

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 8142

Email address

modarres@sina.tums.ac.ir

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

Tehran

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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr. Modares Maryam
Position
Phd Medical education
Other areas of specialty/work
Street address
Faculty of Nursing & Midwifery Tehran University of
Medical Science, Tohid square
City
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
Email
modarres@sina.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr. Modares Maryam
Position
Phd Medical education
Other areas of specialty/work
Street address
Faculty of Nursing & Midwifery Tehran University of
Medical Science, Tohid square
City

Tehran
Postal code
1419733171
Phone
+98 212166927171
Fax
Email
modarres@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mirza Kouchak Khan hospital
Full name of responsible person
Maryam Abunasri
Position
Master
Other areas of specialty/work
Street address
Ostad Nejatollahi street, Karim Khan boulevard
City
Tehran
Postal code
Phone
+98 71 4243 6621
Fax
Email
maryamabunasri.91@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