

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of pelvic floor muscle training using biofeedback on the symptoms and quality of life of the women with pelvic organ prolapse

#### Protocol summary

2019-04-27, 1398/02/07

#### Study aim

Evaluation of the effect of pelvic floor muscle training using biofeedback on the symptoms of the women with pelvic organ prolapse

#### Design

The study only has an intervention group. sample size is 20.

#### Settings and conduct

Patients with pelvic organ prolapse will be referred by a gynecologist after an examination. Patients will be treated at the clinic of the Rehabilitation School of Isfahan University of Medical Sciences and by the responsible student. Treatment will be pelvic floor muscle training using biofeedback. The symptoms of prolapse and urinary incontinence will be measured before intervention and after 12 sessions of treatment.

#### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women aged 20-70 years; Women with stage 2 or 3 prolapse Non-inclusion criteria: Women with neurological and psychological disorders

#### Intervention groups

This study has a group and its intervention, is pelvic floor muscle training using biofeedback.

#### Main outcome variables

Stage of prolapse; quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180828040898N2**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **retrospective**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Zahra Gorji

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5724 1347

##### Email address

zahra.gorji70@ymail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-04-19, 1397/01/30

#### Expected recruitment end date

2019-01-20, 1397/10/30

#### Actual recruitment start date

2018-04-30, 1397/02/10

#### Actual recruitment end date

2018-09-21, 1397/06/30

#### Trial completion date

2018-10-23, 1397/08/01

#### Scientific title

Effect of pelvic floor muscle training using biofeedback on the symptoms and quality of life of the women with pelvic organ prolapse

#### Public title

The effect of biofeedback on the symptoms of the women with prolapse

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women with pelvic organ prolapse Women aged 20 to 70 years

**Exclusion criteria:**

Breastfeeding previous prolapse surgery neurological and psychological disorders untreated urinary tract infection

**Age**

From **20 years** old to **70 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

Actual sample size reached: **20**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical Committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jarib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

87713878710

**Approval date**

2017-01-14, 1395/10/25

**Ethics committee reference number**

IR.NUI.REC.1396.3.759

**Health conditions studied****1****Description of health condition studied**

Pelvic Organ Prolapse

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Stage of pelvic organ prolapse

**Timepoint**

At the beginning of the study and 4 weeks later at the last treatment session

**Method of measurement**

Pelvic Organ Prolapse Quantification system

**2****Description**

Quality of life

**Timepoint**

At the beginning of the study and 4 weeks later at the last treatment session

**Method of measurement**

Prolapse Quality of Life Questionnaire

**Secondary outcomes****1****Description**

Symptoms of urinary incontinence

**Timepoint**

At the beginning of the study and after 4 weeks

**Method of measurement**

International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms questionnaire

**2****Description**

Pelvic floor muscle strength

**Timepoint**

At the beginning of the study and after 4 weeks

**Method of measurement**

Perineometer instrument

**Intervention groups****1****Description**

Intervention group: In this group, patients will receive pelvic floor muscle training using biofeedback. Patients will be treated with Biofeedback for 4 weeks and 3 sessions each week. Each treatment session will be 30 minutes.

**Category**

Rehabilitation

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Zahra Gorji

**Street address**

Soffe Ave., Azady Squar

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**Province**

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**Postal code**

87713-46173

**Phone**

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**Email**

Zahra.gorji70@ymail.com

## 2

### Recruitment center

**Name of recruitment center**

Sedighe Tahere hospital

**Full name of responsible person**

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## 3

### Recruitment center

**Name of recruitment center**

Shahidbeheshty hospital

**Full name of responsible person**

Zahra Gorji

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Motahary Ave

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**Email**

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## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Abbas ali Pourmomeny

**Street address**

Hezar jarib Ave., Azady Squar., Kuye Emam

Neighbourhood

**City**

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**Province**

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**Email**

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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**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Gorji

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

Not applicable