

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Investigating the Effect of Training and Counseling based on the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction in Couples

#### Protocol summary

##### Study aim

The effect of education and counseling based on the self-management empowerment model on childbearing motives, marital satisfaction and sexual satisfaction in couples.

##### Design

Clinical trial with test group, control group, without blinding, randomized

##### Settings and conduct

The target population is couples referring to Bushehr health centers, the research environment of Bushehr Comprehensive Health Centers. The research samples will be selected from the centers (based on the allocation to share sampling that was explained in the sampling section). They will be randomly divided into two control and test groups. Test forms will be designed in Google Doc, informed consent form, demographic information form, and a questionnaire on motives for having children, marital satisfaction, and sexual satisfaction, then a pre-test will be conducted in the test group. and control, intervention is not done in the control group. In the intervention test group, self-management empowerment will be done face-to-face, and then the post-test will be done in both groups, and data analysis will be done using appropriate software.

##### Participants/Inclusion and exclusion criteria

Inclusion: absence of pregnancy; being married; being Iranian; having informed consent; age 18-40 Years old. Exit criteria: secondary infertility; physical and mental illness; failure to attend more than one training session.

##### Intervention groups

In the intervention group, four training and consultation sessions based on the self-management empowerment model will be held; after completing the study, the control group will be given a training booklet.

##### Main outcome variables

1) Childbearing motivation score with childbearing

motivation questionnaire 2) Marital satisfaction score with the Enrich Marital Satisfaction Questionnaire 3) Sexual satisfaction score with the Larson Sexual Satisfaction Questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220830055827N2**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

##### Registration date

2023-12-09, 1402/09/18

##### Registrant information

##### Name

Farahnaz Kamali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3345 0187

##### Email address

f.kamali@bpums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2023-12-10, 1402/09/19

##### Expected recruitment end date

2023-12-31, 1402/10/10

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the Effect of Training and Counseling based on the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction in Couples

**Public title**  
Investigating the Effect of the Self-management Empowerment Model on Childbearing Motives, Marital Satisfaction and Sexual Satisfaction

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Being Literate Being Iranian Being Married Living with a Spouse Age 18-40 Years Not Pregnant Not having a Medical Prohibition for Pregnancy Consent of Wife and Husband to Participate in the Study

**Exclusion criteria:**

Failure to Participate in more than one Counseling Session Participate in Similar Courses at the Same Time Having Secondary Infertility based on Self-report Physical and Mental Illness in a Person or Spouse based on Self-report

**Age**  
From **18 years** old to **40 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **128**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, sampling will be easy and then random allocation will be done in two groups, intervention and control. Blocking will be done using blocks of eight; In this way, the letter A will be assigned to the intervention group and the letter B will be assigned to the control group, and then blocking will be done using Random Allocation software. In each center, sampling will be done in the form of allocation to shares. That is, the number of samples is determined according to the population covered by each center.

**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 Bushehr University of Medical Sciences

**Street address**

School of Midwifery Nursing, Bushehr University of Medical Sciences, Salman Farsi St., Bushehr

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7518759577

**Approval date**

2023-07-11, 1402/04/20

**Ethics committee reference number**

IR.BPUMS.REC.1402.077

## Health conditions studied

### 1

#### Description of health condition studied

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

Childbearing Motivation Score from the Childbearing Motivation Questionnaire

#### Timepoint

At the beginning of the study (before the start of the intervention) and two months after the end of the intervention

#### Method of measurement

Childbearing Motivation Questionnaire

### 2

#### Description

Marital Satisfaction score from Enrich Marital Satisfaction Questionnaire

#### Timepoint

At the beginning of the study (before the start of the intervention) and two months after the end of the intervention

#### Method of measurement

Enrich Marital Satisfaction Questionnaire

### 3

#### Description

Sexual Satisfaction score from Larson's sexual Satisfaction Questionnaire

#### Timepoint

At the beginning of the study (before the start of the intervention) and two months after the end of the intervention

#### Method of measurement

Larson sexual Satisfaction Questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Training and counseling of the self-management empowerment model in four sixty-minute sessions, In an interview manner, During two weeks, there will be two meetings in person each week. Continue the intervention in the form of telephone follow-up in six weeks and a meeting every week to answer questions.

##### Category

Behavior

#### 2

##### Description

Control group: There is no intervention

##### Category

N/A

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

All the clinics of Bushehr city

###### Full name of responsible person

Farhanaz Kamali

###### Street address

City level clinics, Bushehr, Bushehr province

###### City

Bushehr

###### Province

Boushehr

###### Postal code

7518759577

###### Phone

+98 912 936 2377

###### Email

aliyeh.rafiei1400@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Boushehr University of Medical Sciences

###### Full name of responsible person

Akram Farhadi

###### Street address

Deputy of research and technology, Bushehr University of Medical Sciences, Salman Farsi St.

###### City

Bushehr

###### Province

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7518759577

###### Phone

+98 912 936 2377

###### Email

ak.farhadi@gmail.com

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

##### Full name of responsible person

Farhanaz kamali

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Education

##### Street address

School of Midwifery Nursing, Bushehr University of Medical Sciences, Salman Farsi St.

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Bushehr

##### Province

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##### Phone

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**Email**

Farhanazkamali2006@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Farahnaz kamali

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

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**Person responsible for updating data****Contact****Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Farahnaz kamali

**Position**

Assistant professor

**Latest degree**

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**Email**

Farahnazkamali2006@yahoo.com

**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**

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