

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of education of sex behavior in the pregnant women's sexual function in second and third trimester

Protocol summary

Study aim

Determining the effect of sexual behavior training on sexual function of pregnant women in the second and third trimesters

Design

Randomized clinical trial with control group, four parallel group trial; two groups of intervention and control group were selected. This group according to whether or not you participate in pregnancy classes have two sub group. The sample size for each sub group was 21. Given the 10% drop in samples, the sample size was estimated to be 25 in each sub group.

Settings and conduct

50 pregnant women referred to pregnancy classes in Sayyad Shirazi Hospital were selected by convenience sampling and randomly assigned to two groups. The first group, in addition to routine pregnancy training, will receive sexual education during pregnancy and the second group will receive the same routine pregnancy training. At the same time, 50 mothers pregnant mothers who referred to the prenatal clinic of Gorgan health centers were selected by convenience sampling and randomly assigned to two groups. The first group will receive only sex education and the second group will not attend any class. In the first two groups, the FSFI was completed and eight weeks after the completion of the training sessions, and questionnaire will be completed. and in the group without any training, the questionnaire will be completed eight weeks later.

Participants/Inclusion and exclusion criteria

Primiparus pregnant woman; age between 18 and 35 years old; healthy fetus; single fetus; having satisfaction.

Intervention groups

Persons in intervention group will be participate in sexual behavior training class. Control group who have not participated in any sexual educational class.

Main outcome variables

Sexual function of pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039735N1**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Fateme Seifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3245 6900

Email address

fateme.seifi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

2017-09-11, 1396/06/20

Actual recruitment end date

2018-09-11, 1397/06/20

Trial completion date

empty

Scientific title

The effect of education of sex behavior in the pregnant women's sexual function in second and third trimester

Public title

The effect of education of sex behavior in the pregnant women's sexual function

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparus pregnant woman Age: 18-35 years old

Healthy fetus Single fetus Having satisfaction

Exclusion criteria:

History of surgery in the external and Internal genitalia

History of chronic medical conditions (diabetes, heart, kidney, ...) Taking medications other than folic acid and iron Pelvic relaxation

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Random unit: Individual
Randomization Tool: Use Coin 50 pregnant women referred to pregnancy classes in Sayyad Shirazi Hospital were selected by convenience sampling and simple random assigned using coins in two groups. The first group, in addition to routine pregnancy training, will receive sexual education during pregnancy and the second group will receive the same routine pregnancy training. At the same time, 50 mothers among pregnant mothers referred to the prenatal clinic of Gorgan health centers were selected by convenience sampling and simple random assigned using coins in two groups. The first group will receive only sex education and the second group will not attend any class.

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 Golestan University of Medical Sciences

Street address

Road of Shastkolla, Golestan University of Medical Sciences

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2015-01-11, 1393/10/21

Ethics committee reference number

IR.GOUMS.REC.1393.25188169

Health conditions studied

1

Description of health condition studied

Sexual function

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function

Timepoint

Before and after taking part in the educational class

Method of measurement

Sexual Function Questionnaire, FSFI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group will be participate in sexual behavior training class. this group have two sub group. Group 1: only participated in sexual behavior training class.

Category

Behavior

2

Description

Intervention Group will be participate in sexual behavior training class. this group have two sub group. Group2 : Participation in pregnancy classes in addition of sexual behavior training class.

Category

Behavior

3

Description

Control group have two sub group. Group 1: only participated in prenatal educational class and group

Category

Behavior

4

Description

Control group have two sub group. Group 2: who have not participated in any educational class.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital

Full name of responsible person

Fatemeh Seifi

Street address

Nursing & Midwifery Faculty, Golestan University of Medical Sciences, Road of Shastkollah

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Email

f_seifi2016@yahoo.com

Web page address

http://fa.irct.ir/user/trial/31637/update/recruitment_center

2

Recruitment center

Name of recruitment center

Golha health center, Gorgan city

Full name of responsible person

Fatemeh Seifi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

Street address

Road of Shastkollah Golestan University of Medical Sciences

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Email

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Web page address

<http://fa.irct.ir/user/trial/31637/update/sponsor>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Fatemeh Seifi

Position

coach

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Nursing & Midwifery Faculty., Golestan University of Medical Sciences., Beginning of the Road of Shasta Kalateh., 5th Km of Gorgan Kurdkuy Road

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Narjes Sadat Borghei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Email

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Person responsible for updating data

Contact**Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Fateme Seifi

Position

coach

Latest degree

Master

Other areas of specialty/work

Midwifery

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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

Not applicable

Title and more details about the data/document

the information on the main outcome or the like can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

The data will be available for scientific research with reference to the research. In order to access the data, they can reply to the person's email address.

From where data/document is obtainable

Responsible person's email address
Fatemeh_seifi1979@yahoo.com

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

En Applicants can respond to the email of the respondent and receive a response within a week.

Comments