

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of using the pelvic floor muscle training application in comparison with physiotherapy in patients with urinary incontinence

#### Protocol summary

##### Study aim

Determining the efficiency of using the pelvic floor muscle strengthening training application compared to physiotherapy in patients with urinary incontinence.

##### Design

70 patients will be placed in two groups of physiotherapy or application with parallel groups, single blinded and randomized by random allocation software.

##### Settings and conduct

After obtaining written informed consent from the participants, and at the Al-Zahra Hospital in Isfahan, two ICIQ- SF and ICIQ-L were administered in both groups before the intervention and 3 months later. It will be completed during an interview from the beginning of the treatment. In the physiotherapy group, 20-15 physiotherapy sessions will be prescribed. which they will undergo in khorshid physiotherapy center. In the application group, the necessary Kegel exercises are given to the patients. After completing the follow-up period of all patients, the obtained information will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-70 years; Female gender; Persistence of urinary incontinence symptoms at least once a week ; Stress incontinence or Mixed; BMI=20-30; POP grade 1 or 2; - The exclusion criteria are: Pregnancy; Difficulty passing urine; Macroscopic hematuria; Patients whose urinary symptoms were diagnosed in the POP grade 3 or 4.

##### Intervention groups

Patients included in this study are divided into two groups intervention group use the application designed to perform the exercises and Patients in the control group will be treated with pelvic floor muscle physiotherapy for 15-20 sessions.

##### Main outcome variables

Study group: Urinary frequency score (before and after

treatment); Urine leakage score (before and after treatment); The impact score of urinary leakage on the quality of life (before and after treatment); Quality of life score (before and after treatment).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210928052626N1**

Registration date: **2022-11-27, 1401/09/06**

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

Last update: **2022-11-27, 1401/09/06**

Update count: **0**

##### Registration date

2022-11-27, 1401/09/06

##### Registrant information

##### Name

Maede Safari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3786 6001

##### Email address

safari.maede@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the efficacy of using the pelvic floor muscle training application in comparison with physiotherapy in patients with urinary incontinence

**Public title**  
Evaluation of the efficacy of using the pelvic floor muscle training application in comparison with physiotherapy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age : 18-70 y/o Female Urinary incontinence for at least once a week Diagnosed stress or mixed incontinence Vaginal prolapse grade 1 or 2 BMI=20-30

**Exclusion criteria:**  
Difficulty urinating Pregnancy Macroscopic hematuria Urinary symptoms related to grade 3 or 4 of POP

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
first the participants are grouped by degree of urinary incontinence in three groups, then the patient's names are sorted by the alphabetic order, and each of them assigned a number. Patients are randomly assigned to control and intervention groups by random allocation software in individual units. Block randomization will be used with a block size of 6.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
n this study, the patients and the clinical caregiver providing physiotherapy services and the person who teaches the use of the app are aware of which group they belong to. However, the researcher and the analyst do not know about the division of the patients.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical sciences

##### Street address

Kharazmi 3 avenue, Sepahanshahr

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8179975514

#### Approval date

2022-10-19, 1401/07/27

#### Ethics committee reference number

IR.MUI.MED.REC.1401.267

## Health conditions studied

### 1

#### Description of health condition studied

stress or mixed urinary incontinence

#### ICD-10 code

N39.3

#### ICD-10 code description

Stress incontinence (female) (male)

## Primary outcomes

### 1

#### Description

The score obtained in the International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life

#### Timepoint

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

#### Method of measurement

The ICIQ-LUTS-qol questionnaire

### 2

#### Description

The score obtained in the International Consultation on Incontinence Questionnaire - Short Form

#### Timepoint

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

#### Method of measurement

International Consultation on Incontinence Questionnaire - Short Form questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervention group: our designed application is used to train the intervention group with kegel exercises for three months and 30 minutes each day.

#### Category

Rehabilitation

### 2

#### Description

Control group: these patients are prescribed 10-15 physiotherapy sessions for pelvic floor muscle training

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Educational and therapeutic centers of Isfahan

##### Full name of responsible person

Maede Safari

##### Street address

No. 46, Latif dead end, Shadab Ave, Weast Sharif ave, Kharazmi 3 ave, Qadir Blvd., Sepahan shahr Town

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##### Province

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8179975514

##### Phone

+98 31 3650 7377

##### Email

safari.maede@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Mansour Siavash

##### Street address

Isfahan University of Medical Sciences, Hezarjarib Avenue

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3668 0048

##### Email

siavash@med.mui.ac.ir

#### 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

Maede Safari

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Urology

##### Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Services

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##### Province

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##### Postal code

73461-81746

##### Phone

+98 31 3668 0048

##### Email

safari.maede@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Maede Safari

##### Position

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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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**

Resident

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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**

Undecided - It is not yet known if there will be a plan to make this available