

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effectiveness of infertility counselling on the quality of life and emotional level of infertile couples

Protocol summary

Summary

Objectives : the effect of infertility counseling on quality of life and emotional level of infertile couples. Design : The present study is an interventional study with available sampling method for infertile couples referring to the Infertility Center. Setting and conduct : In the even days of the first week ; intervention group samples and in the odd days ; control group samples will be selected and in the next week ; the sampling will be done in the opposite way. The sampling will be continued until the samples will be completed . Major Inclusion Criteria : The first infertility ; first referring to infertility center. Major Exclusion Criteria : Instinctive pregnancy during counseling sessions ; being absent in two sessions from six counseling sessions ; under treatment members of psychiatry and psychology. " Intervention group : " Those who will participate in the study and have entry criteria ; will be given a written testimonial . Then the group will be asked to answer the pretest questionnaire. The group counseling sessions for intervention group will be established by 6 sessions of 45 minutes. At the end of the last session ; the post test was taken from this group . " Control group : " The group will not be given counseling ; but because of complying ethical considerations ; after the post test ; a pamphlet including the summary of the counseling sessions will be given to the control group . Also ; the pretest and post test will be taken from this group .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080124866N4**

Registration date: **2017-10-11, 1396/07/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-11, 1396/07/19

Registrant information

Name

Katayoun Alidoosti

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5219

Email address

alidoosti@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ; Kerman University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of infertility counselling on the quality of life and emotional level of infertile couples

Public title

The effectiveness of infertility counselling on the quality of life and emotional level of infertile couples

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria : The first infertility ; first referring to infertility center. Exclusion Criteria : Instinctive pregnancy during counseling sessions ; being absent in two sessions from six counseling sessions ; under treatment members of psychiatry and psychology .

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

It was used randomized numerical table for randomizing.

Secondary Ids

1

Registry name

not registered

Secondary trial Id

not registered

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Kerman Campus University of Medical Sciences

City

Kerman

Postal code

7617694345

Approval date

2016-09-29, 1395/07/08

Ethics committee reference number

IR . KMU . REC . 1395 . 678

Health conditions studied

1

Description of health condition studied

Quality of life and emotional level in infertility

ICD-10 code

XXI

ICD-10 code description

Chapter XXI Factors influencing health status and contact with health services (Z00-Z99)

Primary outcomes

1

Description

Quality of life

Timepoint

Before intervention ; then At the end of the counseling last session during three month

Method of measurement

The questionnaire included demographic specification and Fertility Quality of Life Questionnaire (FertiQoL) .

2

Description

Emotional levels

Timepoint

Before intervention ; then At the end of the counseling last session during three month

Method of measurement

The questionnaire included demographic specification and the emotional level of infertile patients Questionnaire (Screenivf).

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group " : after coordinating with the head nurse ; the researcher will explain the research purpose to the units under research and they will be satisfied with participating in the study. Those who will participate in the study and will have entry criteria ; will be given a written testimonial .Then the group will be asked to answer the pretest questionnaire. The group counseling sessions for intervention group will be established by 6 sessions of 45 minutes. At the end of the last session ; the post test will be taken from this group .

Category

Other

2

Description

Control group " : The group will not be given counseling ; but because of complying ethical considerations ; after the post test ; a pamphlet including the summary of the

counseling sessions will be given to the control group .
Also ; the pretest and post test will be taken from this group .

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman's Afzalipour hospital
Full name of responsible person
Kobra Alidoosti
Street address
Colleg of Nursing and Midwifery ; Kermam
City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research ; Kerman University of Medical Sciences
Full name of responsible person
Dr Pardakhti
Street address
Kerman ; University of Medical Sciences
City
Kerman

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 ; Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
katayoun Alidoosti
Position

Master in Miwifery
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Tayebeh Mokhtari Sorkhani
Position
Master's degree Student in Midwifery Counseling
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+98 34 3252 6897
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arianmokhtari2@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