

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

l.norouzi@modares.ac.ir

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 Dampezeski
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

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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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**Person responsible for scientific
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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