

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effect of An Educational package on self-efficacy and self-esteem of infertile women

#### Protocol summary

##### Summary

This study aims to evaluate the effect of An Educational package on self-efficacy and self-esteem of infertile women. This is a experimental study with two groups intervention (n=40) and control (n= 40). Sampling method is continuous and randomized controlled trial. In this study 80 Iranian infertile women who are able to read and write , age between 20-45, primary infertility with female factor for at least of 5 years and without known disease and history of psychiatry interventions after completion of demographic and self-esteem questionnaires and infertility self-efficacy scale, will be recruite . Exclusion criteria: pregnancy and women who withdrawal during the study. In the intervention group 40 infertile women ( in 4 groups) will be participated. An educational programs on reproductive system, definition and prevalence of infertility, causes, diagnose and treatment of infertility, assisted reproductive technology and coping with the stress of infertility in four sessions (one session a week, in 4 consecutive week and each session 60-90 minutes) will be provided by the researcher for women gregariously and then booklets will be delivered to the women to recall. The researcher will follow the women 15 days after fourth educational session by the phone. The infertility self-efficacy scale and self-esteem questionnaire will be completed by intervention group in 6 weeks after the last educational session. The infertility self-efficacy scale and self-esteem questionnaire will be completed by control group in 6 weeks after primary completion of them. The educational package's effect will be measured by comparing the infertility self-efficacy and self-esteem scores.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205073034N9**

Registration date: **2012-06-17, 1391/03/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-06-17, 1391/03/28

##### Registrant information

###### Name

Mansoureh Jamshidimanesh

###### Name of organization / entity

Iran University Faculty of Nursing & Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4365 1811

###### Email address

delshad2@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, School of Nursing and Midwifery, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2012-09-22, 1391/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of An Educational package on self-efficacy and self-esteem of infertile women

##### Public title

Effect of An Educational package on self-efficacy and self-esteem of infertile women

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: Iranian infertile women who are able to read and write; age between 20-45years old; primary infertility with female factor for at least of 5 years and have no known disease and history of psychiatry interventions. Exclusion criteria: pregnancy and women who withdrawal during the study.

### **Age**

From **20 years** old to **45 years** old

### **Gender**

Female

### **Phase**

N/A

### **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 School of Nursing and Midwifery,  
Tehran University of Medical Sciences

##### **Street address**

Tohid SQ, East Nosrat Ave

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2012-04-29, 1391/02/10

#### **Ethics committee reference number**

90/130/2719/3/

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Female infertility

### **ICD-10 code**

N97

### **ICD-10 code description**

inability to achieve a pregnancysterility, female NOS

## **Primary outcomes**

### 1

#### **Description**

Infertility self-efficacy scores

#### **Timepoint**

Before intervention and 6 weeks after the end of intervention

#### **Method of measurement**

Infertility self-efficacy Questionnaire

### 2

#### **Description**

Eysenck self-esteem scores

#### **Timepoint**

Before intervention and 6 weeks after the end of intervention

#### **Method of measurement**

Eysenck self-esteem Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Educational group will be implemented by the researcher in 4 sessions of 60-90 minutes, one session a week in 4 consecutive weeks. In the first session the women will be educated about reproductive system, definition and prevalence of infertility, causes, diagnose and treatment of infertility, assisted reproductive technology and coping with the stress of infertility. Then, a booklet, including discussed topics, delivered to recall the women and finally the women' questions will be answered by the researcher. In the second, third and fourth sessions, the educational program will include more complete explanation of treatment of infertility, assisted reproductive technology and coping with the stress of infertility. The infertility self-efficacy scale and self-esteem questionnaire will be completed by intervention group at baseline and 6 weeks after the last educational session.

#### **Category**

Other

### 2

#### **Description**

In control group: The infertility self-efficacy scale and self-esteem questionnaire will be completed at baseline and in 6 weeks after primary completion of them.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Vali e Asr Reproductive Health Center

**Full name of responsible person**

Niloofer Alimanesh

**Street address**Keshavarz Blvd, Imam Khomeini Hospital Complex,  
Vali e Asr Reproductive Health Center**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 Mohammad Ali Cheraghi

**Street address**School of Nursing and Midwifery, Tehran University of  
Medical Sciences Tohid SQ East Nosrat Ave Tehran,  
Iran**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****Person responsible for scientific****inquiries****Contact****Name of organization / entity**School of Nursing and Midwifery, Tehran University of  
Medical Sciences**Full name of responsible person**

Mansoureh Jamshidimanesh

**Position**

MSc Midwifery, Master of Science

**Other areas of specialty/work****Street address**School of Nursing and Midwifery, Tehran University of  
Medical Sciences , Tohid SQ , East Nosrat Ave ,  
Tehran, Iran**City**

Tehran

**Postal code****Phone**

+98 21 6692 7171

**Fax****Email**

jamshidimanesh@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**School of Nursing and Midwifery, Tehran University of  
Medical Sciences**Full name of responsible person**

Mansoureh Jamshidimanesh

**Position**

Midwifery, Master of Science

**Other areas of specialty/work****Street address**School of Nursing and Midwifery, Tehran University of  
Medical Sciences, Tohid SQ , East Nosrat Ave ,Tehran,  
Iran**City**

Tehran

**Postal code****Phone**

+98 21 6692 7171

**Fax****Email**

jamshidimanesh@yahoo.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*