# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of eight weeks of Kegel exercises combined with vitamin D3 and magnesium supplementation on lumbar stabilizer muscle thickness and urinary incontinence severity in postmenopausal women

## Protocol summary


**Study aim**

The study aims to evaluate the effect of 8 weeks of Kegel exercises combined with vitamin D3 and magnesium supplementation on lumbar muscle thickness and urinary incontinence severity in postmenopausal women.

**Design**

A randomized, parallel-group, assessor-blinded clinical trial to assess the impact of Kegel exercises combined with supplements on lumbar muscle thickness and urinary incontinence severity. Participants will be randomized 1:1 into intervention and control groups.

**Settings and conduct**

This randomized, assessor-blinded, parallel-group clinical trial will be conducted in 2025 at a private physiotherapy clinic in Isfahan

**Participants/Inclusion and exclusion criteria**

Inclusion criteria were postmenopausal women aged 60–65 years with urinary incontinence who had not participated in regular exercise programs or used vitamin D or magnesium supplements during the past three months and had no history of pelvic or lumbar spine surgery or severe chronic diseases limiting physical activity. Exclusion criteria included unwillingness to participate, conditions or injuries limiting exercise performance, use of medications affecting muscle or urinary function, recent regular use of vitamin D or magnesium supplements, and any medical contraindication to participation. Detailed criteria are presented in the relevant section.

**Intervention groups**

Participants will be randomly assigned to two groups. The intervention group will perform Kegel exercises for 8 weeks (3 sessions/week, 3 sets of 10 repetitions with 8-second contractions) and receive daily vitamin D3 (2000 IU) and magnesium (200 mg). The control group will receive placebo capsules without exercise.

**Main outcome variables**

Primary outcomes include transversus abdominis and multifidus muscle thickness and urinary incontinence severity.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20260328069015N1**
Registration date: **2026-04-26, 1405/02/06**
Registration timing: **prospective**

Last update: **2026-04-26, 1405/02/06**
Update count: **0**

**Registration date**

2026-04-26, 1405/02/06


**Registrant information**

**Name**

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**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-05-09, 1405/02/19

**Expected recruitment end date**

2026-08-10, 1405/05/19

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of eight weeks of Kegel exercises combined with vitamin D3 and magnesium supplementation on lumbar stabilizer muscle thickness and urinary incontinence severity in postmenopausal women

**Public title**
Effect of Kegel exercises combined with vitamin D and magnesium supplementation on urinary incontinence in postmenopausal wome
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Postmenopausal women aged 60–65 years At least one year since the last menstrual period Presence of urinary incontinence symptoms (based on ICIQ-SF) No regular physical exercise during the past three months No vitamin D or magnesium supplementation during the previous three months No history of pelvic or lumbar surgery No neurological or musculoskeletal disorders affecting pelvic floor function Ability and willingness to attend training sessions and clinical assessments
**Exclusion criteria:**
Unwillingness to participate in the study or failure to sign the informed consent form. Regular participation in intense training programs or professional sports activities at the time of study entry. Regular consumption of vitamin D or magnesium supplements in recent months that cannot be discontinued or controlled. Presence of musculoskeletal, neurological, or systemic diseases or injuries that limit the ability to perform the exercise program. Use of medications that may affect muscle function, the neuromuscular system, or the urinary system. Known allergy or medical contraindication to vitamin D or magnesium supplementation. Presence of acute or uncontrolled chronic diseases that may interfere with the intervention process or study assessments. Any medical condition that, in the opinion of the physician or the principal investigator, would prevent safe participation in the study.autorenewthumb_upthumb_down
**Age**
From **60 years** old to **65 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
After obtaining written informed consent, eligible participants were enrolled in the study. To generate the random allocation sequence, a block randomization method with a fixed block size of 4 was used to ensure balance in the number of participants between the intervention and control groups throughout the recruitment process. The random sequence was generated using the statistical software SPSS version 26 (IBM Corp., Armonk, NY, USA). Specifically, all possible allocation permutations within a four-person block were first defined, including six possible arrangements (AABB, ABAB, ABBA, BAAB, BABA, BBAA), where A represented the intervention group and B represented the control group. Subsequently, a uniform random number was generated for each block using the function RV.UNIFORM(0,1), with the random number generator seed set to 2024 to ensure reproducibility. Based on these random numbers, one of the six possible block arrangements was randomly selected for each block. The blocks were then concatenated sequentially to form the final allocation list. Accordingly, every four consecutive participants were assigned to the intervention and control groups according to the predefined block structure, maintaining a 1:1 allocation ratio within each block. To ensure allocation concealment, the final sequence was encoded and placed into sequentially numbered, opaque, sealed envelopes (SNOSE). The envelopes remained sealed until the moment of participant enrollment and were opened sequentially only after each participant had been formally enrolled in the study. All procedures, including random sequence generation, block selection, seed setting, and envelope preparation, were performed by an independent researcher who had no involvement in participant recruitment, intervention implementation, or outcome assessment, thereby minimizing the risk of selection bias.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In this trial, participants will not be blinded to the intervention they receive; however, the outcome assessor will be blinded to group allocation. The assessor responsible for measuring muscle thickness, pelvic floor strength and endurance, and urinary incontinence scores will have no access to the allocation list, and group information will be kept confidential. Additionally, the statistical analyst will receive coded data (Group A and Group B) to ensure blinded data analysis.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**
This study is a randomized, parallel-group, single-blind clinical trial. The intervention consists of pelvic floor muscle exercises combined with a nutritional supplement. Group allocation will be performed using a computer-generated randomization table, and outcome measurements will be conducted by an assessor blinded to group assignment. Data will be collected through questionnaires, functional tests, and ultrasound assessment of pelvic floor muscles.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committee, Islamic Azad University, Central Tehran Branch

**Street address**
Block A, 13th Floor, Central Headquarters of the Ministry of Health and Medical Education, Simaye Iran St., between South Flamak St. and Zarafshan St., Shahrak-e Ghods (West), Tehran, Iran

**City**
Tehran

**Province**
Tehran

**Postal code**
14588-95611

**Approval date**
2025-12-22, 1404/10/01

**Ethics committee reference number**
IR.IAU.CTB.REC.1404.220

## 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**
Low back pain

**ICD-10 code**
M54.5

**ICD-10 code description**
Low back pain

## Primary outcomes

### 1

**Description**
Urinary incontinence severity

**Timepoint**
Outcome variables will be measured at two time points: at baseline (before the start of the intervention) and at the end of the eighth week after the intervention.

**Method of measurement**
Urinary incontinence severity was assessed using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF).

## Secondary outcomes

### 1

**Description**
Transversus abdominis muscle thickness by ultrasound

**Timepoint**
Baseline (pre-intervention) and Post-intervention (after 8 weeks)

**Method of measurement**
The thickness of the transversus abdominis muscle was measured using rehabilitative ultrasound imaging with a linear probe (7.5–10 MHz). Participants were positioned in the supine position with knees flexed, and measurements were taken along the mid-axillary line between the 12th rib and the iliac crest. Three measurements were obtained and the average value was recorded.

### 2

**Description**
multifidus muscle thickness by ultrasound

**Timepoint**
Baseline (pre-intervention) and Post-intervention (after 8 weeks)

**Method of measurement**
The thickness of the lumbar multifidus muscle was measured using rehabilitative ultrasound imaging at the L4–L5 vertebral level. Participants were positioned in the prone position and the ultrasound probe was placed adjacent to the spinous process. Three consecutive measurements were taken and the mean value was recorded.

### 3

**Description**
Serum 25-hydroxyvitamin D level (25(OH)D)

**Timepoint**
Outcome variables will be measured at two time points: at baseline (before the start of the intervention) and at the end of the eighth week after the intervention.

**Method of measurement**
Serum 25-hydroxyvitamin D levels were measured from fasting blood samples (12-hour fasting) collected between 8 and 10 a.m. using the ELISA method.

### 4

**Description**
Serum magnesium levels

**Timepoint**
Outcome variables will be measured at two time points: at baseline (before the start of the intervention) and at the end of the eighth week after the intervention.

**Method of measurement**
Serum magnesium concentration was determined from fasting blood samples using a standard enzymatic colorimetric method in a clinical laboratory.

## Intervention groups

### 1

**Description**

Intervention group: Participants in the intervention group performed a Kegel exercise program for 8 weeks and simultaneously received vitamin D3 and magnesium supplementation. The exercises were performed three sessions per week, each consisting of three sets of 10 repetitions of pelvic floor muscle contractions, with 8 seconds of contraction followed by 8 seconds of relaxation. In addition, participants received 2000 IU of vitamin D3 and 200 mg of magnesium daily during the intervention period.

**Category**

Rehabilitation

### 2

**Description**

Control group: Participants in the control group received placebo during the 8-week study period. The placebos were prepared as capsules with the same appearance, color, and size as the original supplements but contained no active ingredients and consisted of inert substances such as edible starch or microcrystalline cellulose. The vitamin D placebo was taken once daily, two hours after lunch, and the magnesium placebo was taken once daily at 20:00. These capsules were produced and packaged by Actoverco Pharmaceutical Company. No Kegel exercise program or vitamin D and magnesium supplementation was prescribed for this group, and participants only underwent pre-test and post-test assessments similar to the intervention groups.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Neda-ye Salamat Clinic
**Full name of responsible person**
Dr Abolghasem Kiani
**Street address**
3rd Floor, Bozorgmehr Street, opposite Sadoughi Hospital
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Self-funded / No external financial support
**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Self-funded / No external financial support

**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**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Islamic Azad University
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Fatemeh Beheshtizadeh
**Position**
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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to the need to protect participant confidentiality and prevent disclosure of individual-level data, there is no plan to share Individual Participant Data (IPD). Only aggregated results will be reported in scientific publications.

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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**

Full protocol of the randomized controlled trial including study design, Kegel exercise intervention protocol, vitamin D3 and magnesium supplementation protocol, inclusion and exclusion criteria, measurement procedures including ultrasound assessment of transversus abdominis and multifidus muscles, urinary incontinence assessment using the ICIQ-SF questionnaire, biochemical measurements, and statistical analysis plan.

**When the data will become available and for how long**

The study protocol will become available after completion of the study and publication of the results and will remain accessible for up to 5 years after publication.

**To whom data/document is available**

Academic researchers, journal reviewers, and researchers who submit a scientifically justified request.

**Under which criteria data/document could be used**

The document will be available solely for research, educational, or peer-review purposes. Its use must comply with research ethics principles and protection of participant confidentiality.

**From where data/document is obtainable**

Requests should be sent by email to the responsible investigator.

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

Requests will be reviewed via email. If approved, an electronic copy of the study protocol will be provided. No identifiable participant information will be shared.

**Comments**