

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)

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Email address

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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 centers1**Recruitment center****Name of recruitment center**

Vali e Asr Reproductive Health Center

Full name of responsible person

Niloofer Alimanesh

Street addressKeshavarz Blvd, Imam Khomeini Hospital Complex,
Vali e Asr Reproductive Health Center**City**

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice chancellor for research, Tehran University of
Medical Sciences**Full name of responsible person**

Dr Mohammad Ali Cheraghi

Street addressSchool 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 sourceVice 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

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Medical Sciences**Full name of responsible person**

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Position

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Other areas of specialty/work**Street address**School of Nursing and Midwifery, Tehran University of
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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