

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of Pilates exercises and Proprioceptive neuromuscular facilitation on pain and muscle power in patients with knee joint wear

Protocol summary

Study aim

Determining and comparing the effect of pilates exercises and proprioceptive neuromuscular facilitation on pain and muscle power of patients with knee joint wear.

Design

54 people are divided into three groups of 18 people through block randomization. One group receives Pilates exercises, one group receives proprioceptive neuromuscular facilitation exercises, and one group is the control group that does not receive any exercises.

Settings and conduct

The statistical analyst has no knowledge of the allocation of groups and how it is done. The place of intervention is Shahid Beheshti Hospital, Boyer-Ahmad city. The patients come to the place and the intervention is done for all the group members, then the patients of the next group come and receive the exercises.

Participants/Inclusion and exclusion criteria

All patients with wear and tear of the knee joint, who are between the ages of 20 and 65, can participate in the intervention if they do not have neurological and muscle problems, open wounds in the lower limbs, severe inflammatory diseases, osteoporosis and gout.

Intervention groups

Pilates intervention group receiving Pilates exercises. The intervention node receives proprioceptive neuromuscular facilitation exercises. The control group does not receive any training.

Main outcome variables

the pain; Muscle power; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240512061759N1**

Registration date: **2024-06-12, 1403/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2024-06-12, 1403/03/23**

Update count: **0**

Registration date

2024-06-12, 1403/03/23

Registrant information

Name

Reza Mazarei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-17, 1403/02/28

Expected recruitment end date

2024-07-18, 1403/04/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Pilates exercises and Proprioceptive neuromuscular facilitation on pain and muscle power in patients with knee joint wear

Public title

The effect of Pilates and proprioceptive neuromuscular facilitation on pain and muscle power in knee joint wear

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from wear and tear in one or both knees based on radiographic evidence and the confirmation of an orthopedic doctor Age range between 20 and 65 years

Exclusion criteria:

Knee joint replacement Corticosteroid injection into the desired knee joint during three months before the intervention The presence of an open wound Doing exercise and physical therapy regularly for two months before the intervention Suffering from severe chronic diseases such as lupus, inflammatory arthritis, neurological diseases The presence of diseases that damage the joint such as: osteonecrosis, osteoporosis, rheumatoid arthritis, neuromuscular disease, any symptoms of collagen and vascular disease, arthritis caused by gout and pseudo gout. Not having acceptable cognitive ability The existence of cryptography and dryness in the morning for less than 30 minutes Use of oral corticosteroids one month before the intervention

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected as available sampling from among the patients suffering from wear and tear of the knee joint referring to the hospitals and Shahid Mofatteh Clinic in Yasuj city and will be based on random block allocation which according to the studied groups (three groups) including intervention 1 (Pilates exercises), intervention 2 (proprioceptive neuromuscular facilitation exercises) and control based on the calculated factorial law, i.e. 3! A for intervention group 1 (Pilates exercises), B for intervention group 2 (proprioceptive neuromuscular facilitation exercises) and C for the control group will be compiled based on the table below. 6 5 4 3 2 1 CBA CAB BCA BAC ACB ABC Then, since the estimated sample size is 54 people, three samples are placed in each block, each representative of a study group and their arrangement order is also different, and from these blocks, sampling will be done by placement.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who performs the statistical analysis does not know about the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Yasuj University of Medical Sciences

Street address

Shahid Motahari Blvd, Yasuj, Kohgiluyeh and Boyer-Ahmad Province

City

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Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.YUMS.REC.1402.047

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

knee joint wear

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain score in VAS test.

Timepoint

The time to measure pain is in three stages, respectively: before the start of the intervention, in the middle of the intervention or four weeks after the start of the intervention and after the end of the intervention.

Method of measurement

VAS test to measure pain. Questionnaire of consequences of osteoarthritis and knee injuries (KOOS).

2**Description**

Muscle power score in MMT test.

Timepoint

The time to muscle power is in three stages,

respectively: before the start of the intervention, in the middle of the intervention or four weeks after the start of the intervention and after the end of the intervention.

Method of measurement

MMT test to measure muscle power . Questionnaire of consequences of osteoarthritis and knee injuries (KOOS).

Secondary outcomes

1

Description

Symptoms related to the disease. Daily life activities. Sports and recreational activities. Quality of life related to knee problems.

Timepoint

Before starting the study. Four weeks after the start of the intervention. After the end of the intervention.

Method of measurement

Questionnaire for the outcome of knee injuries and osteoarthritis, abbreviated as KOOS

Intervention groups

1

Description

Intervention group: This group receives Pilates exercises twice a week for eight weeks. the duration of Pilates exercises, including warm-up and cool-down, is about 60 minutes. In the exercises, the principle of overload is observed and gradually the number of exercises and their repetitions are increased.

Category

Rehabilitation

2

Description

Intervention group: This group receives proprioceptive neuromuscular facilitation exercises twice a week for eight weeks. The duration of PNF exercises, including warm-up and cool-down, is about 60 minutes. In the exercises, the principle of overload is observed and gradually the number of repetitions of exercises and sets is increased.

Category

Rehabilitation

3

Description

Control group: They do not receive any sports for eight weeks and are only evaluated with questionnaires and tools at specified times.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Muftah clinic of Yasuj

Full name of responsible person

Reza Mazarei

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Next to Shahid Beheshti Hospital, Yasouj City,
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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sayyed Amin Hosseini

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Eram,Yasuj,Kohgiluyeh and Boyer-Ahmad Province

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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
Yasouj 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
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Person responsible for updating data

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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
The data will be available only to researchers working in academic and scientific institutions.
When the data will become available and for how long
The data will be published in the summer of 1403.
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used

The data will be available only to researchers working in academic and scientific institutions.

From where data/document is obtainable

omidrezamazarei1376@gmail.com

What processes are involved for a request to access

data/document

Requested data and documents will be sent to them as soon as possible and in less than a week.

Comments