

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of sexual health education on self-efficacy and sexual function in primiparous, postpartum women

Protocol summary

Study aim

The purpose of this study of randomized clinical trial is to investigate the effect of sexual health education on postpartum sexual function and sexual self-efficacy in primiparous women in which refer to the health center for postpartum routine care within days of 3-5. In this single-blind clinical trial, the sampling method will be available (easy). A sample of 100 primiparous women will be randomly divided into intervention and control groups. For both groups, a pretest is arranged. afterwards, for intervention group, three health session will be held and the control will receive only routine health care educations. Finally after 8 weeks, there will be a post-test for both intervention and control groups. After collecting questionnaires, data analysis will be performed.

Design

In this study, a number of 100 primiparous women which fit the study conditions and refer to the health center will be selected. Then, participants randomly divide into control and intervention groups.

Settings and conduct

The aim of this study is to evaluate the effect of sexual health education on self-efficacy and sexual function after delivery in primiparous women in health centers of Zahedan. First, a pretest will be taken from both intervention and control groups. Sample of intervention group will receive a designed sexual health education. If the selected sample belongs to the control group, it does not receive any intervention from the researcher, except for the usual care of the centers, which probably does not include any specific sexual health education. Finally, after 8 weeks, the control group and the intervention group at the time of referral to the post-test health centers, will be completed in the form of completing the questionnaires for the second time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: literacy of reading and writing; first birth with a healthy premium or low grade of rapture;

lack of physical and mental disorders after childbirth (depression and psychosis); living by spouse; no history of sexual dysfunctions, mental disorders and addiction before childbirth; healthy singleton and full term; no exposure of major stressful events during pregnancy and after delivery; the absence of illness in pregnancy and after delivery. Exclusion criteria: the absence from more than one session of sexual health education; the occurrence of any acute and unpredictable problem for mother, child or family that leads to anxiety and impact on couples' sexual activity.

Intervention groups

For the intervention group, three sessions of sexual health education are provided. The first session of this training is about 15 to 20 minutes on 3-5 days and the second meeting will take place a week later and the third session will be six weeks after delivery and the control group will only receive routine care.

Main outcome variables

Sexual self-efficacy and sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171108037313N5**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone	+98 33442481	Blinding description	Blindness in this study is single-blind
Email address	pahlavani@zaums.ac.ir	Placebo	Not used
Recruitment status		Assignment	Parallel
Recruitment complete		Other design features	
Funding source	Zahedan University of Medical Sciences	Secondary Ids	empty
Expected recruitment start date	2017-11-21, 1396/08/30	Ethics committees	
Expected recruitment end date	2018-04-20, 1397/01/31	1	
Actual recruitment start date	empty	Ethics committee	
Actual recruitment end date	empty	Name of ethics committee	Ethics committee of Zahedan University of Medical Sciences
Trial completion date	empty	Street address	Mashahir square, Zahedan Nursing and Midwifery Faculty, Sistan and Baluchestan Iran Zahedan Sistan and Baluchestan Iran, Islamic Republic Of
Scientific title	The effect of sexual health education on self-efficacy and sexual function in primiparous, postpartum women	City	Zahadan
Public title	Postpartum sexual education	Province	Sistan-va-Balouchestan
Purpose	Education/Guidance	Postal code	9816743463
Inclusion/Exclusion criteria		Approval date	2017-11-12, 1396/08/21
Inclusion criteria:	Inclusion criteria: literacy of reading and writing; first birth with a healthy premium or low grade of rapture; lack of physical and mental disorders after childbirth (depression and psychosis); living by spouse; no history of sexual dysfunctions, mental disorders and addiction before childbirth; healthy singleton and full term; no exposure of major stressful events during pregnancy and after delivery; the absence of illness in pregnancy and after delivery.	Ethics committee reference number	IR.ZAUMS.REC.1396.227
Exclusion criteria:	Exclusion criteria: the absence from more than one session of sexual health education; the occurrence of any acute and unpredictable problem for mother, child or family that leads to anxiety and impact on couples' sexual activity.	Health conditions studied	
Age	From 18 years old to 35 years old	1	
Gender	Female	Description of health condition studied	Sexual self-efficacy
Phase	N/A	ICD-10 code	Z70.8
Groups that have been masked	Participant	ICD-10 code description	Other sex counseling
Sample size	Target sample size: 100	2	
Randomization (investigator's opinion)	N/A	Description of health condition studied	Sexual function
Randomization description		ICD-10 code	F52
Blinding (investigator's opinion)	Single blinded	ICD-10 code description	Sexual dysfunction, not caused by organic disorder or disease
		Primary outcomes	
		1	
		Description	Sexual self-efficacy

Timepoint

8 weeks after intervention

Method of measurement

Questionnaire

2**Description**

Sexual function

Timepoint

8 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

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

Intervention group: For the intervention group, three sessions of sexual health education are provided. The first session of this training for 15 to 20 minutes on 3-5 and the second session will be a week later and the third session will be six weeks after delivery.

Category

Lifestyle

2**Description**

Control group: Control group samples receive only routine care at the health center.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Sajjad Health Center

Full name of responsible person

Mahnaz Rigi

Street address

Imam Khomeini 19

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815676834

Phone

+98 54 3344 2481

Email

Ehsan.rigi.1395@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Normohammad Bakhshani

Street address

Hassabi field, Campus of Zahedan University of Medical Sciences, Sistan and Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 1341 6708

Email

Pahlavani_86@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Ali Navidian

Position

Phd of Consultation

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Mashahir square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9815676834

Phone
+98 54 3344 2481
Fax
Email
alinavidian@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Zahra Pahlavani Sheikhi
Position
Masters / Academic Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Mashahir square, Zahedan Nursing and Midwifery
Faculty, Sistan and Baluchestan Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3328 5542
Fax
Email
pahlavani_86@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zahedan Medical Sciences
Full name of responsible person
Mahnaz Rigi
Position
Master of Midwifery Consultation
Latest degree
Master
Other areas of specialty/work

Midwifery
Street address
Imam Khomeini 19
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815676834
Phone
+98 915 190 9168
Fax
Email
Ehsan.rigi.1395@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is shared

When the data will become available and for how long

The beginning of the access period 4 months after the publication of the results since 2018

To whom data/document is available

Researchers working in academia and scientific

Under which criteria data/document could be used

Researchers in academia and scientific can access data through articles.

From where data/document is obtainable

pahlavani_86@yahoo.com +98 915 343 6934

What processes are involved for a request to access data/document

After completing the design and analysis of the data through an article in the valid databases in 2018

Comments