

# 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

2016-09-15, 1395/06/25

##### 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, .

##### Registrant information

###### Name

Roghieh Kharaghani

###### Name of organization / entity

Zanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3314 8144

###### Email address

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

#### 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

##### 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 zanzan 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 Zanzan University of Medical Sciences

##### Street address

Ethics committee of Zanzan University of Medical Sciences, First floor, North Side Azadi Boulevard, Zanzan

##### City

Zanzan

##### 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 counseling

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr Roghieh Kharaghani

**Position**

Ph.D of Reproductive Health

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Karmandan town, zanjan

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## Person responsible for updating data

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**Full name of responsible person**

Dr Roghieh Kharaghani

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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*