Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effectiveness of Kegel Exercises and Paula Method on the Severity of Stress Urinary Incontinence in Aged Women in Virtual Training: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the effectiveness of Kegel exercises and Paula method on the severity of stress urinary incontinence in elderly women

Design

The clinical trial have a control group, with parallel groups, without blinding, randomized, on 114 patients. www.randomizer.org site was used for randomization

Settings and conduct

Participants are elderly women complaining of stress urinary incontinence referred to health centers. They will be selected based on inclusion and exclusion criteria. They will be followed in the first, third, ninth and thirteenth weeks. They will be evaluated by ICIQ-UI SF questionnaire, pad weighting, and ultrasonography before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women over 60-year-old; moderate to severe score of stress urinary incontinence based on the ICIQ-UI SF questionnaire; Leakage of urine at least one gram over an hour with pad test; MMSE score above 12 Exclusion criteria: Treatment with other similar exercises in a recent year; Taking medications that have side effects that affect bladder function; History of previous surgery for urinary incontinence; History of pelvic radiotherapy during the last 5 years; Uterine prolapse or cystocele grade 3 or higher; History of pelvic surgery; Heart or respiratory disease or movement disorders; Hysterectomy; Neurological diseases such as multiple sclerosis, Parkinson's, brain tumor, Stroke or spinal cord injury; urinary tract or urinary stones; Chronic constipation

Intervention groups

Intervention Group 1: Paula method; Strengthen the pelvic floor muscles by contracting and expanding the circular muscles in other parts of the body. Intervention Group 2: Kegel exercises; Strengthen the pelvic floor muscles by Contraction and expansion them. Control Group: Routine Measures

Main outcome variables

ICIQUI-SF Score; Pad Weight; Bladder neck descent; The amount of VLPP

General information

Reason for update

Due to the corona virus epidemic and personal problems of the researcher, the sampling process started with a delay

Acronym

IRCT registration information

IRCT registration number: **IRCT20210219050410N1**
Registration date: **2021-07-20, 1400/04/29**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **2**

Registration date

2021-07-20, 1400/04/29

Registrant information

Name
Haniye Ezatmoghadam
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 7780 7784
Email address
h.moghadam@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-11-25, 1402/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Kegel Exercises and Paula Method on the Severity of Stress Urinary Incontinence in Aged Women in Virtual Training: A Parallel Randomized Clinical Trial

Public title

Comparing the Effectiveness of Kegel Exercises and Paula Method on the Severity of Stress Urinary Incontinence in Aged Women in Virtual Training: A Parallel Randomized Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All 60-year-old and above female cases referred to health centers Women with moderate to severe stress urinary incontinence based on ICIQ-UISF questionnaire Women with MMSE scores above 12 for cognitive abilities Women with urine leakage at least one gram/hour in the pad test

Exclusion criteria:

Women treated with other similar exercises over the last year Women under medications with side-effect on bladder function Women diagnosed cases of oregonomegaly Women with a previous history of surgery for urinary incontinence Women with a history of pelvic radiation therapy during the last 5 years Women with uterine prolapse or cyctocel, grade 3 or above Women with a history of pelvic surgery Women with cardiac, respiratory or motor disorders Women with a history of hysterectomy Women with urinary tract infections or urinary stones Women with chronic constipation Women with some neurological diseases such as multiple sclerosis, Parkinson's, brain tumor, stroke, and spinal cord injury

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three groups (two in intervention groups and one in control group) through randomization and based on the production of random numbers strings through software. (www.randomizer.org) In order for the number of assignments to each group to be equal, the block method of volume 6 is used to create a random allocation sequence because participants are gradually entered into the study. The allocation concealment will be done centrally. In this way, the assignment sequence will be done by someone outside the research team. Upon each person entering the study, the researcher will contact the person and assign the person to the group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Training instructions and follow-ups will be implemented virtually.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Haft-e Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۴۷

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.SHMU.REC.1400.074

Health conditions studied

1

Description of health condition studied

Stress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female)

Primary outcomes

1

Description
The amount of Bladder neck descent
Timepoint
Before the intervention and one week after the intervention in the Kegel group (ninth week) and one week after the intervention in the Paula and control groups (13th week)
Method of measurement
Sonography

2

Description
The amount of pressure in which urine leakage occurs. (VLPP)
Timepoint
Before the intervention and one week after the intervention in the Kegel group (ninth week) and one week after the intervention in the Paula and control groups (13th week)
Method of measurement
Sonography

Secondary outcomes

1

Description
Pad weight
Timepoint
Before the intervention and one week after the intervention in the Kegel group (ninth week) and one week after the intervention in the Paula and control groups (13th week)
Method of measurement
Notebook Digital scale machine

2

Description
Stress urinary incontinence score in ICIQ-UI SF questionnaire
Timepoint
Before the intervention and one week after the intervention in the Kegel group (ninth week) and one week after the intervention in the Paula and control groups (13th week)
Method of measurement
ICIQ-UI SF Questionnaire

Intervention groups

1

Description
Intervention group: Paula method, which includes a group of circular muscle exercises to return proper functioning of the body, allows to strengthen the pelvic floor muscles by contracting and expanding the circular muscles in other parts of the body such as the eyes, lips, hands and nose. Paula method will be taught to the elderly people via CD and a link to download educational videos and brochures, and the elderly people will be asked to do this method for 12 weeks and every week for 45 minutes. People are encouraged to perform this method daily for 15-45 minutes. Treatment companions can also contact the person in charge of the investigation in case of any questions or problems
Category
Rehabilitation

2

Description
Intervention group: Kegel exercises is the contraction and expansion of the pelvic floor muscles and leads to strengthening of the pelvic floor muscles. These exercises last for 8 weeks and 10 sets a day. Each time involves 10-12 seconds of contraction and 10-12 seconds of rest
Category
Rehabilitation

3

Description
Control group will receive the routine intervention in treatment centers
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Haniyeh Ezzatmoghaddam
Street address
Imam Hossein Hospital, 28 meters end of Ayatollah Tawhidi, Imam Street
City
Shahroud
Province
Semnan
Postal code
۳۶۱۶۹۵۱۸۳۵
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
imamhosein@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohamad Hassan Emamian
Street address
Haft-e Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran
City
Shahroud
Province
Semnan
Postal code
3617473947
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
emamian@shmu.ac.ir
Web page address
https://www.shmu.ac.ir

Grant name
Research
Grant code / Reference number
924
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Haniyeh Ezzatmoghaddam
Position
MSc Student of Geriatric Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Haft-e Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
h.moghadam@shmu.ac.ir
Web page address
https://www.shmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Ali Dadgari
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Gerontology
Street address
Haft-e Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
dadgari@shmu.ac.ir
Web page address
https://www.shmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Haniyeh Ezzatmoghaddam
Position
MSc Student of Geriatric Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Haft-e Tir Sq, Shahroud University of Medical Sciences, Shahroud, Iran
City
Shahroud
Province
Semnan
Postal code

3614773947

Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

h.moghadam@shmu.ac.ir

Web page address

https://www.shmu.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the patients' demographic information can be shared after unidentifying individuals. All the results of the pad test, ultrasound and urinary incontinence questionnaire can be shared with caregivers after unidentified individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Project partners

Under which criteria data/document could be used

People who do similar research

From where data/document is obtainable

It will be done by email with the person in charge of the project

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

The data will be available to individuals via email

Comments