

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 Mahdiah 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)

Phone

+98 21 8865 5366

Email address

hashemieh_chehreh@sbmu.ac.ir

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

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**

Mahdijeh Hospital, Saboohi Infertility Center

Full name of responsible person

Elaheh Mazaheri

Street address

Mahdijeh Hospital, Fadaian Islam St.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email**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

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9331

Email

zarghi@sbmu.ac.ir

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

Street address

Nursing and Midwifery School, Crossroads Valieaser
with Niaesh, Valieaser St.

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2518
Email
hashemieh_chehreh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Giti Ozgoli
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Nursing and Midwifery School, Crossroads Valieaser with Niaiesh, Valieaser St.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2518
Email
g.ozgoli@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hashemieh Chehreh
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Reproductive Health
Street address
Nursing and Midwifery School, Crossroads Valieaser with Niaiesh, Valieaser St.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2518
Email
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