

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The survey effect of pelvic floor muscle exercises on sexual self-efficacy and sexual quality of life in nulliparous women after childbirth

Protocol summary

Summary

Objectives: Survey effect of pelvic floor muscle exercise on sexual self-efficacy and sexual quality of life, in nulliparous women after childbirth Design: This study is a clinical trial is designed as a before and after. method: this study perform on 104 women refer to selected health centers of Mashhad after obtaining informed consent . sampling will be done as two-stage (class - cluster) and women Be selected who are eligible and at 8 weeks after childbirth. and place in two groups(control-intervention) randomly. After examination including height, weight, BMI and pelvic examination is completed questionnaires by the researcher. Both groups received routine postpartum care training in the face to face for 30 minutes. In addition, the intervention group received a 30 minute face to face training about Kegel exercises. And from them are asked to do these exercises twice daily, and 20 to 15 times per shift their pelvic floor muscles contracted for 10 seconds and to relax for 10 seconds. This exercise should be repeated 20 times (5 min). After 2 minutes of rest, repeat the exercise for 3 times of 5 minutes. The participants will be required in the absence of muscle fatigue Increase the number of exercise to 35 times. Also a Booklet and a training audio CD will be given to the intervention group about Kegel exercises and pelvic floor muscles . Then will be given them the check list recorded of daily exercises . The researcher checks by phone participation of Kegel exercises and other problems. The samples will be asked to return 4 and 8 weeks later to evaluate the problems and Correct method exercises and again will be assessed sexual self efficacy, sexual quality of life at 12 weeks and 16 weeks. Inclusion criteria: Primiparous, vaginal delivery,at 8 weeks after childbirth,healthy singleton infant. Exclusion criteria: Couples addiction drug and alcohol, Couple with a spiritual and medical disease, Postpartum complications, be a professional athlete.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062313750N1**
Registration date: **2013-07-05, 1392/04/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-05, 1392/04/14

Registrant information

Name

Zahra Zare

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Email address

zare901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy Mashhad University of Medical Sciences

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey effect of pelvic floor muscle exercises on sexual self-efficacy and sexual quality of life in nulliparous women after childbirth

Public title

The survey effect of pelvic floor muscle exercises on sexual self-efficacy and sexual quality of life in nulliparous women after childbirth

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: being resident of Mashhad and Iran; be nulliparous and 8 weeks passed of delivery; be vaginal delivery; have a healthy baby; be married and she is only spouse; currently lives with her husband; sex be resumed after delivery and BMI be between 30-20.

Exclusion criteria: couples addiction drug and alcohol; couple with a spiritual and medical disease; postpartum complications; be a professional athlete; stressful events occurred during the last month for couples; history of pelvic surgery or irradiation in the reproductive system; uterine prolapse or cystocele or rectocele grade 3 and 4; perineal signs of infection; inflammation; erythema and severe discharge. Exclusion criteria during the study: continues to be a reluctance to participate in research; become pregnant during the study; have not intercourse; regular exercise during the study; exercises have not done regularly and correctly.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mashhad University of Medical Sciences

Street address

Mashhad

City

Mashhad

Postal code

Approval date

2013-06-08, 1392/03/18

Ethics committee reference number

911064

Health conditions studied

1

Description of health condition studied

Pelvic organ prolapse in women

ICD-10 code

N81

ICD-10 code description

Female genital prolapsed

Primary outcomes

1

Description

sexual self efficacy

Timepoint

Before the intervention and 2 months after the intervention.

Method of measurement

SSES-F

2

Description

sexual quality of life

Timepoint

Before the intervention and 2 months after the intervention.

Method of measurement

SQOL-F

Secondary outcomes

1

Description

Marital satisfaction

Timepoint

Before the intervention and 2 months after the intervention.

Method of measurement

Questionnaires

Intervention groups

1

Description

The intervention group will be asked their pelvic floor

muscles contracted at home twice daily, each for about 20-15 minutes and 20-15 for 10 seconds and then 10 seconds to relax. The exercises is performed in different positions (supine, standing, semi-recumbent, sitting, quadruped). At the same time, participants are encouraged increase the number of exercises in the absence of muscle fatigue to 35 times per shift gradually.

Category

Rehabilitation

2**Description**

The control group Training will be given routine postpartum care in the face to face for 30 minutes and Possible questions in this context to be answered. An educational pamphlet given to them on the care.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emamat Center

Full name of responsible person

Zahra Zare

Street address

Mashhad. Boulevard Emamat - Emamat 28 First Ave Intersection

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2**Recruitment center****Name of recruitment center**

Ali Ebn Abitaleb Center

Full name of responsible person

Zahra Zare

Street address

Shohada Square, St. Shirazi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy Mashhad University of Medical Sciences

Full name of responsible person

Research Deputy Mashhad University of Medical Sciences (Mohammad Ramezani)

Street address

Mashhad. Ebn Sina Street, Building Qureshi

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Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ramezani

Position

Research Assistant

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Position

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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