Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 primparous 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
Email address
pahlavani@zaums.ac.ir

Recruitment status
Recruitment complete
Funding source
Zahedan University of Medical Sciences

Expected recruitment start date
2017-11-21, 1396/08/30
Expected recruitment end date
2018-04-20, 1397/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Postpartum sexual education
Purpose
Education/Guidance
Inclusion/Exclusion criteria
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.
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.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Blindness in this study is single-blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahadan University of Medical Sciences
Street address
Mashahir square, Zahedan Nursing and Midwifery Faculty, Sistan and Baluchestan Iran Zahedan Sistan and Baluchestan Iran, Islamic Republic Of
City
Zahadan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2017-11-12, 1396/08/21
Ethics committee reference number
IR.ZAUMS.REC.1396.227

Health conditions studied

1

Description of health condition studied
Sexual self-efficacy
ICD-10 code
Z70.8
ICD-10 code description
Other sex counseling

2

Description of health condition studied
Sexual function
ICD-10 code
F52
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
Sxual 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 3-5and 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