

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of Pilates exercise on quality of life and sexual function of postmenopausal women

Protocol summary

Study aim

The effect of Pilates exercise on quality of life and sexual function of postmenopausal women

Design

Quasi - experimental study with control group, without randomization and blinding

Settings and conduct

Sampling will be conducted in two selected health centers of Tehran University of Medical Sciences. They will be selected by purpose, according to the health center equipment for holding the Pilates classes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Natural menopause, Age 40-60 years old, At least one year after the last menstrual period, Married and living in a stable life with spouse, Having at least reading and writing skills, Ability to attend in exercise sessions, BMI between 30-20 Exclusion criteria: Menopause followed by surgery, Menopause under 40 years, Husband with multiple partnership, Regular exercise during the last 3 months, Taking Phytoestrogens or hormonal Supplements, Acute heart disease, acute mental disease, chronic disease, malignancy (cancer) Disabling Sexual Disease, Sexual Disability or premature ejaculation in husband, Occurrence of stressful experiences in the last 3 months, Failure to attend in 3 sessions of Pilates exercises continuously, or 5 sessions intermittently

Intervention groups

The intervention method in this study will be Pilates exercises for 12 weeks, 2 times a week lasting 60 minutes, and will be conducted by the researcher who has been trained by an expert Pilates coach. There will be no intervention for the control group, and the women of this group will continue to perform their routine activities, and will just fill up the registration form for sports exercises ; so if they have any exercise program, they will record it and at the end 12 weeks of intervention, CD of training Pilates exercises will be given to the control group.

Main outcome variables

Quality of life Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N4**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-30, 1397/03/09**

Update count: **0**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

Maryam Damghanian

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

m-damghanian@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pilates exercise on quality of life and sexual function of postmenopausal women

Public title

The effect of Pilates exercise on quality of life and sexual function of postmenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

natural menopause age 40-60 years old at least one year after the last menstrual period Married and living a stable life with spouse Having at least reading and writing skills Ability to attend exercise sessions BMI between 30-20 Full physical health

Exclusion criteria:

Menopause followed by surgery Menopause under 40 years Husband with multiple partnership Regular exercise during the last 3 months Taking Phytoestrogens or hormonal Supplements for treatment Acute heart disease, acute mental illness, chronic disease, malignancy (cancer) Disabling Sexual Disease Sexual Disease or premature ejaculation in husband Occurrence of stressful experiences in the last 3 months Failure to attend in 3 sessions of Pilates exercises, continuously or 5 sessions, intermittently

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **98****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, 12 weeks Pilates training is provided to intervention group including postmenopausal women with inclusion criteria referring to the Farmanfarmaian health center. While there is no intervention for the control group, including postmenopausal women who meet the inclusion criteria referred to the Meysam Health Center. The questionnaires will be completed at the beginning of the study and 12 weeks later, and the Pilates training CD will be given to them at the end of the

study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Nursing and Midwifery and Rehabilitation Faculty of Tehran University of Medical

Street address

Nursing and Midwifery Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4864

Health conditions studied**1****Description of health condition studied**

Sexual Function

ICD-10 code

F66.2

ICD-10 code description

Sexual relationship disorder

Primary outcomes**1****Description**

Quality of life

Timepoint

At the beginning of the study, after the end of the intervention

Method of measurement

SF36 quality of life questionnaire

2**Description**

Sexual Function

Timepoint

At the beginning of the study, after the end of the intervention

Method of measurement

FSFI Sex Function Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Pilates exercises will be conducted for 12 weeks, 2 times a week for 60 minutes, and will be done by a researcher trained by an expert Pilates coach.

Category

Other

2

Description

Control group: There will be no intervention for the control group, and the people of this group will continue to perform their routine activities, and the registration form for exercises will be provided to this group to register if they have any exercise program.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farmanfarmaian Health Center

Full name of responsible person

Maryam Damghanian

Street address

School of Nursing & Midwifery, East Nosrat Ave,
Towhid Square.Tehran, Iran

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2

Recruitment center

Name of recruitment center

Meisam Health Center

Full name of responsible person

Maryam Damghanian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sahar Zamani Ahmadmahmodi

Position

MSC Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

There is no more information

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