Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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

Street address
Ayatollah Heidari Blvd.

City
Ilam

Province
Ilam

Postal code
6931975397

Phone
+98 84 3333 4500

Email
rezawest10@gmail.com

Web page address
http://emamhospital.medilam.ac.ir/

2

Recruitment center

Name of recruitment center
Kousar Hospital

Full name of responsible person
Alireza Vasiee

Street address
Imam Ali Boulevard

City
Ilam

Province
Ilam

Postal code
6931975397

Phone
+98 84 3222 0239

Email
rezawest10@gmail.com

Web page address
https://kousarhospital.wixsite.com/farsi

3

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Alireza Vasiee

Street address
Ilam Seyed Al-Shohada Boulevard

City
ilam

Province
Ilam

Postal code
6931975397

Phone
+98 84 3334 1037

Email
rezawest10@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Alireza Vasiee

Street address
Bangangab, Ilam University of Medical Sciences

City
Ilam

Province
Ilam

Postal code
6939177143

Phone
+98 84 3222 7091

Email
rezawest10@gmail.com

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
Nursery

Street address
Bangangab, Ilam University of Medical Sciences, Educational Management

City
ilam

Province
Ilam

Postal code
6939177143

Phone
+98 84 3222 7134
Email
rezawest10@gmail.com

Person responsible for scientific 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
Nursery
Street address
Bangangab, Ilam University of Medical Sciences, Educational Management
City
Ilam
Province
Ilam
Postal code
6939177143
Phone
+98 84 3222 7134
Email
rezawest10@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Alireza Vasiee
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Danesh Square, Hoveyzeh St., 17th Alley
City
Ilam
Province
Ilam
Postal code
6931373847
Phone
+98 84 3222 7091
Email
rezawest10@gmail.com

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