

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of sexual health education program with Pelvic Muscle Exercise on Knowledge, function and sexual satisfaction in pregnant women

Protocol summary

Summary

Objective: The purpose of this clinical trial study was to investigate the effect of the educational program of sexual health with Pelvic Muscle Exercise on the knowledge, function and sexual satisfaction of pregnant women. Study population: pregnant women with age between 18 to 35 years old. Inclusion criteria: To be pregnant; The gestational age More than 6 weeks ; Having a written and signed informed consent. Exclusion criteria: Having high-risk pregnancy and obstetric complications. . Sample size: 60 cases was done in two groups of 30 pregnant woman (intervention and control) with pretest and posttest design. Study intervention: four 120-minute training sessions will be held within two weeks. Study outcome: Evaluation of the effect of educational program on the knowledge, function and sexual satisfaction of pregnant women compared to control group. fill the questionnaires of the Hooper Sexual knowledge scale, Female Sexual Function Index (FSFI), Hudson sexual satisfaction scale will be assessed Beginning of study and six months post-intervention

Name of organization / entity

Zahedan Branch Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 937 659 5977

Email address

a.sarani@iauzah.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan Branch Islamic Azad University

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071235033N1**

Registration date: **2017-09-18, 1396/06/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-18, 1396/06/27

Registrant information

Name

Azade Sarani

Scientific title

The effect of sexual health education program with Pelvic Muscle Exercise on Knowledge, function and sexual satisfaction in pregnant women

Public title

The effect of sexual health education program on sexual function in pregnant women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: To be pregnant; The gestational age must be defined (from 6 weeks equivalent to first care to 28 weeks based on LMP or sonography as ultrasound; Must be Muslim and Iranian; Must be located in the city of Zahedan; Having a written and signed informed consent; Having a health record in the selected centers

;Having a mutual life with her husband. exclusion criteria:Completed questionnaires incompletely ;Did not attend in the classes; Did not do the exercise according to the training protocol; Having addiction to the drug, smoking, and hookah (according to her ideas or words); Having a background of medical illness; Taking medications that have an effect on sexual response; Having high-risk pregnancy and obstetric complications.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Zahedan University of Medical Sciences

Street address

Hesabi Field

City

Zahedan

Postal code**Approval date**

2017-07-23, 1396/05/01

Ethics committee reference number

IR.ZAUMS.Oth.REC.1396.5

Health conditions studied**1****Description of health condition studied**

sexual function

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction, not caused by organic

disorder or diseases

Primary outcomes**1****Description**

Sexual knowledge

Timepoint

Before intervention, 6 week after intervention

Method of measurement

Hooper Sexual knowledge scale

2**Description**

Sexual function

Timepoint

Before intervention, 6 week after intervention

Method of measurement

Female Sexual Function Index (FSFI)

3**Description**

sexual satisfaction

Timepoint

Before intervention, 6 week after intervention

Method of measurement

Hudson sexual satisfaction scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The presentation of a educational program with the strengthening of pelvic floor muscle on sexual health during pregnancy using a book and compact disc, developed by the research team, will train for approximately 120 minutes in two weeks in four sessions. The training sessions in the selected centers with the number of participants in each session will be 8-10 people. Educational books and compact discs will be given to pregnant women at the end of the first session and they will be asked to study the next session of the book themselves and their spouses and ask their questions at the next educational session. Each week, to ensure that the exercises are carried out The researchers conducted a telephone call in an effective manner and a number of times, and they were given a checklist to record the number of exercises.

Category

Lifestyle

2**Description**

Control group: routine prenatal care

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Erfan health center

Full name of responsible person

Simin Rigi

Street address

Hesabi Field

City

Zahedan

2

Recruitment center

Name of recruitment center

Sajad health center

Full name of responsible person

Mahdiye Janabadi

Street address

Hesabi Field

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan Branch, Islamic Azad University,zahedan,iran

Full name of responsible person

Ahmad Mehraban

Street address

Islamic Azad University College Street Complex

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan Branch, Islamic Azad University,zahedan,iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan Branch, Islamic Azad University,zahedan.iran

Full name of responsible person

Azade Sarani

Position

Master of Midwifery, academic staff: senior lecturer

Other areas of specialty/work

Street address

Islamic Azad University College Street Complex

City

Zahen

Postal code

Phone

+98 54334226898

Fax

Email

saraniazade@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences,zahedan,iran

Full name of responsible person

Shahindokht Navabi Rigi

Position

Master of Midwifery, academic staff: senior lecturer

Other areas of specialty/work

Street address

Mashahir Field, nursing and midwifery school

City

Zahedan

Postal code

Phone

+98 54 3344 2482

Fax

Email

shahinnavabi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zahedan Branch, Islamic Azad University,zahedan,iran

Full name of responsible person

Azade Sarani

Position

Master of Midwifery, academic staff: senior lecturer

Other areas of specialty/work

Street address

Islamic Azad University College Street Complex

City

Zahedan

Postal code

Phone

+98 54 3342 2689

Fax**Email**

saraniyazade@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty