

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Investigating the effect of self-care application compared to routine care on the quality of life of patients with pelvic organ prolapse.

#### Protocol summary

##### Study aim

Determining the effect of self-care application on the quality of life of women with pelvic organ prolapse

##### Design

A randomized clinical trial, with a control group with parallel groups, on 64 patients. Without blinding, randomization will be done by random allocation software.

##### Settings and conduct

Place of conducting this study: Women's Clinic of Imam Reza Hospital (AS); Women's Clinic of Hazrat Qaim Hospital; Women's Clinic of Umm El Benin Hospital; Gynecology Clinic in Mashhad. It will be done on 64 women with pelvic organ prolapse. This study is not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having symptoms of pelvic organ prolapse; Physician confirmation by examination for prolapse  $\leq$ III according to POP-Q; Literate to read and write, have a smartphone or tablet under the Android system, the ability to use a smartphone. Exclusion criteria: suffering from any type of urinary incontinence with a moderate to high degree based on the ICIQ-UI SF questionnaire; celibacy; use of neuroleptics; use of antagonists; pregnancy; history of hip surgery in the past year; History of pelvic physiotherapy in the last year.

##### Intervention groups

Intervention group: women with pelvic organ prolapse  $\leq$ III according to POP-Q, who meet the criteria for entering the research and install, study and implement the self-care application in addition to routine care and recommendations. Control group: women with pelvic organ prolapse  $\leq$ III according to POP-Q, who met the criteria for entering the research and received education related to prolapse face-to-face and pamphlets.

##### Main outcome variables

Quality of Life; Knowledge

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230923059497N1**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

##### Registration date

2023-12-02, 1402/09/11

##### Registrant information

##### Name

Zohra Mosavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3375 4017

##### Email address

mousaviz991@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-27, 1402/09/06

##### Expected recruitment end date

2024-02-18, 1402/11/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of self-care application compared to routine care on the quality of life of patients with pelvic organ prolapse.

#### Public title

The effect of using the application on the quality of life of women with pelvic organ prolapse

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Having symptoms of pelvic organ prolapse Physician confirmation by examination for prolapse less or equal to III according to POP-Q Having a smartphone or tablet under the Android system The ability to use a smartphone Literate to read and write

##### Exclusion criteria:

Suffering from any type of urinary incontinence with a moderate to high degree based on the ICIQ-UI SF questionnaire Use of neuroleptics Use of antagonists pregnancy Celibacy History of pelvic physiotherapy in the last year History of pelvic surgery in the last year Childbirth in the past year Use of pessary

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 64

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

People will be randomly divided into intervention and control groups. In this study, permutation blocks method will be used to generate the sequence of random assignment of people to the studied groups. The sequence of random allocation of people will be done using Random Allocation Software and the block size of four. There are six blocks in this study.

#### 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

Ethics Committee of Mashhad University of Medical Sciences

#### Street address

Shahid Doctor Khwarazmi Educational Complex, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913199

#### Approval date

2023-06-30, 1402/04/09

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1402.070

### Health conditions studied

#### 1

##### Description of health condition studied

pelvic organ prolapse.

##### ICD-10 code

N81.81

##### ICD-10 code description

Perineocele

### Primary outcomes

#### 1

##### Description

The score obtained in the quality of life questionnaire for prolapse disorders

##### Timepoint

The beginning of the study (before the start of the intervention) and two months after its start

##### Method of measurement

Quality of life questionnaire for prolapse disorders

#### 2

##### Description

Degree of prolapse

##### Timepoint

The beginning of the study (before the start of the intervention) and two months after its start

##### Method of measurement

POP-Q system

### Secondary outcomes

#### 1

##### Description

The score obtained in the prolapse knowledge questionnaire.

##### Timepoint

At the beginning of the study (before the start of the intervention) and two months after the intervention

##### Method of measurement

Prolapse knowledge questionnaire.

## 2

### **Description**

The score obtained in the incontinence questionnaire

### **Timepoint**

At the beginning of the study (before the start of the intervention) and two months after the intervention

### **Method of measurement**

Incontinence knowledge questionnaire

## **Intervention groups**

### 1

#### **Description**

"Intervention group:" These people watch and practice pelvic floor muscle strengthening exercises with the application 30 minutes a day for 2 months and have access to the educational content in the application and the quality of life form related to pelvic organ prolapse. They will complete the research at the beginning and 2 months after receiving the application.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: These women will receive face-to-face prolapse education and pamphlets and will complete the quality of life form related to pelvic organ prolapse at the beginning of the study and 2 months after receiving the pamphlet and face-to-face education. .

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Zohra Mosavi

##### **Street address**

Imam Reza Hospital; Imam Reza Square; Ibn Sina Street

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

1377591766

##### **Phone**

+98 51 3842 6082

##### **Email**

mousaviz991@mums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Umm al-Binin Hospital

##### **Full name of responsible person**

Zohra Mosavi

##### **Street address**

At the corner of Ayatollah Behjat 16; Zarineh intersection

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9144663090

##### **Phone**

+98 51 3223 1065

##### **Email**

oah.it@mums.ac.ir

##### **Web page address**

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem Hospital

##### **Full name of responsible person**

Zohra Mosavi

##### **Street address**

At the beginning of Ahmad Abad Street, Dr. Ali Shariati Square, Mashhad

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9176699199

##### **Phone**

+98 51 3840 0000

##### **Email**

Quaem.Medical.Center@mums.ac.ir

##### **Web page address**

<https://quaem.mums.ac.ir>

### 4

#### **Recruitment center**

##### **Name of recruitment center**

Gynecology clinic

##### **Full name of responsible person**

Zohra Mosavi

##### **Street address**

Nesl Omid clinic, second floor, Pasteur 5; Pasteur; Ahmedabad,

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

1377591766

##### **Phone**

+98 51 3846 7145

**Fax**  
+98 51 3847 4012  
**Email**  
nasle.omid96@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Mohsen Tafaghodi  
**Street address**  
Research and Technology Vice-Chancellor; Qureshi Building; next to Hoizeh Cinema, Daneshgah Street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9138813944  
**Phone**  
+98 51 3841 1538  
**Fax**  
**Email**  
tafaghodim@mums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Vice President of Research and Technology of Mashhad University of Medical Sciences and Health Services  
**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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Zahra Hadizadeh talasaz  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**

Shahid Doctor Khwarazmi Educational Complex,  
University Campus, East Gate of Ferdowsi University  
of Mashhad, Azadi Square.

**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
+98 51 3859 1511  
**Email**  
HadizadehZ@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Zahra Hadizadeh talasaz  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Shahid Doctor Khwarazmi Educational Complex,  
University Campus, East Gate of Ferdowsi University  
of Mashhad, Azadi Square.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913199  
**Phone**  
3-38591511 051  
**Fax**  
**Email**  
HadizadehZ@mums.ac.ir  
**Web page address**  
<http://nurse.mums.ac.ir/index.php>

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Zohra Mosavi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Shahid Doctor Khwarazmi Educational Complex,  
University Campus, East Gate of Ferdowsi University

of Mashhad, Azadi Square.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

: 9137913199

**Phone**

0098513754017

**Email**

mousaviz991@mums.ac.ir

**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