Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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

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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

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

۸۱۷۴۶-۷۳۴۶۱

Approval date

2013-07-23, 1392/05/01

Ethics committee reference number

392369

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

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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
11ر

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

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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