Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The effect of group counseling based on choice theory on irrational parenthood cognition and marital quality in infertile women

Protocol summary

Summary

Ayatollah Mousavi hospital will be selected as the Infertility Center of Zanjan. 517 cases from about 2,000 cases will be chosen with a systematic random method. Infertile women will be contacted for completing a questionnaires. The questionnaire will be completed with self – report method. If it is not possible to complete the questionnaire by person, trained interviewers will be completed it by phone. Among those willing to participate in counseling sessions, 50 available people will be divided to intervention (n = 25) and control (n = 25) groups using blocked randomization design. The control group will receive no counseling.The intervention group will be divided into two groups of 8 and one group of 9 participants. The intervention group will receive 9 sessions of 90-minute group counseling based on the choice theory. All sessions will be held in the Mousavi hospital preparation for childbirth classes by researcher. In order to achieve higher efficacy, all participants will receive positive key messages at the end of each session. At the end of each two counseling sessions, main points of each session will be presented. For the single blinding two months after the last session, the questionnaire will be completed in both the intervention and control groups by trained interviewers, who are unaware of the group assignment of people, .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428352N2**
Registration date: **2016-09-15, 1395/06/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-15, 1395/06/25

Registrant information

Name
Roghieh Kharaghani
Name of organization / entity
Zanjan University of Medical Sciences
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Iran (Islamic Republic of)
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r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling based on choice theory on irrational parenthood cognition and marital quality in infertile women

Public title

The effect of group counseling based on choice theory on irrational parenthood cognition and marital quality in infertile women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria; Irrational parenthood cognition and marital quality scores between 25 and 75 percent of the total score; Primary infertility type based on the history; Female or mixed infertility type based on the history; Lack of psychological problems in couple based on the history; Living in zanjan city; Not receiving medication for psychological problems in the last 6 months; Passing at least 6 months to 15 years or more after first diagnosis of infertility; Aged between 15-40 years old; No substance abuse in couples; At least secondary school education in women; Employment of husbands; Having a cell phone; Having tendency to participate regularly in counseling sessions; Lack of children from previous marriage in couple Exclusion criteria: Having no tendency to participate in counseling sessions and absence of two session; Not filling out 20 percent of questionnaires by participants; Diagnosing of mental disorders at any stage of the study

Age
From **15 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
study will be done in two phases; descriptive and experimental

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Ethics committee of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanjan

City
Zanjan

Postal code

Approval date
2016-07-09, 1395/04/19

Ethics committee reference number
zums.rec.1395.99

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97

ICD-10 code description
Inability to achieve a pregnancy sterility, female NOS

Primary outcomes

1

Description
Irrational parenthood congition

Timepoint
At baseline and two month after the intervention

Method of measurement
Irrational parenthood congition scale

2

Description
Marital quality

Timepoint
At baseline and two month after the intervention

Method of measurement
Marital quality scale based on Glasser choice theory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: The intervention group of 25 persons will be divided into two groups of 8 and one group of 9 participants. The intervention group will receive 9 sessions of 90-minute group counseling based on the choice theory. In order to achieve higher efficacy, all participants will receive positive key messages at the end of each session. At the end of each two counseling sessions, main points of each session will be presented.

Category
Behavior

2

Description
Intervention 2: The control group of 25 persons will receive no counseling.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Mousavi Hospital Infertility Clinic

Full name of responsible person
Arezoo Safaei Nezhad

Street address
Infertility Clinic, Road Gavazang, Ayatollah Mousavi Hospital, Zanjan

City
Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology of Zanjan University of Medical Sciences

Full name of responsible person
Dr Alireza Shoghli

Street address
Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanjan

City
Zanjan

Grant name
پایان نامه

Grant code / Reference number
A-11-980-4

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

Title of funding source
Vice Chancellor for Research and Technology of Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Arezoo Safaei Nezhad

Position
Msc student of midwifery counseliing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Ph.D of Reproductive Health

Other areas of specialty/work

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Person responsible for updating data

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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