

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Kegel exercise effect on urinary incontinence, frailty index and self-esteem in elderly men after Transurethral Resection of Prostate (TURP) in Ilam county in 2021 (a randomized, single-blinded, controlled clinical trial)

Protocol summary

Study aim

Determining the effect of Kegel exercise on Urinary Incontinence, Frailty Index, and Self-esteem in the elderly after Prostatectomy

Design

The study has a control group and an intervention group, each group of 38 people and a total of 76 patients will be present in the study. Balance-block randomization with 4 permutations will be used for random allocation. Blocks used include: 1.CCII, 2. CICI, 3. CIIC, 4. IICC, 5. ICIC and 6. ICCI in which the letter I(Intervention) and the letter C (control) will be. RAS (Research Analysis and Statistics) software was used to generate random blocks.

Settings and conduct

The study site is the patient's place of residence. The study method will include 60 Kegel exercises daily for 12 weeks. But no softening will be done for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Transurethral Resection of Prostate (TURP), no history of other pelvic surgeries, no diagnosis of prostate cancer after surgery according to biopsy and pathology results, living in Ilam province, obtaining a score of 24 and above in MMSE, a score of 4 and above In the Urinary Incontinence Diagnosis Questionnaire, a score higher than 5 in the Edmonton Frailty Scale Questionnaire Exclusion criteria: Any hospitalization after the intervention, Urinary Tract Infection immediately after surgery, use of drugs to control urinary incontinence, candidate for chemotherapy after surgery due to diagnosis of other types of cancer

Intervention groups

The intervention group will perform 60 Kegel exercises daily for 12 weeks after surgery. The control group will not perform any exercises.

Main outcome variables

Decreased Urinary Incontinence; Increase Self-esteem; decreased frailty; positive effect of increased Self-esteem on decrease frailty

General information

Reason for update

Change of writing in the title of the article for printing

Acronym

IRCT registration information

IRCT registration number: **IRCT20211110053030N1**

Registration date: **2021-12-27, 1400/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-05, 1401/08/14**

Update count: **1**

Registration date

2021-12-27, 1400/10/06

Registrant information

Name

Alireza Vasiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3222 7091

Email address

rezawest10@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-03-11, 1400/12/20
Actual recruitment start date
 2021-12-22, 1400/10/01
Actual recruitment end date
 2022-03-01, 1400/12/10
Trial completion date
 2022-06-22, 1401/04/01

Scientific title
 Effects of Kegel exercise effect on urinary incontinence, frailty index and self-esteem in elderly men after Transurethral Resection of Prostate (TURP) in Ilam county in 2021 (a randomized, single-blinded, controlled clinical trial)

Public title
 Kegel exercise effect on incontinence, Frailty index, and Self-esteem in elderly men after Prostatectomy

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Transurethral Resection of Prostate (TURP) in at least one day and at most 3 days Age 65 years and older Lack of other history of pelvic surgery Failure to diagnose prostate cancer after surgery based on biopsy and pathology Willingness to participate in research and to have Informed Consent Primary and higher literacy rates Achieving a score of 24 and above in the Mini-Mental State Examination (MMSE) to determine whether he is teachable and has no dementia Score 4 or higher on the Urinary Incontinence Diagnosis Questionnaire (QUID) Score higher than 5 on the Edmonton Frailty Scale (EFS)
Exclusion criteria:
 Having a urinary tract infection immediately after surgery Having a heart attack and stroke after entering the intervention

Age
 From **65 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **76**
 Actual sample size reached: **76**

Randomization (investigator's opinion)
 Randomized

Randomization description
 After entering the research based on the inclusion criteria, Balance-block randomization with 4 permutations will be used to assign individuals to control and intervention groups as random allocation 1.CCII, 2. CICI, 3. CIIC, 4. IICC, 5. ICIC and 6. ICCI were in which the letter C (control) and the letter I (intervention). RAS (Research Analysis and Statistics) software will be used to generate random blocks, and a random number table will be used to select each block. Envelopes will be embedded to hide the created sequence, which will be

exactly the same. They are written random codes and each code will represent a type of a block that will contain 4 letters (P or G). The list of codes prepared for each envelope will be determined by the research team and the final list will be at the discretion of the lead researcher. This method will ensure that the doctor or nurse prescribing the training does not know the type of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

We blind interviewers the have rule for data gathering form participants as he/she just access of codes prepared for each envelope (randomization step) and no other information may lead to leak of random sequences.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

Street address

Bangangab, Ilam University of Medical Sciences, Research and Technology Building

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.MEDILAM.REC.1400.167

Health conditions studied

1

Description of health condition studied

Urinary Incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

2

Description of health condition studied

Frailty Index

ICD-10 code
ICD-10 code description

3

Description of health condition studied

Self esteem

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Urinary incontinence

Timepoint

Before enrollment, 8 weeks after enrollment, one month after enrollment

Method of measurement

Abridged Form of the International Urinary Incontinence Counseling Questionnaire (ICIQ)

2

Description

Frailty Index

Timepoint

Before enrollment, 8 weeks after enrollment, one month after enrollment

Method of measurement

Edmonton Frailty scale(EFS)

3

Description

Self-esteem

Timepoint

Before enrollment, 8 weeks after enrollment, one month after enrollment

Method of measurement

Rosenberg Self-Esteem Scale (RSES)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Kegel exercise includes a series of contractions that target the pelvic floor muscles (bladder muscles, valvular muscles, pelvic muscles). After being eligible for the study, the people in the intervention group will be asked how to do the Kegel exercise. First, to identify the location of the pelvic floor muscles, we explain to the person that when you are urinating, try to cut off and connect your urine flow. It is the pelvic floor muscles that cut and connect the flow of your urine. Do this for two or three times to find out the exact location and work of these muscles. Then, after the patient

identifies his pelvic floor muscles, we ask him to contract these muscles for five seconds (count from one thousand and one to one thousand and five) and relax these muscles after counting. This move is a Kegel sport. The intervention group will perform sixty of these contractions daily three times a day (20 in the morning, 20 at noon, and 20 at bedtime) for 12 weeks. In the eighth week of the intervention group, the questionnaires on fragility, self-esteem, and urinary incontinence will be completed again. Then, one month after the end of the Kegel exercise, in the twelfth week of the presence of individuals in the intervention group, the three mentioned questionnaires will be completed again and the data will be entered into SPSS V.21 software for analysis. The intervention group will receive a pamphlet introducing the pelvic floor muscles and how the Kegel exercise was performed by the research team using credible sources, as well as a checklist in which the Kegel exercise is expected to be counted and counted. Placed, will receive. In addition, the members of the intervention group will have the contact number of the researcher to contact him in case of questions or need guidance. The researcher will also be in contact with the members of the intervention group on a weekly basis to check the manner and number of Kegel exercises performed to check the eligibility of individuals to participate in the continuation of the study. In addition, the informed consent form will be obtained from individuals at the beginning of the research.

Category

Treatment - Other

2

Description

Control group: The subjects in the control group did not do any kegel exercises after entering the study, and the subjects in this group after the eighth week and one month after the twelfth week of the study, fragility questionnaires, self-esteem, and urinary incontinence were complete the option and the data will be entered into SPSS V.21 software for analysis. Of course, in order not to be deprived of the benefits of research, the pamphlet will receive how to do Kegel exercise, with the difference that in this pamphlet, the number of Kegel exercises to do, the reason for doing Kegel exercise is not written. In addition, people in the control group will have the contact number of the researcher to contact him in case of questions or need guidance. The researcher will also check the absence of Kegel exercise and the control group's awareness of the existence of such exercise by being in contact with the control group on a weekly basis to check the eligibility of individuals to participate in the continuation of the research. In addition, the informed consent form will be obtained from individuals at the beginning of the research.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Ilam

Full name of responsible person

Alireza Vasiee

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2

Recruitment center

Name of recruitment center

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Web page address

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3

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Alireza Vasiee

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

No

Title of funding source

No - possible costs are paid by the student himself.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Mosayeb Mozafari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Alireza Vasiee
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All potential data can be shared after identifying individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Doctors, nurses, surgeons, and staff of health centers

Under which criteria data/document could be used

Prerequisites for submitting an application include use for referral for reference, faculty or student being a researcher or working in a hospital or surgical clinic.

From where data/document is obtainable

The responsible author can be contacted at the email address: mozafaric@yahoo.com and the student's email address: rezawest10@gmail.com

What processes are involved for a request to access data/document

After completing the study and publishing the results, by sending an email to the responsible author, he can access the documents for a maximum of 6 weeks.

Comments