Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The effect of pelvic floor muscle exercises on postpartum sexual function in primiparous women with impaired sexual function

Protocol summary

Study aim
Determining the effectiveness of pelvic floor muscle exercise in primiparous women with postpartum sexual dysfunction

Design
This study is a randomized controlled trial.

Settings and conduct
Cluster random sampling was performed in several health centers in Babol city.

Participants/Inclusion and exclusion criteria
Inclusion in the study: Primiparous women who had a normal delivery or cesarean section 3 to 6 months ago. Ability to read and write, to have sustained sexual activity for at least the last four weeks, to have breastfeeding, to have a sexual function score (FSFI) of less than 26.5 Not included in the study: history or having severe psychiatric disorders, history or having physical illness, users of drugs that cause sexual dysfunction, experience of a stressful event in the last trimester, women who had a traumatic delivery with severe perineal rupture, women who their spouse has masculine factors of sexual dysfunction.

Intervention groups
Intervention group: Kegel exercises and training on how to do it and continue for 8 weeks Control group: Breastfeeding training and its different positions and related training according to the national protocol for breastfeeding promotion

Main outcome variables
Improvement of Female Sexual Function Index after the intervention was the main variable

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200122046228N2**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **retrospective**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date
2020-12-02, 1399/09/12

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-29, 1398/07/07

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
2019-10-02, 1398/07/10

Actual recruitment end date
2020-01-21, 1398/11/01

Trial completion date
2020-04-08, 1399/01/20

Scientific title
The effect of pelvic floor muscle exercises on postpartum sexual function in primiparous women with impaired sexual function

Public title
The effect of pelvic floor muscle exercises on postpartum sexual function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women had normal or cesarean delivery three to six months prior to the commencement of the study. Primiparous women aged 18 to 40. Women are literate (can at least read and write). Women have sexual intercourse with their husbands regularly at least during the last four weeks. Women have breastfeeding. Women have a total Female sexual function index (FSFI) score less than 26.5, which is the cutoff score for diagnosing female sexual dysfunction according to the reference.

Exclusion criteria:

Women with severe psychiatric disorders including severe depression, psychotic disorder and bipolar disorder Women with history of drug abuse Women with chronic conditions Women who take drugs such as barbiturates, benzodiazepine, antidepressants, and antihypertensive which cause sexual dysfunction. Women who have experienced a stressful event over the last three months (death or acute illness of close family members or relatives, or major change in lifestyle). women who have had a traumatic delivery with severe perineal laceration. Women whose husbands have male factors of sexual dysfunction.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After checking inclusion and exclusion criteria, participants are randomly allocated to two groups using permuted block randomization. The size of each permuted block is four and 20 of them will be produced using the statistical software. Since the sampling is performed in four different centers and an allocation ratio of 1: 1 to two groups of intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the samples were selected from four comprehensive health centers of the city of Babol using cluster sampling. Before the intervention, the weight and height of the eligible women were measured. Then their social and demographic characteristics were recorded and they completed the female sexual function index (FSFI) questionnaire. After that, the samples were randomly assigned to two groups using permuted block randomization. The intervention group was divided into groups of 8 to 12 and each group received two face-to-face training sessions every week for two weeks. Each session was held for 120 minutes and the participants were taught the anatomy and physiology of the reproductive system in men and women, the male and female sexual response cycle, the stages of sexual function, and how to perform pelvic floor exercises (once a week). The correct way to do the Kegel exercise is to do 10 contractions of one to three seconds and then take a rest for three seconds. The number and duration of contractions should then increase gradually based on one’s ability in a way that they will be able to do 90 to 100 contractions per day and each contraction should last for five minutes followed by a 5-minute rest. On the other hand, just the same as the intervention group, the control group was divided into groups of 8 to 12 and the members received two 120-minute face-to-face training sessions per week for two weeks. In these sessions, the participants were given lessons about breastfeeding and its different positions and techniques according to the national protocol for promoting breastfeeding. The necessary follow-ups were performed on a weekly basis for both groups through a phone call made by the midwife of each center for at least six weeks. A checklist for recording the daily exercises was also given to the participants to help them provide an accurate weekly report and facilitate further review. The total duration of the treatment was eight weeks (two weeks of training and six weeks of follow-up). At the end of the study, training manuals on sexual function and pelvic floor exercises were provided for the control group. In the intervention group the eligible women were trained to do the pelvic floor exercises. In this regard, they were taught the correct ways to perform Kegel exercises using verbal explanations, pictures and videos. They were also given checklists for their daily exercises. The control group received two 120-minute training sessions every week in breastfeeding and different breastfeeding positions according to the national protocol for promoting breastfeeding.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.MUBABOL.HRI.REC.1398.244

Street address

Faculty of Medicine, Department of Midwifery, University of Medical Sciences, Ganj Afrooz St., Babol, IRAN

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Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.244

Health conditions studied

1

Description of health condition studied

Postpartum female sexual dysfunction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Female Sexual Function Index

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Using the localized standard questionnaire, it is the index of female sexual function, which is the cut-off point for the existence of a score disorder of 26.5.

Secondary outcomes

1

Description

A secondary consequence of this study is the reduction of urinary stress incontinence

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence

Intervention groups

1

Description

Intervention group: Intervention group: Eligible women were trained to do the pelvic floor exercises. In this regard, they were taught the correct ways to perform Kegel exercises using verbal explanations, pictures and videos. They were also given checklists for their daily exercises

Category

Treatment - Other

2

Description

Control group: received two training sessions every week in breastfeeding and different breastfeeding positions according to the national protocol for promoting breastfeeding. Duration of each session was 120 minutes

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service center of Sultan Mohammad Taher

Full name of responsible person

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Sponsors / Funding sources

1

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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

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Public

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available