Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Exercis 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

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

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

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 diseas

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
saraniazade@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