 1397/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling on stress and gender role attitude of infertile women

Public title

The effect of counseling on stress and female behaviors of infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Have medical diagnosis based on infertility Iranian nationality Fluent in Persian Infertility with female factor At least the reading and writing skills Age between 18_44 years old

Exclusion criteria:

Having psychiatric issues, according to one's own words Infertility with male factor Not attending 5 at least 3 sessions of counseling sessions

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Use the random numbers table

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

Vice-Chancellor for Research in Alborz University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, Alborz University of Medical Sciences, above Taleghani Square, Taleghani Square, Karaj, Alborz, Iran

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2018-01-19, 1396/10/29

Ethics committee reference number

IR.ABZUMS.REC.1396.161

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Stress

Timepoint

Before intervention, after intervention, one month after intervention

Method of measurement

Newton Infertility Stress Questionnaire

2

Description

Gender Roll Attitude

Timepoint

Before intervention, after intervention, one month after intervention

Method of measurement

Homami`s Gender Role Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 7 non-Bargain women are grouped together in five groups of seven, and a two-hour counseling session for 5 sessions (90 minutes), delivered in a speech, question and answer file, according to the British Infertility Advice Protocol, gender role attitude, rights and health Fertility will be advised and followed up by phone call. To avoid facing the control and intervention group, it is attempted to arrange classrooms on different days of the week and in coordination with contributors through telephone conversations. Session 1: The purpose of the study, the presentation of information on infertility, the emotional consequences of infertility, how to create them and their relationship with infertility, methods and treatment protocol, drug side effects, success rate, how to use drugs and their side effects Second session: how to donate gametes and Embryo, fertility storage, uterus rental, talking about sexual problems, identifying women's thoughts and centralized feelings about infertility by discussing group discussions and expressing their opinions and exercising relaxation 9. (1. Mind-to-Muscle Technique 2. Technique Muscle to mind) Session 3: Helping to adapt to conditions, stress and sexual

performance, exercises of lawmaking with reflection of the mind The focus is on women's respiration, based on the BIRITISH protocol and relaxation practice. Fourth part: 10, the expression of women's rights and discussion of other roles of women in life and practice of relaxation. The fifth session: the summing up of past sessions and the way Stress control (advise on exercise, especially hiking, starting a new pastime, meditating, and eating a stress relieving diet) and relaxation exercises. The sessions will be validated by the faculty members of the midwifery department at the university.

Category

Behavior

2**Description**

Control group: In the control group, no advice is given to individuals, and at the end of the workbook, the contents of the stress control methods are given to both groups (control and intervention).

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roivish Infertility Centers and Ibn Sina Kamali Branch

Full name of responsible person

Dr. Sara Eesmaelzadeh Saeh

Street address

Infertility Center, Azimi Hospital, Golestan, 18, and Avicenna Infertility Center Kamali Branch: Shahid Square, Seyyed Alshohada St.

City

karaj

Province

Alborz

Postal code

3134877179

Phone

+98 26 3222 2021

Email

esmaelzadeh1360@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research in Alborz University of Medical Sciences

Full name of responsible person

Mohamad Nourisepeher

Street address

Research Deputy of Alborz University of Medical Sciences, Azimiyeh-Alborz Square, Iran

City

KARAJ

Province

Alborz

Postal code

0098

Phone

+98 26 3255 8920

Email

z.ehsan90@gmail.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 in Alborz 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**

Alborz University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saeieh

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing Midwifery-Golestan-i-Baghestan-Alborz-Iran

City

karaj

Province

Alborz

Postal code**Phone**

+98 912 623 2569

Email

esmaelzadeh1360@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

دانشگاه علوم پزشکی البرز

Full name of responsible person

Sara Esmaelzadeh Saeieh

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing Midwifery-Golestan-i-Baghestan-
Alborz-Iran

City

alborz

Province

Alborz

Postal code

Phone

+98 912 623 2569

Email

esmaelzadeh1360@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh saieh

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing Midwifery-Golestan-i-Baghestan-
Alborz-Iran

City

karaj

Province

Alborz

Postal code

Phone

+98 912 623 2569

Email

esmaelzadeh1360@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data can be shared after unidentifiable

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Public

Under which criteria data/document could be used

For use in studies allowed.

From where data/document is obtainable

z.ehsan90@gmail.com

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

The application will be sent to the project implementer by email and within 24 hours will receive the necessary items.

Comments