Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Cognitive-Behavioral Stress Management Education on Infertility Related Stress, Marital Quality and Marital Satisfaction in Infertile Couples

Protocol summary

Study aim

Determining the effect of cognitive-behavioral education on infertility-related stress and marital quality and marital satisfaction in infertile couples

Design

Two parallel group randomized of infertile couples were selected to participate in this study (10 couples in intervention group and 10 couples in control group). This study was not blind.

Settings and conduct

This randomized study was conducted on 20 couples of Saboohi Infertility Center in Mahdieh Hospital of Tehran. The data collection tool was standard questionnaires of fertility problems, Enrich marital satisfaction and marital quality. At first, the primary test was performed in two groups (intervention and control) and then again, the test was performed immediately and two weeks after intervention with the same questionnaire in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranians, have reading and writing skills, live in Tehran, have no known psychological problems, have not experienced severe stressful events such as close relatives or job loss during the past 6 months, Initial infertility. Exclusion criteria: Non-cooperation

Intervention groups

In intervention group was performed 8 educational intervention sessions for 180 minutes using lecturing method, question answer method, focus group discussion and slideshows. The control group received only 2 infertility counseling sessions 180-minute.

Main outcome variables

Infertility related stress, marital quality, marital satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170807035540N3**
Registration date: **2018-07-20, 1397/04/29**
Registration timing: **retrospective**

Last update: **2018-07-20, 1397/04/29**
Update count: **0**

Registration date

2018-07-20, 1397/04/29

Registrant information

Name

Hashemieh Chehreh

Name of organization / entity

School of Nursing & Midwifery,Shahid Beheshti University of Medical Science,

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

2018-05-10, 1397/02/20

Actual recruitment end date

2018-06-10, 1397/03/20

Trial completion date
empty

Scientific title
The Effect of Cognitive-Behavioral Stress Management Education on Infertility Related Stress, Marital Quality and Marital Satisfaction in Infertile Couples

Public title
The Effect of Education on Infertility Stress, Marital Quality and Marital Satisfaction

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Iranians couples have reading and writing skills live in Tehran have no known psychological problems have not experienced severe stressful events such as close relatives or job loss during the past 6 months have primary infertility
Exclusion criteria:
Non-cooperation

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In the random sampling process of couples in two groups of intervention and control, random allocation software for clinical trails was used. Using this software, data about the number of samples, the number and names of the groups were given to Excel software, and the output was taken from the random list of the groups.

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 Shahid Beheshti University of Medical Sciences
Street address
Nursing and Midwifery School, Crossroads Valieaser with Niaiesh, Valieaser St.
City
Tehran
Province
Tehran
Postal code
1985717443

Approval date
2016-07-18, 1395/04/28

Ethics committee reference number
1395.500.IR-SBMU.PHNM

Health conditions studied

1

Description of health condition studied
Marital quality

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Marital satisfaction

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Infertility-related stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Marital quality

Timepoint
Before the intervention, immediately after the intervention and two weeks after the intervention

Method of measurement
Fertility Marital Quality Questionnaire

2

Description
Marital satisfaction

Timepoint
Before the intervention, immediately after the intervention and two weeks after the intervention

Method of measurement
Marital Satisfaction Questionnaire

3

Description
Infertility related stress
Timepoint
Before the intervention, immediately after the intervention and two weeks after the intervention
Method of measurement
Fertility problem or Infertility-related Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention included 8 training sessions 180-minute in the intervention group that it was carried out by question and answer method, focused group discussion and slideshow. The intervention included the Infertility counseling, Marital counseling, Problem solving and conflict resolution techniques, Social support, relaxation and breathing exercises.
Category
Other

2

Description
Control group: The control group received only 2 infertility counseling sessions 180-minute. This counseling was carried out by question and answer method, focused group discussion and slideshow. This consultation included definition of infertility and its causes, treatment methods, treatment costs and the impact of infertility on marital relationships.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh Hospital, Saboohi Infertility Center
Full name of responsible person
Elaheh Mazaheri
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, beside the Taleqani hospital, Yaman St, Shahid Chamran highway
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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 Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hashemieh Chehreh
Position
Ph.D. student of reproductive health
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Associate professor
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hashemieh_chehreh@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable