

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The impact of the implementing of empowerment program on the quality of life and thoughts in infertile women

#### Protocol summary

##### Summary

The aim of this research is evaluation of the impact of implementing empowerment program on the quality of life and believes in infertile women. This is randomized clinical trial study. The sample size is 80 infertile woman in Imam khomeini and Mirza kouchak khan infertility clinics that 40 infertile women will be selected from each hospital and will be randomly assigned into two intervention (20 people) and control (20 people) groups . Participants Inclusion criteria: infertility due to female factors; primary infertility; literacy; being Iranian; Muslim; Lack of physical and mental illness; aged 18 to 40 years. Exclusion criteria: physical and mental illness identified; become pregnant during the study; not participate in all meetings of the intervention. Intervention based on empowerment programs in four structures of knowledge, self-efficacy, training participation and evaluation will be conducted including five sessions meeting groups for two hours each week until 5 weeks and two session individual meeting. The data will be collected using three questionnaires consisted of demographic characteristics, quality of life and irrational parenthood cognition scale will be completed before and three months after intervention. Main outcome variables is studying the effectiveness of empowerment program on the quality of life and believes in infertile women

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201410236284N9**  
Registration date: **2015-10-24, 1394/08/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-24, 1394/08/02

##### Registrant information

###### Name

Maryam Modarres

###### Name of organization / entity

Tehran university of Medical sciences

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##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2015-04-19, 1394/01/30

##### Expected recruitment end date

2015-09-21, 1394/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of the implementing of empowerment program on the quality of life and thoughts in infertile women

##### Public title

Education based on empowerment model on thinking and quality of life in infertile women

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: infertility due to female factor; primary infertility; literacy; Iranian; Muslim; Lack of physical and mental illness; aged 18 to 40 years.  
Exclusion criteria: physical and mental illness identified; become pregnant during the study; not participate in all meetings of the intervention .

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**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**

Ethics committee of Tehran University of Medical sciences

**Street address**

6th floor, Central organization of University, edge of Qods avenue, Keshavarz blvd, Tehran

**City**

Tehran

**Postal code****Approval date**

2015-03-04, 1393/12/13

**Ethics committee reference number**

9111373001-1

**Health conditions studied****1****Description of health condition studied**

Infertility

**ICD-10 code**

N97.9

**ICD-10 code description**

Female infertility, unspecified

**Primary outcomes****1****Description**

Quality of life

**Timepoint**

Pre test, 3 months after intervention

**Method of measurement**

Quality of life questionnaire

**2****Description**

Irrational parenthood cognitions

**Timepoint**

Pre test, 3 month after intervention

**Method of measurement**

Irrational parenthood cognitions scale

**Secondary outcomes****1****Description**

Psychological aspect of the quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**2****Description**

Physical aspect of the quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**3****Description**

Social aspect of the quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**4****Description**

Sexual aspect of quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**5****Description**

Spirituality aspect of the quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**6**

**Description**

Economic aspect of the quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**7**

**Description**

Emotional aspect quality of life

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Quality of life questionnaire

**8**

**Description**

Irrational parenthood cognitions

**Timepoint**

Pre test and 12 weeks after intervention

**Method of measurement**

Irrational parenthood cognitions scale

**Intervention groups**

**1**

**Description**

Intervention is based on empowerment model which has four steps: knowledge, self-efficacy, training participation and evaluation. The first step (perceived threat) empowerment program will try to increase awareness and understanding of the nature and consequences of the infertility. The first step is two hours instructive sessions with a week interval. The second step which is problem solving, is two hours group discussion sessions under the supervision of the researcher and a psychologist(Group discussions and choose the best solution). In the third step (educational participation), will try to increase the efficacy through educational participation. The fourth step is evaluation done in two stages. The first stage involve asking two questions orally at the beginning of each session and The second stage is the final evaluation that instruments will be completed again by the sample. The meeting will be held in the form of individual and group(5 sessions of group and 2 individual sessions). Group meetings are once a week and Individual sessions are times that women come to evaluate the fertility and the aims of Individual sessions is for basic familiarity with each women and answer demographic questionnaire and evaluation of basic capacity and quality of life.

**Category**

Other

**2**

**Description**

The control group only received the routine therapies and services of the fertility center. No counseling was included for this group.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mirza Kouchak Khan hospital

**Full name of responsible person**

Maryam abunasri

**Street address**

Ostad Nejatollahi street, Karim Khan boulevard

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

maryam abunasri

**Street address**

End of Keshavarz Blvd, Imam Khomeini Hospital

**City**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical sciences

**Full name of responsible person**

Dr. Masoud Yunesian

**Street address**

5th floor, Central building of Tehran University of Medical sciences, edge of Qods Av, Keshavarz blvd, Tehran

**City**

Tehran

**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, Tehran 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*

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## Person responsible for general inquiries

### Contact

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## Person responsible for scientific inquiries

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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*