

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### The Study of Effect of Education of Sexual Health Promotion Package on Sexual Health Dimensions of Pregnant Women

#### Protocol summary

##### Study aim

To determine the effect of education of sexual health promotion package in woman during pregnancy

##### Design

This study is a longitudinal clinical trial. 225 pregnant women referred to Health Centers were randomly divided into three groups of 75 (intervention, self-educated, control).

##### Settings and conduct

In this study, 225 participants of the samples (75 participants in each groups) referred to Health Centers (The State-run Hospitals and health service centers) in Rasht, were selected randomly. In the intervention group, the training was given by lecture method, the second group were self-educated and the third group were control group (without education).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age less than 14 weeks; women's age between 15- 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, acute illness, etc. Exclusion criteria: happening any problem during the study.

##### Intervention groups

In the intervention group, women was taught 90 minutes through lecture, question and answer method in 3 sessions. In the self-educated group, sexual health package (package of pregnant women) was given to them. In the control group was without education.

##### Main outcome variables

Changes in pregnancy sexual response (PSRI) score; Change in sexual function score; Change in sexual quality of life score; Change in sexual violence score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190427043398N1**

Registration date: **2019-06-02, 1398/03/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-02, 1398/03/12**

Update count: **0**

##### Registration date

2019-06-02, 1398/03/12

##### Registrant information

##### Name

Shiva Alizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8865 5466

##### Email address

shiva.alizadeh@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-01, 1397/06/10

##### Expected recruitment end date

2019-06-20, 1398/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Study of Effect of Education of Sexual Health Promotion Package on Sexual Health Dimensions of Pregnant Women

**Public title**

To Determine the Effect of Education of Sexual Health Promotion Package in Woman During Pregnancy

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Inclusion criteria: gestational age less than 14 weeks; women's age between 15- 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, acute illness, etc.

**Exclusion criteria:**

Unwillingness of pregnant women to participate in the study

**Age**

From **15 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **225**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sampling method was done by cluster random sampling in areas of Rasht. In the beginning, Rasht was divided into five regions (East, West, North, South, and Center). The name of the five regions was written separately on paper. Simple randomly was drawn and three regions (East, West, Center) were selected. Then again, in each cluster (region), the name of comprehensive health care centers was written separately on a paper and was simple randomly drawn. In the lottery, the first name of the center was in the intervention group; the second name of the center was in the self-education group and the third in the control group (Three centers in each area).

**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 Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2016-07-18, 1395/04/28

**Ethics committee reference number**

IR.SBMU.PHNM.1395.495

**Health conditions studied****1****Description of health condition studied**

Sexual Health

**ICD-10 code**

Z70.9

**ICD-10 code description**

Sex counseling, unspecified

**Primary outcomes****1****Description**

Sexual Response in pregnancy

**Timepoint**

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

**Method of measurement**

Pregnancy Sexual Response Inventory (PSRI)

**2****Description**

Sexual function

**Timepoint**

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

**Method of measurement**

Female Sexual Function Index (FSFI)

**3****Description**

Sexual Quality of life

**Timepoint**

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

**Method of measurement**

Sexual Quality of life Questionnaire

**4****Description**

Sexual Violence

**Timepoint**

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

**Method of measurement**

Sexual Violence Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First Intervention group: Face-to-Face training is provided to pregnant women in three sessions -90 minute- during pregnancy (first session in the first trimester, second session in the second trimester, third session in the third trimester); through lecture, Question and Answer training provided by the researcher. The Sexual Health Package was designed based on the clinical guidelines of NICE. According to this pattern, the package was designed after searching in the guidelines, books, sexual health packages of various countries, as well as articles. Then, the sexual health package was validated by the Delphi method, using the opinions of specialists and experts in various cities of Iran. This package (In two parts for health care providers and pregnant women) was designed to provide educational content that include the most important aspects of sexual health during pregnancy (for each trimester of pregnancy, an educational session).

**Category**

Behavior

**2****Description**

Second intervention group: Self-educated group: Sexual health package (package of pregnant women) was given to them at the beginning of pregnancy.

**Category**

Behavior

**3****Description**

Control group: Just Routine care was taken in the control group and they did not receive any training packages and intervention. Routine care is prenatal care, which is done based on Iran's Ministry of Health's Pregnancy Care Guidelines and WHO guidelines, such as vaccination, blood pressure control, weight measurement, nutrition counseling for pregnant women.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Comprehensive Health Service Centers in Rasht

**Full name of responsible person**

Shiva Alizadeh

**Street address**

Mozhdeh building., Second Alleyway., Bayanii Street., Heshmat Intersection

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**Email**

shiva.alizadeh@sbmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**Full name of responsible person**

Afshin Zarghi

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Intl\_office@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Shiva Alizadeh  
**Position**  
PhD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Reproductive Health  
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School of Nursing and Midwifery, Shahid Beheshti  
University of Medical Sciences, Niayesh intersection.,  
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shiva.alizadeh@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Giti Ozgoli  
**Position**  
Associated professor  
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Ph.D.  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Shiva Alizadeh  
**Position**  
PhD student  
**Latest degree**  
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**Other areas of specialty/work**  
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**Street address**  
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Vali-e-Asr  
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shiva.alizadeh@sbmu.ac.ir

## 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

Yes - There is 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

### 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

The data will be accessible 6-12 month after publishing the results.

### To whom data/document is available

researchers in academic institutes were allowed to access data

### Under which criteria data/document could be used

with stating the reference

### From where data/document is obtainable

sending email to corresponding author through:  
g.ozgoli@gmail.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**