

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

The effect of a pelvic floor muscle exercise program on sexual function of women during pregnancy and after delivery: a randomized controlled trial

Protocol summary

Summary

This randomized controlled trial aims to determine the effect of a pelvic floor muscle exercise program on female sexual performance during pregnancy and after childbirth. 84 nulliparous women at 17-20 weeks of gestation aged 18-35 years referring to health centres of Sari city-Iran will be recruited and randomized into two treatment and control groups using stratified block randomization with block sizes of 4 and 6 and allocation ratio 1:1. A person not involved in sampling and data collection will put group identification paper into sequentially numbered sealed opaque packs to conceal allocation sequence. The exercises will be done twice a day; 8-12 set of contractions at each time, every set includes a strong contraction with a maximum possible power holding for 6-8 seconds followed by 3 or 4 contractions in shorter period, with a 10-seconds resting after each contraction. The treatment group will get practical and written education about the exercises at the recruitment day. Accuracy of the exercise performance will be checked at different positions at three about 30-minutes meetings held at 22-24, 28-30, 34-36 weeks of gestation. Also, telephone follow-up will be done weekly in the first month and every other week afterwards. The control group will get usual care. Sexual function, pelvic floor muscle strength, and health related and sexual quality of life will be assessed at 28th-30th weeks of gestation and at third month after birth and urinary incontinence at 34th-36th weeks and the third month after delivery by someone not aware of allocation of the people in the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403013706N22**

Registration date: **2014-04-04, 1393/01/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-04-04, 1393/01/15

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-04-10, 1393/01/21

Expected recruitment end date

2014-07-10, 1393/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a pelvic floor muscle exercise program on sexual function of women during pregnancy and after delivery: a randomized controlled trial

Public title

The effect of a pelvic floor muscle exercise program on sexual function of women during pregnancy and after delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Having a record at the health centres, 2. Having middle school or above education, 3. No history of previous delivery, 4. Having a single pregnancy, 5. Aged 18 to 35 years, 6. Gestational age of 17-20 weeks, 7. Permanent marriage and living with husband. Exclusion criteria: 1. Addiction to drugs and alcohol, 2. History of two or more abortions, 3. Experience of severe emotional stress within the previous three months, 4. Physical or mental diseases affected on sexual function (e.g., depression, mania, limb amputation or paralysis, the phobias, vaginismus, 5. Taking medicines affected on sexual function (including blood pressure drugs, thiazide diuretics, anti-depressants, anti-histamines, barbiturates, narcotics, Diazepines and amphetamines, cocaine), 6. History of any pregnancy-related complications limited sexual performance according physician advice (e.g., placenta previa, cervical cerclage) 7. Underlying medical diseases (cardiovascular, gastrointestinal, respiratory, epilepsy, blood pressure), 8. Pelvic floor muscle strength of Level one or less (according to the Oxford grading criteria) or hereditary disease affecting connective tissue (such as Marfan syndrome, muscular dystrophy) or maternal abnormalities in the reproductive system, 9. Having over 12 urinary incontinence episodes per day, 10. Addiction or mental or physical problems of husband affecting on couple sexual function

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Only outcome assessor will be blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Tabriz University of Medical Sciences

Street address

Research Deputy, 3rd floor, Central building No 2, Tabriz University of Medical Sciences, Golgasht st., Tabriz, Iran

City

Tabriz

Postal code

Approval date

2014-02-19, 1392/11/30

Ethics committee reference number

92203

Health conditions studied

1

Description of health condition studied

Maternal diseases

ICD-10 code

099

ICD-10 code description

Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

sexual function

Timepoint

At baseline, 28-30 weeks of gestation, 3 months after delivery

Method of measurement

FSFI Questionnaire

Secondary outcomes

1

Description

Pelvic floor muscle strength

Timepoint

At baseline, 28-30 weeks gestation, 3 months after delivery

Method of measurement

Oxford grading system

2

Description

Health-related Quality of Life

Timepoint

28-30 weeks of gestation, 3 months after delivery

Method of measurement

Sf-36 questionnaire

3

Description

Quality of sexual life

Timepoint

28-30 weeks of pregnancy

Method of measurement

SQOL-f Questionnaire

4

Description

Urinary Incontinence

Timepoint

36-34 weeks of gestation, 3 months after delivery

Method of measurement

ICIQ-SF questionnaire.

Intervention groups

1

Description

Intervention group: Pelvic floor exercises will be done twice a day; 8-12 set of contractions at each time, every set includes a strong contraction with a maximum possible power holding for 6-8 seconds followed by 3 or 4 contractions in shorter period, with a 10-seconds resting after each contraction. The treatment group will get practical and written education about the exercises at the recruitment day. Accuracy of the exercise performance will be checked at different positions at three about 30-minutes meetings held at 22-24, 28-30, 34-36 weeks of gestation. Also, telephone follow-up will be done weekly in the first month and every other week afterwards.

Category

Prevention

2

Description

Control group will receive regular care and will get education on personal hygiene and care of the newborn at one session at 28- 30 weeks of gestation

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Public health centers in Sari city

Full name of responsible person

Zahra Pourkhiz- MSc student in midwifery

Street address

Sari, Shahband street, Province health center

City

Sari

2

Recruitment center

Name of recruitment center

Clinic 1

Full name of responsible person

Zahra Pourkhiz- MSc student in midwifery

Street address

Amyrmazndrany Street, opposite the mosque Abolfazl

City

Sari

3

Recruitment center

Name of recruitment center

Clinic 2

Full name of responsible person

Zahra Pourkhiz - MSc student in midwifery

Street address

shohda Square, in front of Technical-Professional

City

Sari

4

Recruitment center

Name of recruitment center

Clinic 3 (Resalat)

Full name of responsible person

Zahra Pourkhiz - MSc student in midwifery

Street address

Rahband street, Lane Ghanbari

City

Sari

5

Recruitment center

Name of recruitment center

Clinic 4 (Clinic Adibi martyr)

Full name of responsible person

Zahra Pourkhiz - MSc student in midwifery

Street address

Imam Reza Boulevard, Tajan Bridge

City

Sari

6

Recruitment center

Name of recruitment center

Clinic 6 (Clinic of Red Crescent)

Full name of responsible person

zahra.pourkhiz - MSc student in midwifery

Street address

Saat Square, 18 day street

City

Sari

7

Recruitment center

Name of recruitment center

clinic 7 (Shahid Babaie)

Full name of responsible person

Zahra Pourkhiz - MSc student in midwifery

Street address

Rahband street

City

Sari

8

Recruitment center

Name of recruitment center

Clinic 8

Full name of responsible person

Zahra Pourkhiz - MSc student in midwifery

Street address

Rahband street

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Research Deputy, 3rd floor, Central building No 2 ,
Tabriz University of medical Sciences, Golgasht st.,
Tabriz, Iran

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research deputy of Tabriz 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

Midwifery Department, Faculty of Nursing &
Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Zahra Pourkhiz

Position

MSc student in midwifery

Other areas of specialty/work

Street address

Kousar Dormitory, South Shariati Ave, Tabriz, Iran

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Fax

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Midwifery Department, Faculty of Nursing and
Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh-Charandabi

Position

Associate Professor, PhD in Reproductive Health

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

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Sakineh Mohammad-Alizadeh

Position

Associate Professor, PhD in Reproductive Health

Other areas of specialty/work

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alizades@tbzmed.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