

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effect of Sexual Education on the Sexual Function of Pregnant Women and Postpartum Referring to Health Services Centers

Protocol summary

Registration timing: **prospective**

Study aim

To determine the effect of women's sexual education on their sexual function during pregnancy and postpartum

Last update: **2018-09-21, 1397/06/30**

Update count: **0**

Design

In this study, 150 pregnant women referred to Health Services Centers are randomly divided into two groups of 75; that in the intervention group, the training will be given by lecture method and the second group will be witnessed.

Registration date

2018-09-21, 1397/06/30

Registrant information

Name

Shiva Alizadeh

Name of organization / entity

Islamic Azad university of rasht

Country

Iran (Islamic Republic of)

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gelayolalizadeh@iaurasht.ac.ir

Settings and conduct

This study is a longitudinal clinical trial. 150 participants of the samples referred to health service centers in Rasht (75 participants in each groups), will be selected randomly (in different regions in terms of economic and social status).

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian nationality; gestational age less than 14 weeks; women's age under 45 years; Having informed consent to participate in the study; Lack of history of medical diseases; lack of consumption of the medication that affect sexual function; lack of drug addiction; lack of high risk pregnancy criteria; lack of experience of an acute stress during recent years such as child's death, wife's betrayal, acute illness, etc.

Exclusion criteria: happening any problem during study.

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2020-04-03, 1399/01/15

Intervention groups

In the intervention group, women will be taught 90 minutes through lecture, question and answer method.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Changes in sexual function score; Change in sexual distress score.

Trial completion date

empty

General information

Scientific title

The Effect of Sexual Education on the Sexual Function of Pregnant Women and Postpartum Referring to Health Services Centers

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131207015697N2**

Registration date: **2018-09-21, 1397/06/30**

Public title

The Effect of Sexual Education on the Sexual Function of

Pregnant Women and Postpartum

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality; Gestational age less than 14 weeks; Women's age under 45 years; Having informed consent to participate in the study; Lack of history of medical diseases; Lack of consumption of the medication that affect sexual function; Lack of drug addiction; Lack of high risk pregnancy criteria; Lack of experience of an acute stress during recent years such as child's death, Wife's betrayal, Acute illness, etc.

Exclusion criteria:

Iranian nationality; Gestational age less than 14 weeks; Women's age under 45 years; Having informed consent to participate in the study; Lack of history of medical diseases; Lack of consumption of the medication that affect sexual function; Lack of drug addiction; Lack of high risk pregnancy criteria; Lack of experience of an acute stress during recent years such as child's death, Wife's betrayal, Acute illness, etc.

Age

To 45 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description

The city's health services centers will be selected randomly (in different parts of the city based on the economic and social status), in each region some of these centers will be used for intervention and others will be witnesses.

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 Guilan University of Medical Sciences

Street address

Shahid Siadati Street, Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2018-08-18, 1397/05/27

Ethics committee reference number

IR.GUMS.REC.1397.194

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 disease

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention

Method of measurement

FSFI Questionnaire

2

Description

Sexual Distress

Timepoint

Before intervention; At the beginning of each subsequent intervention; Four weeks after the last intervention

Method of measurement

Sexual Distress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Face-to-Face training is provided to pregnant women in five sessions -90 minute- through lecture, Question and Answer, PowerPoint training provided by the researcher.

Category

Behavior

2

Description

Control group: Just Routine care is done in control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Services Centers in Rasht

Full name of responsible person

Shiva Alizadeh

Street address

No 6, Mozhdeh building, Second Alleyway, Bayanii Street, Heshmat Intersection

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Shadman Nemati

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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

Rasht 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

Islamic Azad University

Full name of responsible person

Shiva Alizadeh

Position

Faculty Member and Lecturer

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

A report including An Introduction, Methodology, Results and Discussion

When the data will become available and for how long

Access Period 1 Months After Publication

To whom data/document is available

All Officials and Experts of the Ministry of Health and Medical Education

Under which criteria data/document could be used

The applicant's commitment to preserve of the authors' names of this research if it is used

From where data/document is obtainable

A formal application letter to the health department of Guilan University of Medical Sciences or email this letter to the liaison author of this research project, named Shiva Alizadeh and E-mail: gelayolalizadeh@yahoo.com

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

A application letter must include the name of the applicant, used item, scientific title of the research project or article.

Comments