Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Isfehan

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

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
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Maede Safari
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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