Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

: The Co-effect of sensate focus technique and pelvic floor muscle exercises education on sexual quality of life and sexual function in primiparous women after vaginal delivery

Protocol summary

Study aim

The aim of this study is valuating the CO- effect of sensate focus technique and pelvic floor muscle exercises education on sexual quality of life and sexual function in primiparous women after vaginal delivery.

Design

This study will be a Phase III of clinical trial. The subjects will be simple randomly assigned into two groups Control and intervention with 41 participants.

Settings and conduct

In the practical training of pelvic floor exercises, the researcher, after evaluating the vaginal pelvic floor strength, will ask the participants to constrict the pelvic floor muscles on the researcher's fingers and based on the dynamic bearing of the pelvic floor muscle and the time of fatigue They have been train for a 5-10 second contraction followed by a 3 second rest period, . sensate focus exercises are also taught in lectures, along with educational slides and related images. The health center of Baharestan, under the supervision of the Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Primiparous women with normal delivery at reproductive age which starting sexual intercourse after delivery

Intervention groups

In the intervention group, a face-to-face training session is conducted by the researcher in the form of lectures and practical training of pelvic floor exercises and speech training, along with the presentation of slides and educational images of the technique of sensory concentration in the presence of the spouse will be done.

Main outcome variables

Sensate focus technique; Pelvic floor muscle exercises; Sexual quality of life; Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181218042041N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Elham Hamdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5632 5542

Email address

mehrasa168@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
: The Co-effect of sensate focus technique and pelvic floor muscle exercises education on sexual quality of life and sexual function in primiparous women after vaginal delivery

Public title
sensate focus technique and pelvic floor muscle exercises education on sexual quality of life and sexual function

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Primiparous women with normal delivery at reproductive age Starting sexual intercourse after delivery Not having a known disease The absence of complications (diseases, bleeding, abortion) during pregnancy and delivery Not having mental illness monogamous husband and living with his wife now and during the study ability to Read and Write Persian Language in the 8-10 weeks after vaginal delivery Being Iranian and living in Tehran Having a healthy infant Having exclusive Breastfeeding couples without addiction to drugs and alcohol infants who had not been hospitalized at the time of the study Non-use of drugs that affect sexual function Non-stressed during the past month The absence of uterine prolapse and cystocell and rectus grade 3 and 4 Not having urinary tract infection Not having history of pelvic surgery (coloporphy, restoration) The absence of active lesions or lesion in the genital area that interferes with sex (penetration). Not having a history of infertility Not having a hard labor (vacuum, lengthy stretch)

Exclusion criteria:
Unwillingness to stay in the study Getting pregnant while studying Failure to do regular exercise training

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **41**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done simply.

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
Ethics committee of Tarbiat Modares University of Medical Sciences

Street address
NO.4Milane 4 West Arghavan Ave.golestan Baharestan City Saveh Road

City
Tehran

Province
Tehran

Postal code
3759118378

Approval date
2019-01-01, 1397/10/11

Ethics committee reference number
IR.MODARES.REC.1397.166

Health conditions studied

1

Description of health condition studied
sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Improving sexual function

Timepoint
One month and then two months later

Method of measurement
questionnaire of female sexual function index (FSFI)

Secondary outcomes

1

Description
Improving sexual quality of life(SQOL-F)

Timepoint
One month and then two months later

Method of measurement
The questionnaire sexual quality of life -female(SQOL-F)

Intervention groups

1

Description

Intervention group: A face-to-face teaching session is provided by the researcher in the form of lectures and practical training of pelvic floor exercises and speech training, along with presentation of slides and Educational pictures educational for sensate focus technique in the presence of the spouse. This two-hour training will be held in classes with 3-5 couples

Category

Behavior

2

Description

Control group: There will be no intervention in the control group and at the end of the intervention period, the training will be provided to the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Baharestan city centeral clinic

Full name of responsible person

Elmira soleimani javan

Street address

No. 98, Mokhaberat ave., Alghadir Blv.,BaharestanTown

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mohammad Taghi Ahmadi

Street address

No. 7, Jalal Al-Ahmad Highway., Tehran., Iran

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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

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shadab Shahali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I will not publish

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

I will not publish

When the data will become available and for how long

I will not publish

To whom data/document is available

I will not publish

Under which criteria data/document could be used

I will not publish

From where data/document is obtainable

I will not publish

What processes are involved for a request to access data/document

I will not publish

Comments

I will not publish