

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Pilates exercise on urinary incontinence and sexual function of middle-age women

Protocol summary

Study aim

The aim of this study was to determine the effect of Pilates exercise on urinary incontinence and sexual function in middle-aged women.

Design

Clinical trial, two groups, simple randomization of even and odd on 100 women with urinary incontinence and sexual dysfunction

Settings and conduct

In this study, among all middle-aged women referred to the health center (clinic of Imam Khomeini Hospital), 60 middle-aged women with urinary incontinence and sexual dysfunction who were eligible for the study will be examined. Took. In the Pilates exercise intervention group, it will be performed under the supervision of a Pilates instructor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: urinary incontinence and impaired sexual function; age range 60 to 65 years old; having the physical and mental ability to cooperate with research; minimum reading and writing skills

Intervention groups

Intervention group: Pilates exercises under the supervision of a Pilates instructor. Control group: there will be no intervention.

Main outcome variables

Urinary incontinence and sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210922052554N1**

Registration date: **2021-10-16, 1400/07/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-16, 1400/07/24**

Update count: **0**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name

fatemeh aminizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 0000

Email address

aminizadeh.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-12-01, 1400/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pilates exercise on urinary incontinence and sexual function of middle-age women

Public title

The effect of Pilates on urinary incontinence and sexual function of women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Urinary incontinence and impaired sexual function Age

range 60 to 65 years old Having the physical and mental ability to cooperate with research Minimum reading and writing skills

Exclusion criteria:

Reluctance to continue cooperation Occurrence of any physical condition requires medical treatment and care Occurrence of any mental condition requires medical treatment and care Occurrence of any problem such as loss of loved ones and hospitalization that the person is unable to continue studying.

Age

From **60 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, even and odd, odd numbers will be in the intervention group and even numbers will be in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Ahvaz University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.AJUMS.REC.1400.341

Health conditions studied

1

Description of health condition studied

Middle-aged women with urinary incontinence and sexual dysfunction

ICD-10 code

F52.8

ICD-10 code description

Other sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Urinary incontinence

Timepoint

Measurement of urinary incontinence before and 6 weeks after intervention

Method of measurement

ICIQ-UI Urinary Incontinence Questionnaire

2

Description

Sexual function

Timepoint

Measurement of sexual function before and 6 weeks after the intervention

Method of measurement

PISQ -12 Sexual Function Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: performing 6 pilates exercises under the supervision of a pilates instructor. These exercises include stretching, extension, abdominal exercises and shaking the heel and foot, which will be done in different positions of sleeping, sitting and standing, depending on the level of readiness of the person.

Category

Rehabilitation

2

Description

Control group: There will be no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Ahvaz

Full name of responsible person

Alireza Ghanbaran

Street address

Imam Khomeini Hospital, Shohada Square, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mina Iravani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Aminizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Fax**Email**

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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

No - There is not 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