Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Kegel exercises combined with abdominal exercises on symptom severity, quality of life, sexual satisfaction, and sleep quality in middle-aged women with urinary incontinence.

Protocol summary

Study aim

The aim of the present study was to compare the effects of two methods of Kegel exercises and Kegel exercises plus abdominal exercises on urinary incontinence symptoms, quality of life, and sleep quality in middle-aged women.

Design

A quasi-experimental design with two experimental groups and one control group, with parallel, double-blind, randomized groups, will be implemented on 60 middle-aged women with urinary incontinence. Lottery will be used for randomization.

Settings and conduct

This study includes a pre-test and post-test and will compare the effects of two methods: Kegel exercises alone and Kegel exercises combined with abdominal exercises on urinary incontinence symptoms, quality of life, and sleep quality in young middle-aged women. The location of the exercises will be Arad Physiotherapy Clinic in Rasht. In this study, the researchers participating in the pre- and post-test assessments and the statistical expert will be unaware of how individuals are assigned to groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age range 40 to 55 years, 2) Diagnosis of urgent urinary incontinence by an obstetrician or urologist, 3) Consent to participate in the study, 4- 6 months or more since the previous delivery, Exclusion criteria: 1- Having a urinary tract infection, 2- Current drug treatments and physiotherapy treatment, 3- Pregnancy, 4- Having surgery related to urinary incontinence, 5- Having concomitant physical and mental diseases such as cancer, heart disease, schizophrenia, and physical disability.

Intervention groups

Kegel exercise group and Kegel exercise group combined with abdominal exercises

Main outcome variables

Urinary incontinence symptoms, quality of life, sleep quality, psychological well-being, body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039517N16**
Registration date: **2026-10-30, 1405/08/08**
Registration timing: **retrospective**

Last update: **2026-10-30, 1405/08/08**
Update count: **0**

Registration date

2026-10-30, 1405/08/08

Registrant information

Name

Soleyman Ansari Kolachahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-26, 1405/04/05

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Kegel exercises combined with abdominal exercises on symptom severity, quality of life, sexual satisfaction, and sleep quality in middle-aged women with urinary incontinence.

Public title
The effect of Kegel exercises combined with abdominal exercises on middle-aged women with urinary incontinence.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 40 to 55 years Urgent urinary incontinence diagnosis by an obstetrician-gynecologist or urologist Consent to participate in research 6 months or more have passed since the previous birth
Exclusion criteria:
Having a urinary tract infection Use of common drug treatments and physiotherapy treatment Pregnancy Having surgery related to urinary incontinence Having co-morbid physical and mental illnesses such as cancer, heart disease, schizophrenia, and physical disabilities
Age
From **40 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
60 middle-aged women with urinary incontinence will be selected by convenience sampling method. A simple randomization method will be employed, with the individual as the unit of randomization. To generate the random sequence, participants will be numbered sequentially upon entry, and each will be assigned with an equal probability to one of the three groups (two intervention groups and one control group) using a random number table (or random number generator software). To ensure allocation concealment, the group assignment for each participant will be placed in separate, numbered, and sequentially sealed envelopes. These envelopes will be opened by an independent person (other than the researcher) only after the final registration and obtaining written informed consent from each participant, thereby minimizing allocation bias.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, the persons responsible for evaluating and collecting information, as well as the data analyst, are unaware of the type of intervention and the participants in the research groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Islamic Azad University- Babol Branch
Street address
Babol Azad University, Rahimi Highway, Babol
City
Babol
Province
Mazandaran
Postal code
37381-47471
Approval date
2026-01-19, 1404/10/29
Ethics committee reference number
IR.IAU.BABOL.REC.1404.169

Health conditions studied

1

Description of health condition studied
Urinary incontinence
ICD-10 code
R32
ICD-10 code description
stress incontinence and other specified urinary incontinence

Primary outcomes

1

Description
Severe urinary incontinence symptoms
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
It will be measured through the Urinary Incontinence Questionnaire - Short Form of Avery et al. (2004).

Secondary outcomes

1

Description
Waist to hip ratio
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
To measure waist circumference, the narrowest area between the last rib and the upper part of the pelvis and the hip circumference will be measured with a tape measure and as the largest circumference around the hips.

2

Description
Psychological well-being
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
The Riff Psychological Well-Being Questionnaire (2002) will be used.

3

Description
Sexual function
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
The Rosen (2000) Female Sexual Function Questionnaire will be used.

4

Description
Quality of life
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
Quality of life will be measured through the questionnaire for people with urinary incontinence by Wegener, Patrick, Bavendam, Marty, and Bushing (1996).

5

Description
Sleep quality
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
It will be measured through the Pittsburgh Sleep Quality Questionnaire by Boyce et al. (1989).

6

Description
Body composition
Timepoint
48 hours before the intervention and 48 hours after 12 weeks of intervention
Method of measurement
For each individual, the body mass index (BMI) will be calculated from the ratio of weight in kilograms to the square of height in meters.

Intervention groups

1

Description
Intervention group: 1: Kegel exercises: The exercises in this group include a series of pelvic floor muscle contractions for 6 to 8 seconds and a 5-second rest, which will be performed in different positions: lying down, sitting, and standing. These exercises will be performed every day of the week (15 minutes each time) for 12 consecutive weeks.
Category
Treatment - Other

2

Description
Intervention group: 2: Kegel exercises with abdominal exercises: This group will perform Kegel exercises according to the program of Group 1. In addition, for the abdominal exercises, participants will be instructed to contract their abdominal muscles by pulling their navel towards their spine in a lying position and contracting them strongly and statically, then try to touch the farthest point of their feet with their fingertips.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuroscience Center, Poursina Hospital, Rasht
Full name of responsible person
Dr Soleyman Ansari
Street address
Rasht, Nurse Street
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41937-13194
Phone
+98 13 4401 0013
Email
solomonansri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Alireza Seidavi
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Lakan blv
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Guilan
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Phone
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adibsaberf@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Fahimeh Adibsaber
Position
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Person responsible for updating data

Contact
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Islamic Azad University
Full name of responsible person
Fahimeh Adibsaber
Position
faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
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Postal code
4147654919
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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