

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of pelvic floor muscle training with vaginal cones along with The Knack manoeuvre on the severity of incontinence and quality of life in women with urinary stress incontinence

Protocol summary

Study aim

Determining the effectiveness of pelvic floor muscle exercises with vaginal cone with the Knack maneuver on the severity of incontinence and quality of life in women with stress urinary incontinence

Design

76 participants are screened with qualification and by random allocation of 2 blocks with excel software, they are divided into two groups of intervention and control, and after a preliminary evaluation session, they are finally recruited.

Settings and conduct

This study is performed in the pelvic floor physiotherapy clinic of the Faculty of Rehabilitation Sciences, Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: existence of stress urinary incontinence (without emergency incontinence) based on the patient's own statements, by filling out a standardized questionnaire to diagnose urinary incontinence (QUID); having a leak of urine with at least one episode during the last month; age 30 to 70 years old; no uncontrolled blood pressure; no surgical history due to incontinence; no chronic degenerative diseases that affect nerve and muscle tissue (diabetes, MS); no history of childbirth in less than two months; not being pregnant. Exclusion criteria: advanced urogenital prolapse (stage III - stage IV); existence of urogenital infection; perform any treatment (pharmacological and physical) for incontinence during the study; inability to perform the proposed methods; patient dissatisfaction with continued cooperation with the research team.

Intervention groups

Intervention group: A group that exercises pelvic floor muscles with a vaginal cone, along with the Knack maneuver (n = 38). Control group: A group that exercises pelvic floor muscles with a vaginal cone (n =

38).

Main outcome variables

Severity of urinary incontinence; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049719N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Leila Parsamoin

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pelvic floor muscle training with vaginal cones along with The Knack manoeuvre on the severity of incontinence and quality of life in women with urinary stress incontinence

Public title

Effects of vaginal cones along with the Knack manoeuvre on urinary stress incontinence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Existence of stress urinary incontinence (without emergency incontinence) based on the patient's own statements, by filling out a standardized questionnaire to diagnose urinary incontinence (QUID) Having a leak of urine with at least one episode during the last month Age 30 to 70 years No uncontrolled blood pressure No surgical history due to incontinence No chronic degenerative diseases that affect nerve and muscle tissue (diabetes, MS) No history of childbirth in less than two months Not pregnant

Exclusion criteria:

Advanced urogenital prolapse (stage III - stage IV) Existence of urogenital infection Receive any treatment (pharmacological and physical) for incontinence during the study Inability to perform the proposed methods Patient dissatisfaction with continued cooperation with the research team

Age

From **30 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

76 participants are screened with competence and by random allocation of 4 blocks as follows, they are divided into two groups of intervention and control. Block1: AABB Block2: ABBA Block3: ABAB Block4: BABA Block5: BBAA Block6: BABA We write 6 modes on 6 cards and pick one of these cards by accident.

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 Iran University of Medical Sciences

Street address

Fifth Floor, Headquarters of Iran University of Medical Sciences, between Chamran and Sheikh Fazlollah, Hemmat Highway,

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Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.IUMS.REC.1399.990

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

Stress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence

Primary outcomes**1****Description**

Severity of urinary incontinence

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Urinary Diary

2**Description**

Incontinence quality of life

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Incontinence quality of life questionnaire

Secondary outcomes

1

Description

The rate of involuntary leakage of urine during stress

Timepoint

Before the start of the study (before the intervention), 12 weeks after the intervention

Method of measurement

Urinary diary

2

Description

Number of leaks

Timepoint

Before the start of the study (before the intervention), 12 weeks after the intervention

Method of measurement

Urinary diary

3

Description

The strength of the pelvic floor muscles

Timepoint

Before the start of the study (before the intervention), 12 weeks after the intervention

Method of measurement

Dynamometer

Intervention groups

1

Description

Intervention group: First, the size of the cone that each patient should use to start training is determined by vaginal examination with two fingers. The appropriate cone is gently inserted into the female vagina by the researcher in the dorsal recumbent position while the tip of the cone and its nylon thread point down. Will be placed. If the participant's vagina is larger than two fingers in diameter, it will most likely be difficult for her to hold the small cone, in which case we will start with the larger cone. If the cone is inserted correctly, the participant should feel comfortable and the cone should not move. From now on, the weight is added to the empty cone. We start with the lowest value and whenever the patient is able to hold the cone with that weight inside his vagina, we try the heavier weight so that eventually the patient can no longer hold that weight in his vagina. With this amount of weight, the patient should start his exercises from the open arch position. In this case, we instruct the patient to try to hold the weight for 5 seconds and gradually 10 seconds by contracting the vaginal area (ie, contracting and pulling up the pelvic floor muscles). When he could easily hold the weight for 10 seconds, then he practiced standing. In this case, too, he should hold the cone in his vagina by contracting the pelvic floor muscles. The

contraction time also gradually increases from 5 seconds to 10 seconds. Once the patient is able to easily hold the cone in a standing position for 10 seconds, he or she can progress the exercise and gradually keep the cone from 5 seconds to 10 seconds while walking by contracting the pelvic floor muscles. It should be noted that the patient should relax the pelvic floor muscles for ten seconds after every 5 to 10 seconds of contraction. Exercise is done twice a day for 3 to 10 minutes at a time. When a person can easily hold the cone while walking for 10 seconds, he can start with a heavier weight in the open arch position, and similarly, the patient can exercise by increasing the weight and changing the position, ie standing from the open arch and walking position. Develops. In addition to training the pelvic floor muscles by the vaginal cone, the intervention group is also trained in maneuvering. In this way, the pelvic floor physiotherapist teaches the participant that any activity that is associated with increased intra-abdominal pressure, such as coughing, sneezing, lifting heavy weights, climbing stairs, or similar activities, first and foremost. Before that activity occurs, contract the pelvic floor activity and gradually try to contract the pelvic floor muscles at the exact moment the activity occurs, thus improving the maneuver.

Category

Rehabilitation

2

Description

Control group: The participants of the control group also follow the same treatment protocol (similar to the intervention group) without maneuvering for 12 weeks. Patients are asked to record the time of weight gain and change in their position in each amount of weight in the relevant table.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pelvic floor clinic, School of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Leila Parsamoin

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

Research Assistant of Iran University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Leila Parsamoin

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

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

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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