

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Assessing the effect of sex education package on sexual function on nulliparous pregnant women in the first trimester

#### Protocol summary

##### Summary

The purpose of this randomized clinical trial is to examine the effect of sex education package on the sexual function of nulliparous pregnant women in the first trimester. The statistical population of this research includes all the nulliparous women who go to prenatal clinic of Lolagar and Arash hospital of Tehran to receive routine prenatal care. This study will be on 100 Nulliparous pregnant women who are in the first trimester, and who are qualified to participate for this research. The main inclusion criteria involves not being prohibited by medical reason to have sexual activity, not using the medicines effecting their individual sexual response; and the main exclusion criteria involves abortion, and hyperemesis gravidarum. After taking a written testimonial, the researcher asked the qualified women to fill the questionnaires of demographic information, midwifery information, and the female sexual function index. Randomly and every other week, the participants are assigned to two groups of intervention and control. In the intervention group, participants will be trained about sexual health during pregnancy, using training book and CDs which are provided by the research team. The control group will receive routine prenatal care. Training session will be held once a week, for two sequential weeks and each for 60 minutes. Training book and CDs will be given to the pregnant women at the end of the first session. The participants and their husbands can be counseled for sexual health via telephone.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081123590N1**

Registration date: **2015-09-25, 1394/07/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-25, 1394/07/03

##### Registrant information

###### Name

Leila Norouzi

###### Name of organization / entity

Faculty Of Medical Seinces, Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8288 3809

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University

##### Expected recruitment start date

2014-05-10, 1393/02/20

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the effect of sex education package on sexual function on nulliparous pregnant women in the first trimester

##### Public title

The effect of sex education package on sexual function of nulliparous pregnant women in the first trimester

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous pregnant women in the first trimester; No contraindication for sexual activity due to medical reasons, like: threatened abortion, inevitable abortion, history of infertility, multiple pregnancy; No history of addiction or habitual alcohol consumption by the woman and/or her husband; Not currently taking drugs that may affect on sexual response (Anti-hypertension, Thiazide diuretics, Anti-depression, Anti-histamines, Barbiturates, Narcotics, Diazepines, Amphetamines, Cocaine); Not currently suffering from physical or psychological disease; Not known disorder in sexual function; No severe emotional stress in past 3 months; Live with a permanent spouse; At least literate; Be Iranian  
Exclusion criteria: Abortion; Hyperemesis gravidarum; No sexual activity

## 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: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Tarbiat Modares University

##### Street address

Jalal Ale Ahmad and Shahid Chamran Highways,  
Tarbiat Modares University, Tehran, Iran

##### City

Tehran

##### Postal code

14115-111

#### Approval date

2013-11-30, 1392/09/09

#### Ethics committee reference number

52/4996 ↵

## Health conditions studied

### 1

#### Description of health condition studied

Sex education in 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 intervention, 4 week after intervention

#### Method of measurement

Female Sexual Function Index (FSFI) that will be self administered

## Secondary outcomes

### 1

#### Description

Pregnancy anxiety

#### Timepoint

Before intervention, 4 week after intervention

#### Method of measurement

Pregnancy Related Anxiety Questionnaire (PRAQ) that will be self administered

## Intervention groups

### 1

#### Description

Intervention group: implementation of a sex education package. At first, group education will be conducted in groups with 8-10 women in the selected prenatal centers in two sessions, approximately sixty minutes each session, once a week for two consecutive weeks. One of the research team members, a midwife with special education in sexual health in pregnancy, will teach at the sessions using an educational book and compact disk Compiling by the research team. The book and compact disk will be given to the pregnant women at the end of the first session. The women will be asked to study the book (themselves and their husbands) till the second educational session and ask their questions in the session. The subjects and their husbands in the interventional group can also get telephone counseling about sexual health.

#### Category

Lifestyle

2

**Description**

Control group: Routine prenatal care

**Category**

Lifestyle

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Lolagar Hospital

**Full name of responsible person**

Leila Norouzi

**Street address**

Khosh Street, Between Azerbaijan and Dampezesghi Streets, Tehran, Iran

**City**

Tehran

2

**Recruitment center**

**Name of recruitment center**

Roentan Arash Hospital

**Full name of responsible person**

Leila Norouzi

**Street address**

Baghdarnia Street, Farjam Street, Tehranpars Second Square, Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Dr. Yaaghob Fathollahi

**Street address**

Jalal Ale Ahmad and Shahid Chamran Highways, Tarbiat Modares University, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tarbiat Modares University

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Leila Norouzi

**Position**

Postgraduate Student of Midwifery

**Other areas of specialty/work**

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**Full name of responsible person**

Dr. Minoor Iamyian

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Associate Professor

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**Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*