Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of sex education with the husband's participation to promote couples’ sexual functioning during pregnancy.

Protocol summary

Summary

This study is designed with the aim of evaluation the effectiveness of sex education with participant couples during pregnancy on sexual function and sexual satisfaction during pregnancy. This nonrandomized control trial will be done on 120 Couples attending to one of hospital centers Located in Tehran. Couples will assign to three groups, Group A: husband and pregnant women received sex education together, Group B: pregnant women received sex education alone and Group C: pregnant women received routine prenatal care, but no advice on sex (control). Data will collect by five questionnaires including FSFI, ISS, MWSSQ, IIEF and demographic characteristics. The inclusion criteria are prim gravid; living permanently with a spouse; single pregnancy. Exclusion criteria are cervix incompetent; threatened abortion. After completing a written consent, each participant completes a coded unknown pre-test questionnaire. In the intervention group A and B, the sex education classes will be held in two sessions (90 minutes) once a week for two consecutive weeks in the related health centers.Educational content in the first session includes anatomy and physiology of the female and male reproductive system, sexual cycle and orientation with erotic organ. The second session includes sexual behavior during pregnancy and safe position during pregnancy. In this study, the control group received only the center's routine care. The educational session will conduct through lectures, photo and genital models during pregnancy. Sexual function and sexual satisfaction couples will assess four weeks after the intervention, end of second and third trimester in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101930388N1**

Registration date: **2017-01-14, 1395/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-14, 1395/10/25

Registrant information

Name

Masumeh Heidari

Name of organization / entity

Tarbiat Modares University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 0000

Email address

masumeh.heidari@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tarbiat Modares University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-08-05, 1395/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of sex education with the husband's participation to promote couples’ sexual functioning during pregnancy.

Public title
Effective of sex education during pregnancy on sexual function Couple
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: primigravid; single pregnancy; Couples live together Exclusion criteria: cervix incompetent; threatened abortion
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The samples were assigned to three groups: the first couples in group A, the second couples in group B and the third couples in control group assigned and will be repeated.

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares University of Medical Sciences
Street address
No. 7, Jalal Al Ahmad Street, Tehran
City
Tehran
Postal code
14115-1411
Approval date
2015-04-28, 1394/02/08
Ethics committee reference number
ir.tmu.rec.1394.39

Health conditions studied

1

Description of health condition studied
Sexual function and sexual satisfaction in couples during trimester pregnancy
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Sexual function and sexual satisfaction of couples
Timepoint
Before intervention, 4 week after intervention, end of Second trimester and end of Third Trimester of Pregnancy
Method of measurement
Questionnaire FSFI, WMSSQ, IIEF, SSI

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Control group: Pregnant women received routine prenatal care but no advice on sex education during pregnancy.
Category
Other

2

Description
Intervention group B: pregnant women received sex education during pregnancy alone in two sessions (90 minutes) once a week for two consecutive weeks.
Category
Lifestyle

3

Description
Intervention group A: Pregnant women and husband two sessions (90 minutes) once a week for two consecutive weeks received sex education during pregnancy together.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Najmiei Hospital

Full name of responsible person
Shah Hoseinie

Street address
Street Jomhori, Street Intersection of Hafez, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research, Tarbiat modares University of Medical Sciences

Full name of responsible person
Movahedi

Street address
No. 7, Jalal Al Ahmad Street, Tehran

City
Tehran

Grant name
-

Grant code / Reference number
-

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

Title of funding source
vice chancellor for research, Tarbiat modares University of Medical Sciences

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
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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