

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of educational intervention on the sexual performance of marginalized women in eastern Iran

#### Protocol summary

##### Study aim

The effect of designed educational intervention on women's sexual performance

##### Design

The clinical trial has two intervention groups and one control group, which will be randomly selected from the health centers of Zabol University of Medical Sciences. The sample size is 34 for each group and 68 for the two groups, which is considered to be 76 people in total.

##### Settings and conduct

The research environment in this study was the health care centers of marginalized areas under the supervision of Zabol University of Medical Sciences, so that 4 out of ten marginalized areas were randomly selected. Then, a health center was randomly selected from each region in a one-stage cluster. Then, in each center, sampling will be done in an accessible and continuous manner. In this way, all marginalized women who are eligible to enter the study were included in the study after providing full explanations about the purpose of the study and obtaining informed written consent. And finally, they were randomly assigned to two intervention and control groups.

##### Participants/Inclusion and exclusion criteria

The conditions for entering the study included married women aged 15-49, non-lactating, non-pregnant, with no history of any physical or mental illness and living in marginalized areas. Exclusion criteria include the individual's unwillingness to continue participating in the study, the occurrence of pregnancy during the study period

##### Intervention groups

consisting of an intervention group (sexual education about improving sexual performance) and a control group

##### Main outcome variables

Improvement of sexual performance after completion of educational intervention

#### General information

##### Reason for update

Considering the effect size to determine the sample size, the number of sample size was reduced to 76

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231121060133N1**

Registration date: **2023-12-01, 1402/09/10**

Registration timing: **prospective**

Last update: **2024-03-05, 1402/12/15**

Update count: **1**

##### Registration date

2023-12-01, 1402/09/10

##### Registrant information

##### Name

Maryam Koochakzai

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3342 3792

##### Email address

m61.parsa@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-06-04, 1403/03/15

##### Expected recruitment end date

2024-10-06, 1403/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of educational intervention on the sexual performance of marginalized women in eastern Iran

## Public title

Investigating the effect of educational intervention on the sexual performance of women living in the marginal areas of eastern Iran

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

1-Women aged 15-49 2- Married and currently living with his wife 3- He should not have acute communication problems with his wife 4- Not during pregnancy and breastfeeding 5- Be a resident of marginal areas 6- Not suffering from a known physical or mental illness 7- Not suffering from severe depression (score less than 29 in the Beck BID-II questionnaire) 8- Having sexual activity in the past month 9-Sexual function disorder in the person (female sexual function score of 26 or less (FSFI)). 10- According to the woman's statement, her husband does not have any sexual dysfunction. 11- It is possible to reach the person within the next 4 months 12- He has not participated in any written training course related to marital problems

### Exclusion criteria:

1- The individual's unwillingness to continue attending the study 2- Occurrence of pregnancy during the study period 3- Occurrence of severe family disputes with spouse during the study period 4- The occurrence of unfortunate and stressful events during the study period (such as death of parents, death of children, etc.)

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **76**

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, the participants will be divided into two intervention and comparison groups by random block method. In this way, all possible modes of placing the letters A and B in blocks of four will be considered, which include a total of 6 modes. These 6 modes are numbered from 1 to 6, and the number of blocks of 4 needed will be determined based on the number of studied samples. Then, according to the required number of blocks, we will line up a random number based on the table of random numbers one after the other; Of course, numbers above 6 will not be considered. Finally, based on the order of the numbers extracted from the table, the blocks related to each number will be listed in order, and when the samples enter the study, each person will acquire a specific letter according to the obtained order. For

example, according to the order (AABB/ABAB), the 5th person will be in group A.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Due to the nature of the intervention, it is not possible to blind the researcher and the participant. In order to blind the outcome assessor, the questionnaires will be completed by the researcher's assistant.

## Placebo

Not used

## Assignment

Parallel

## Other design features

The design of the intervention will be based on the sexual health model

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

##### Street address

School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

#### Approval date

2022-08-17, 1401/05/26

#### Ethics committee reference number

( IR. TUMS.FNM. REC.1401.067)

## Health conditions studied

### 1

#### Description of health condition studied

Educational needs on sexual dysfunction

#### ICD-10 code

F52

#### ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

## Primary outcomes

### 1

#### Description

Changes in sexual performance scores between the two groups

### **Timepoint**

12 weeks after the last intervention session

### **Method of measurement**

FSFI questionnaire

## **Secondary outcomes**

### 1

#### **Description**

The quality of a woman's sexual life

#### **Timepoint**

12 weeks after the end of the intervention

#### **Method of measurement**

Questionnaire of Sexual Quality of Life-Female

## **Intervention groups**

### 1

#### **Description**

Intervention group: Sex education programs in this study were implemented in Three 120-minute sessions with an interval of one week. And it was presented in the form of lectures, questions and answers, group discussions and pamphlets. In the first week, the program included the introduction of the anatomy and physiology of the female reproductive system and factors affecting the sexual cycle. In the second week, the program focused on sexual dysfunction, helping women try lifestyle changes, and building motivation. The third week, the program was based on communication and negotiation skills for conflict resolution and to summarize and review the previous materials. At the end of each session, we answered the specific questions of the participants. A post-test was conducted after 12 weeks from the last training session. In case of any questions, the researchers gave the participants a phone number. In this study, the control group only received the routine program of reproductive health education. Evaluation of the effect of training sessions was done 12 weeks after the last training session in the intervention group and 12 weeks after the initial completion of the questionnaire in the control group. At the end of the training package, it was provided to the control group.

#### **Category**

Other

### 2

#### **Description**

Control group: Receiving a three-session face-to-face educational intervention on the topic of reproductive health is done according to the routine program of the health center.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health centers under the supervision of Zabul University of Medical Sciences

##### **Full name of responsible person**

Maryam Koochakzai

##### **Street address**

NO.6.Mirhoseini Blvd, Zabol Town

##### **City**

Zabol

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9861954959

##### **Phone**

+98 54 3342 3792

##### **Email**

m61.parsa@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr Akbar Fotouhi

##### **Street address**

Research and Technology Dept, 6th floor, Central University Organization, corner of Quds St, Keshavarz Bolvar

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 8163 3698

##### **Email**

vcr@sina.tums.ac.ir

##### **Web page address**

<https://vcr.tums.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Elham Ebrahimi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Faculty of Nursing and Midwifery, EastNusrat St,  
Tawheed Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6692 7171

**Email**

Ebrahimi-308@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Elham Ebrahimi

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Associate Professor

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Ph.D.

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**Email**

Ebrahimi-308@yahoo.com

**Web page address**

<http://fnm.tums.ac.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Elham Ebrahimi

**Position**

Associate professor J

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Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Participants data is confidential

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available