Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Effectiveness of the Sexual Health Education Program on the Sexual Self Efficacy, Marital Adjustment and Intimacy of Infertile Women

Protocol summary

Study aim

Determine the Effectiveness of the Sexual Health Education Program on the Sexual Self Efficacy, Marital Adjustment and Intimacy of Infertile Women

Design

A randomized, controlled, clinical trial, with parallel groups, single blind that a total of 60 subjects will assign to in a 1:1 ratio into two groups of 30, including a intervention group, and a control group. interventions by Computer-aid randomization.Sample size was calculated as 24 subjects in each group to yield an 80% power with 95% Confidence level, accuracy = 10.5, and approximate standard deviation (SD) = 13.01 based on previous studies for each group. After consideration of subjects dropping out of the research (30%), a total of 60 eligible infertile women will select in equal 2 groups (30 person in each group).

Settings and conduct

This study will conduct at Fatemeh Zahra Infertility and Reproductive Health Center of Babol University of Medical Sciences in Babol, Iran. The blind will be designed in terms of the analyzer, and by giving code to the groups, the nature of the groups for the analyzer is not known.

Participants/Inclusion and exclusion criteria

Satisfactory informed consent to the study Infertility women who did not want to treat infertility until two months later. Duration of infertility for more than 1 year The ability to read and write at least Have a lasting sexual activity (at least four weeks) The availability of the spouse Permanent marriage Failure to participate in completing the questionnaire Failure to answer more than 10% of the questionnaire questions Having psychological support

Intervention groups

The intervention group will participate in a total of four two-hour group sessions of sex education and relaxation training . The control group will receive routine center counseling.

Main outcome variables

sexual self-efficacy, adjustment and marital intimacy

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20190203042601N1**
Registration date: **2019-04-10, 1398/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-10, 1398/01/21**
Update count: **0**

Registration date

2019-04-10, 1398/01/21

Registrant information

Name

Sara Banaha

Name of organization / entity

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-30, 1398/01/10

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of the Sexual Health Education Program on the Sexual Self Efficacy, Marital Adjustment and Intimacy of Infertile Women

Public title

Effectiveness of the Sexual Health Education Program on the Sexual Self Efficacy, Marital Adjustment and Intimacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

 Conscious consent to enter the study Infertility women who did not want to treat infertility until two months later. Duration of infertility for more than 1 year The ability to read and write at least Have a lasting sexual activity (at least four weeks) Age of at least 20 and maximum 40 years The availability of the spouse Permanent marriage Consumers of drugs that cause sexual dysfunction, such as barbiturates, benzodiazepines (diazepam, oxazepam, chlordiazepoxide), antidepressants, antihypertensive drugs, etc.

Exclusion criteria:

 Failure to participate in completing the questionnaire Failure to answer more than 10% of the questionnaire questions Having psychological support (participating in psychotherapy sessions, relaxation techniques, yoga, etc.) An experienced stressful event in the last three months (death or acute illness of close relatives, a major change in lifestyle)With the above criteria, 60 infertile women enter the study and will be randomly assigned to experimental and control groups.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 infertile eligible women will be selected in two equal groups (30 women in each group). Random assignment will be provided by simple random allocation to provide the possibility of unpredictability of intervention unauthorized access. To generate a random assignment sequence from the computerized software program Random allocation will be used to generate random sequences. Random assignment method using randomized computer software as Roandom smple of cases It will be in two equal categories (Approximately 50% of all cases)

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyzer (evaluator of outcome).

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Babol University of Medical Sciences

Street address

ganjafrouze street

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.235

Health conditions studied

1

Description of health condition studied

sexual self efficacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual Self Efficacy

Timepoint

Before the intervention and four weeks after its.

Method of measurement

Sexual self-efficacy measurement tool is a standard self-efficacy questionnaire.

2

Description

Marital Adjustment

Timepoint

Before the intervention and four weeks after its.

Method of measurement

Marital adjustment will measure using Graham-bi spinner Marital Adaptation Inventory (DAS: Dyadic Adjustment Scale).

3

Description

Marital Intimacy

Timepoint

Before the intervention and four weeks after its.

Method of measurement

Marital intimacy will measure using Marital Intimacy Needs Questionnaire Bagarozzi (2001((MINQ).

Secondary outcomes

1

Description

sexual function

Timepoint

Before the intervention and four weeks after its.

Method of measurement

Iranian Version of the Female Sexual Function Inventory (IV-FSFI).

Intervention groups

1

Description

Intervention group:The intervention group will participate in a total of four two-hour group sessions of sex education and relaxation training will present in the form of lectures, Q&A, group discussions, booklets and CD.

Category

Behavior

2

Description

Control group: The control group will not receive any interventions. They will receive only routing consoling of center. To observe the ethics of research, the members of the control group will refer to a sex therapy clinic at the end of the four-week trial and educational package will given to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Infertility and Reproductive Health Center of Babol University of Medical Sciences in

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name

Babol University of Medical Sciences

Grant code / Reference number

5086

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

Yes

Title of funding source

Babol 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
Babol University of Medical Sciences

Full name of responsible person
Sara Banaha

Position
Consultant

Latest degree
Bachelor

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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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Regarding the subject of the protocol that related to sexual matters, the more details of data is subject to the approval of the Ethics Committee of babol medical science of university

When the data will become available and for how long
Regarding the subject of the protocol that related to sexual matters, the accessibility of data is subject to the approval of the Ethics Committee of babol medical science of university

To whom data/document is available

Regarding the subject of the protocol that related to sexual matters, those who are allowed to access the data, is subject to the approval of the Ethics Committee of babol medical science of university

Under which criteria data/document could be used

Regarding the subject of the protocol that related to sexual matters,terms of use, is subject to the approval of the Ethics Committee of babol medical science of university

From where data/document is obtainable

The Ethics Committee of babol medical science of university

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

Send letter to the Ethics Committee of babol medical science of university

Comments

No Comment