Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

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.

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).

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.

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

Main outcome variables
Changes in sexual function score; Change in sexual distress score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131207015697N2**
Registration date: **2018-09-21, 1397/06/30**
Registration timing: **prospective**

Last update: **2018-09-21, 1397/06/30**
Update count: **0**

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)

Phone
+98 13 1422 2154

Email address
gelayolalizadeh@iaurasht.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2020-04-03, 1399/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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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Phone
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Email
research@gums.ac.ir
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
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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