Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of pelvic floor muscle training with vaginal cones along with The Knack manouvre 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

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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 manouvre 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 manouvre 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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Postal code
1498753634
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
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Sponsors / Funding sources

1

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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

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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