# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The survey effect of pelvic floor muscle exercises on sexual self-efficacy and sexual quality ofl 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**
Iran (Islamic Republic of)
**Phone**
+98 915 871 0529
**Email address**
zarez901@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 ofl life in nulliparous women after childbirth

**Public title**
The survey effect of pelvic floor muscle exercises on sexual self-efficacy and sexual quality ofl 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

**City**

Mashhad

**2**

**Recruitment center**

**Name of recruitment center**

Ali Ebn Abitaleb Center

**Full name of responsible person**

Zahra Zare

**Street address**

Shohada Square, St. Shirazi

**City**

Mashhad

## 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

**City**

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**

Mashhad. University Avenue - Qureshi Building - Third Floor - Room 307

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1843 3363

**Fax**

**Email**

ramresearch@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Faculty of Nursing Midwifery, Mashhad

**Full name of responsible person**

Nahid Golmakani

**Position**

MSc

**Other areas of specialty/work**

**Street address**

Mashhad, University Street, Ibn Sina Street, Faculty of Nursing and Midwifery

**City**

Mashhad

**Postal code**

9137913199

**Phone**

+98 51138591511

**Fax**

**Email**

nms.it@mums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Zare

**Position**

Student

**Other areas of specialty/work**

**Street address**

Faculty of Nursing Midwifery, Mashhad

**City**

Mashhad

**Postal code**

**Phone**

**Fax**

**Email**

zarez901@mums.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*