

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Zabul 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 Zabul 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

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9861954959

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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

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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

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Full name of responsible person

Elham Ebrahimi

Position

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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