

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### A comparative study on the effect of face-to-face or group education during the pregnancy period and postpartum on sexual function of the couples

#### Protocol summary

##### Summary

Comparison of the effect of face to face education with group education on sexual function during pregnancy in couples was the purpose of this research, randomized, not blinded, No placebo controlled, multi center, phase trials does not apply in this study, Study population: all pregnant women and their husbands have medical family files (records) in the Isfahan health clinics, Isfahan, Iran, Inclusion criteria: Iranian nationality; Muslim; gestational age more than 20 weeks; women's age under 40 years and men's age around 50 years; Having informed consent to participate in the study. Exclusion criteria: history of medical diseases; consumption of the medication that affect sexual function; addiction in couples; having high risk pregnancy criteria; having experience of an acute stress during recent years such as child's death, spousal treason; acute disease in any of the couples, postpartum depression; use of vacuum or forceps during delivery; birth trauma; birth weight babies over than 4000 gr; postpartum vaginal disorders; and infant mortality. Sample size: 64 couples in each study group (face-to-face education group and group education), Intervention time: during pregnancy, Primary outcome: demographic characteristics include: couple's age, couple's education, length of marriage, and number of pregnancies and children. Female and male Sexual Function Index.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014080518500N2**  
Registration date: **2015-07-06, 1394/04/15**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-06, 1394/04/15

##### Registrant information

###### Name

Maryam Mohammadi Mahdiabadzade

###### Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1826 2498

###### Email address

maryammohamady@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-03-10, 1391/12/20

##### Expected recruitment end date

2014-04-14, 1393/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study on the effect of face-to-face or group education during the pregnancy period and postpartum on sexual function of the couples

##### Public title

A comparative study on the effect of face-to-face or group education during the pregnancy period and

postpartum

392369

## Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: Iranian nationality; couples' being a Muslim; gestational age of over 20 weeks; women's age under 40 years and men's age around 50 years; signing a written consent form by the couples to attend the study; no history of medical diseases in couples; no consumption of the medication contraindicating with sexual function; no addiction to drugs in any of the couples; no high risk pregnancy; and no experience of an acute stress during recent years such as a child's death, spousal treason; acute disease etc in any of the couples, Exclusion criteria; postpartum depression; The use of vacuum or forceps delivery; birth trauma; weighing more than 4000 gr at birth; postpartum vaginal disorders; infant mortality.

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Isfahan University of Medical Sciences

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran

##### Street address

Isfahan University of Medical Sciences, Isfahan, Iran

##### City

Isfahan

##### Postal code

81146-73461

#### Approval date

2013-07-23, 1392/05/01

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

sexual function

#### 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

pre test, One month after the intervention and 10 weeks after delivery

#### Method of measurement

Female Sexual Function Index(FSFI) and Brief form of Sexual Function Inventory (BSFI)

## Secondary outcomes

### 1

#### Description

A comparative study on the effect of face-to-face or group education

#### Timepoint

Before the intervention, after intervention, 10 weeks after delivery

#### Method of measurement

Female Sexual Function Index(FSFI) and Brief form of Sexual Function Inventory (BSFI)

## Intervention groups

### 1

#### Description

Intervention "face-to-face education" In the face-to-face education group, education is conduct in a 90-120 min session through questions and answers and the educational issues, determine by the researcher for each couple with the help of an educational software and slide show, are conduct.

#### Category

Behavior

### 2

#### Description

Intervention "group education" In the group education group, the subjects are divide into three 10-13 subject groups and the education is conduct similar to face-to-

face education group during a 120-min session.

**Category**

Behavior

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Amirhamze Clinic

**Full name of responsible person**

Ms Godarzi

**Street address**

Amirhamze Clinic, Amirhamze, Isfahan

**City**

Isfahan

2

**Recruitment center**

**Name of recruitment center**

Navabsafavi Clinic

**Full name of responsible person**

Ms Tabatabae

**Street address**

Navabsafavi Clinic, Sq Ahmadabad, Isfahan

**City**

Isfahan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Vice Chancellor for research of Isfahan University of Medical Sciences Ashraf Kazemi

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

115

**Grant code / Reference number**

2350

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

Yes

**Title of funding source**

Isfahan 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**

Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of

**Full name of responsible person**

Maryam Mohammadi Mahdiabadzade

**Position**

Msc

**Other areas of specialty/work**

**Street address**

Isfahan University of Medical Sciences, Isfahan, Iran

**City**

Isfahan

**Postal code**

**Phone**

+98 31 3681 6512

**Fax**

**Email**

ba\_zendegy@yahoo.com;

maryammohamady@nm.mui.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of

**Full name of responsible person**

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**Email**

ba\_zendegy@yahoo.com;

maryammohamady@nm.mui.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of

**Full name of responsible person**

Maryam Mohammadi Mahdiabadzade

**Position**

Msc

**Other areas of specialty/work****Street address**

243, Apartments ghazal, 15 Khordad street, Sq  
Mehrab, Yazd

**City**

Yazd

**Postal code**

8916815735

**Phone**

+98 35 3826 2498

**Fax****Email**

ba\_zendegy@yahoo.com;  
maryammohamady@nm.mui.ac.ir

**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*