

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Effect of Structural Education on the Sexual Function of Pregnant Women Referred to Health Centers in Baharestan

Protocol summary

Study aim

The main objective of the project: Determining the effectiveness of structured education on female sexual function in pregnancy

Design

Design: Randomized, Not blinded, placebo not used. Statistical population: Pregnant women referred to health centers in the city of Baharestan, Tehran province. Inclusion criteria: Pass at least 4 weeks after giving birth to the mother, Maximum gestational age 34 weeks. The exclusion criteria will be: There is a history of preterm labor, There is a history of cervical failure, The presence of Placenta Previa. The sample size included 80 patients.

Settings and conduct

The study population is pregnant women referring to health centers in Baharestan, Tehran province. To do this, at first, four centers of eight urban health centers and the days when a researcher in each center will be present to register pregnant women will be drawn in the draw. In each center, any pregnant woman entering the study is enrolled in the scheme. This will continue until the number of registered people reaches 20. This will be done in all four selected centers. Pregnant women complete the FSFI questionnaire in both control and intervention groups. This is a questionnaire on sexual feelings and responses in the last 4 weeks. In the intervention group, using a training package based on the content of the training, 4 groups will be trained during one week. 2 weeks after the completion of the sessions, the questionnaires will be completed again by the mothers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pass at least 4 weeks after giving birth to the mother; maximum gestational age 34 weeks; not having a history of abortion. The exclusion criteria will be: history of preterm labor; history of cervical failure; presence of placenta previa.

Intervention groups

Pregnant women complete the FSFI questionnaire in both control and intervention groups. This is a questionnaire on sexual feelings and responses in the last 4 week. In the intervention group, using a training package based on the content of the training, 4 sessions will be held within a week of group training. In the control group, training is also provided on the benefits of breastfeeding and normal delivery. Two weeks after the end of the sessions, the questionnaires are completed again by the mothers.

Main outcome variables

Expected outcomes: the results of this study suggest that structured education improves the sexual function of pregnant women, it is suggested that the knowledge gained be used to provide a functional training package in health centers and sexual health centers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140907019077N14**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Sonia Oveisi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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soveisi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source
Qazvin University of Medical Sciences

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-01-20, 1396/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Structural Education on the Sexual Function of Pregnant Women Referred to Health Centers in Baharestan

Public title
The effectiveness of structured education on sexual function of pregnant women

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Pass at least 4 weeks after giving birth to the mother
Maximum gestational age 34 weeks
Exclusion criteria:
There is a history of preterm labor
There is a history of cervical failure
The presence of Placenta Previa

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects registered in this study are divided into two intervention and control groups by random allocation method. At this stage, using the Balanced Block Randomization method, the samples are divided into 5 blocks, which, depending on whether they are in block A or B, are placed in the intervention or control group.

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Boulevard, Qazvin

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qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.QUMS.REC.1396.315

Health conditions studied

1

Description of health condition studied

Female sexual function during pregnancy

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual function

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

Secondary outcomes

1

Description

Desire

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

2

Description

Arousal

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

3

Description

Lubrication

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

4

Description

Orgasm

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

5

Description

Satisfaction

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

6

Description

Pain

Timepoint

Before and two weeks after intervention

Method of measurement

Female sexual function index questionnaire

Intervention groups

1

Description

Intervention group: First, the sexual performance questionnaire is completed by the mothers and their sexual function is measured. Then, participants participate in educational sessions based on the designed training package. The group training sessions are held within a week, which includes 4 sessions for 60 minutes. Two weeks after completing the training sessions, the sexual performance questionnaire will be completed by pregnant mothers.

Category

N/A

2

Description

Control group: First, the sexual performance questionnaire is completed by the mothers and their sexual function is measured. In this group, training is provided on the benefits of breastfeeding and normal delivery, and the sexual performance questionnaire is completed after two weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

valieasr health service center

Full name of responsible person

Mahnaz esmaili

Street address

Shahid Rajaei Square, Shahid Kouhpaee St.

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2

Recruitment center

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Qazvin University of
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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
Vice Chancellor for research of Qazvin 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

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available