

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Tarbiat Modares University of Medical Sciences

Full name of responsible person

Masumeh Heidari

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Person responsible for scientific inquiries

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Person responsible for updating data

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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