Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of infertile couple's skills promotion package on Management Sexual relationship

Protocol summary

Study aim
The effect of infertile couple's skills promotion package on Management Sexual relationship

Design
Clinical trial with control group, with parallel groups, randomized with random number table, on 72 infertile couples

Settings and conduct
In this study, 72 infertile couples who referred to Mahdieh Hospital Infertility Center affiliated to Shahid Beheshti University of Medical Sciences and Health Services, after obtaining informed consent will be randomly assigned into intervention and control groups. In the intervention group, infertile couple's skills promotion package will be provided in 4 sessions, and no education will be provided to the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: female infertility, At least 2 years of infertility history, Iranian nationality, age of 20 to 45 years, no known mental illness,Having informed consent to participate in the study, Lack of consumption of Psychological drugs and Having sexual activity exclusion criteria: occurrence of stressful events (such as death of relatives, divorce ....) and pregnancy during the study

Intervention groups
Infertile women and their husbands in the intervention group will receive infertile couple's skills promotion package in 4 sessions -90 minutes, during 2 weeks through lecture and Question-Answer method . The infertile couple's skills promotion package was designed after a review study and a quantitative research and then searching in the literature.Infertile women and their husbands in the control group will not receive any intervention by the researcher during the study.

Main outcome variables
Iranian couples' sexual compatibility score, Larson's sexual satisfaction (women and their husbands) and women's sexual function score for infertile women and International Sexual Performance Index score for their husbands

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190530043770N1**
Registration date: **2020-10-14, 1399/07/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-14, 1399/07/23**
Update count: **0**

Registration date
2020-10-14, 1399/07/23

Registrant information

Name
niloofar alimanesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2641 7121

Email address
nalimanesh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-10-31, 1399/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of infertile couple's skills promotion package on Management Sexual relationship

Public title
The effect of infertile couple's skills promotion package on Management Sexual relationship

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Female infertility at least 2 years of infertility history Iranian nationality age of 20 to 45 years no known mental illness Lack of consumption of psychological drugs Having sexual activity Having informed consent to participate in the study

Exclusion criteria:
the occurrence of stressful events (such as death of relatives, divorce ....) pregnancy during the study

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by using random numbers in Excel software: First, in a column, the groups will be entered as B, A, below each other, because the number of samples in each group is 36, so 36 B, A, will be entered below each other. In the opposite column, random numbers will be generated by using the rand function. In the next step, by using the sort function, random numbers will be sorted from small to large or inverse, so the order of the groups, B, A, will be changed. By the new order, individuals Will be allocated to intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This experimental study is a randomized clinical trial with a control group. The statistical population consist of Iranian infertile couples with female infertility referred to Mahdieh Hospital Infertility Center affiliated to Shahid Beheshti University of Medical Sciences and Health Services. This study will perform on 72 Iranian infertile couples (36 infertile couples in the intervention group and 36 infertile couples in the control group). Sampling method will be by available sampling. The questionnaires were completed by the samples who will signed the written consent. Then a list of samples will be prepared, then by the table of random numbers, The intervention and control group will be determined

Secondary Ids

1

Registry name
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی شهید بهشتی

Secondary trial Id
IR.SBMU.PHARMACY.REC.1398.119

Registration date
2019-07-15, 1398/04/24

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Vali-e-Asr St., Niayesh Intersection, Opposite to Shahid Rajaei Heart Hospital, Niayesh Educational and Research Complex, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-07-15, 1398/04/24

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.119

Health conditions studied

1

Description of health condition studied
Female infertility

ICD-10 code
N97

ICD-10 code description
N97

Primary outcomes

1

Description
Female sexual function score

Timepoint
At the beginning of the study (before the intervention) - 6 weeks after the end of the intervention

Method of measurement
Female Sexual Function Index (FSFI)

2

Description
International index of erectile function score
Timepoint
At the beginning of the study (before the intervention) - 6 weeks after the end of the intervention
Method of measurement
International index of erectile function (IIEF)

3

Description
Sexual satisfaction score
Timepoint
At the beginning of the study (before the intervention) - 6 weeks after the end of the intervention
Method of measurement
Larson Sexual Satisfaction Questionnaire

4

Description
Sexual compatibility score
Timepoint
At the beginning of the study (before the intervention) - 6 weeks after the end of the intervention
Method of measurement
Iranian Couples Sexual compatibility Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention includes 4 training sessions (duration of each session 90 minutes) for 2 consecutive weeks (2 sessions per week) for the intervention group. The educational content includes information about the anatomy of the reproductive system and the process of reproduction and sexual anatomy, sexual response, sexual cycle physiology, factors affecting sexual response, sexual disorders in four areas of sexual desire, arousal, orgasm, pain and treatment strategies.The statistical population consists of Iranian infertile couples with female infertility referred to Mahdieh Hospital Infertility Center affiliated to Shahid Beheshti University of Medical Sciences and Health Services. After selecting the center and obtaining the necessary licenses, the researcher will introduce himself to the patients and explain the objectives of the research, mentioning the optional of the Participation and the confidentiality of information, and will proceed to available sampling. The questionnaires will be completed in a quiet environment and in a separate room by the samples who have signed the written consent. Then a list of samples wil be prepared and the intervention and control group will be determined by random number table.
Category
Other

2

Description
Control group:Infertile women and their husbands in the control group will not receive any intervention by the researcher during the study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Center of Mahdieh Hospital
Full name of responsible person
niloofar alimanesh
Street address
Vali-e-Asr St., Niayesh Intersection, Opposite to Shahid Rajaei Heart Hospital, Niayesh Educational and Research Complex, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8820 2512
Email
nalimanesh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
afshin zarghi
Street address
Velenjak, Daneshjoo Boulevard, Arabi St., Shahid Beheshti University of Medical Sciences
City
Tehran
Province
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Postal code
1983963113
Phone
+98 21 2243 9781
Email

Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

niloofar alimanesh

Position

PhD student in Reproductive Health

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Valiasr St., Niayesh Intersection, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

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Phone

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Email

nalimanesh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

zohre keshavarz

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Valiasr St., Niayesh Intersection, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

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keshavarzzohre57@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

niloofar alimanesh

Position

PhD student in Reproductive Health

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

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City

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Province

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Phone

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Email

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the main outcome is shared without the names of the participants.

When the data will become available and for how long

The data will be available between 6 and 12 months after the results are published.

To whom data/document is available

Researchers at scientific institutes are allowed to access the data

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Correspondence with the responsible author via email keshavarzzohre57@gmail.com

What processes are involved for a request to access data/document

The application letter must include the name of the applicant, the person used and the scientific title of the research project or article.

Comments