Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Combined Aquatic and Pilates Exercises on Pain, Mobility, Functional Disability, and Quality of Life in Women with Mild to Moderate Lumbar Disc Herniation

Protocol summary

Study aim

The effect of 8 weeks of combined aquatic and Pilates training on pain, mobility, functional disability, and quality of life in women with mild to moderate lumbar disc herniation

Design

Clinical trial with control group, with parallel groups, single-blind, random, phase 3 on 45 patients. The Rand Function of the Excel software was used for randomization.

Settings and conduct

This study was a single-blind randomized clinical trial conducted on women with mild to moderate lumbar disc herniation at Pardisan Sports Center in Tehran, Iran. The assessors and the statistician responsible for data analysis were blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Female gender; Mild to moderate lumbar disc herniation; Exclusion Criteria: Withdrawal of consent or unwillingness to continue participation; Exacerbation of pain during the intervention period

Intervention groups

The statistical sample of the present study included women with mild to moderate lumbar disc herniation, from whom 45 people who met the inclusion criteria were selected purposefully and were divided by simple randomization into three groups of 15 people: control, aquatic exercise, and combined aquatic and Pilates exercise. The control group performed their daily routines. The aquatic exercise group, aquatic exercise program, and combined group performed Pilates exercises in addition to the aquatic exercise program.

Main outcome variables

Low back pain intensity at rest and activity; Lumbar spine flexion range of motion; Functional disability; Quality of life

General information

Reason for update

Acronym

APLD

IRCT registration information

IRCT registration number: **IRCT20180521039762N2**
Registration date: **2025-10-01, 1404/07/09**
Registration timing: **retrospective**

Last update: **2025-10-01, 1404/07/09**
Update count: **0**

Registration date

2025-10-01, 1404/07/09

Registrant information

Name

Afshin Moghadasi

Name of organization / entity

University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 3793 4208

Email address

afshin.moghadasi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-21, 1403/06/31

Expected recruitment end date

2024-11-19, 1403/08/29

Actual recruitment start date

2024-10-21, 1403/07/30

Actual recruitment end date

2024-12-19, 1403/09/29

Trial completion date
2025-01-18, 1403/10/29

Scientific title
The Effect of Combined Aquatic and Pilates Exercises on Pain, Mobility, Functional Disability, and Quality of Life in Women with Mild to Moderate Lumbar Disc Herniation

Public title
The Effect of Aquatic and Pilates Exercises on Pain and Quality of Life in Women with Lumbar Disc Herniation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Age between 30 and 50 years Mild to moderate lumbar disc herniation, diagnosed by an orthopedic specialist and confirmed by MRI report, without indication for surgical intervention Referral and recommendation from a specialist physician for participation in aquatic or exercise-based therapy

Exclusion criteria:
No history of other diseases or injuries that are incompatible with exercise No history of surgery Not pregnant

Age
From **30 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Actual sample size reached: **39**

Randomization (investigator's opinion)
Randomized

Randomization description
In this trial, participants who meet the eligibility criteria and provide informed consent will be randomly assigned to one of the three study groups using simple randomization. A sequential list of all eligible participants will be prepared. Group allocation will then be determined by a computer-generated random sequence (using software such as Random Allocation Software or the RAND function in Microsoft Excel). For each participant, a random number will be generated, and based on this number, the participant will be assigned to one of the three groups. The probability of allocation to each group is equal, and no researcher involvement or bias will influence the randomization process.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is conducted as a single-blind trial. Participants are aware of their assigned study group, as it is necessary to provide them with sufficient information to adhere to the intervention protocols. However, the researchers administering the interventions are blinded to group allocation, which is managed by an independent researcher. This approach helps minimize bias in the delivery of interventions.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Payame Noor University

Street address
Payame Noor University, Nakhl St., Artesh Blvd., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
193954697

Approval date
2024-09-13, 1403/06/23

Ethics committee reference number
IR.PNU.REC.1403.309

Health conditions studied

1

Description of health condition studied
Lumbar disc herniation

ICD-10 code
M51.06

ICD-10 code description
Intervertebral disc disorders with myelopathy, lumbar region

Primary outcomes

1

Description
Pain intensity at rest and activity

Timepoint
Before intervention and 8 weeks after intervention

Method of measurement
Visual numerical scale

2

Description

Functional disability

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Oswestry Low Back Pain Disability Questionnaire

3

Description

Quality of life

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

SF-36 Quality of Life Questionnaire

4

Description

Spinal flexion range of motion

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Modified Modified Schober Test

Secondary outcomes

1

Description

Pain intensity at rest and activity

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Visual numerical scale

2

Description

Functional disability

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Oswestry Low Back Pain Disability Questionnaire

3

Description

Quality of life

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

SF-36 Quality of Life Questionnaire

4

Description

Range of motion of lumbar flexion

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Modified Modified Schober Test

Intervention groups

1

Description

First intervention group (Combined Aquatic + Pilates Group): Participants in the combined group followed the same 8-week, thrice-weekly supervised program, with sessions lasting about 60 minutes (10 minutes warm-up, 45 minutes main exercises, 5 minutes cool-down). The 45-minute main segment was divided equally between aquatic exercises (20–25 minutes) and Pilates exercises (20–25 minutes). Each exercise was performed in three sets, with positions held for 10–30 seconds and short recovery periods of 10–20 seconds between sets. Aquatic exercises were performed in the pool under hydrotherapy supervision. Pilates exercises were conducted in a gym hall within the same facility under the supervision of a certified Pilates instructor, with emphasis on breathing control, pelvic-lumbar stabilization, thoracic alignment, shoulder positioning, and head-neck alignment.

Category

Rehabilitation

2

Description

Second intervention group (Aquatic Exercise Group): Participants in the aquatic group engaged in an 8-week program consisting of three supervised sessions per week, each lasting approximately 60 minutes (10 minutes warm-up, 45 minutes aquatic exercises, 5 minutes cool-down). A total of 11 aquatic exercises were performed in the pool, with each exercise completed in 3–5 sets, holding positions for 10–30 seconds. Rest intervals of 10–20 seconds were allowed between sets. The intensity and number of repetitions were gradually increased over the course of the program. Sessions took place in an indoor pool (water temperature 31–33 °C) under the supervision of a licensed hydrotherapy instructor.

Category

Rehabilitation

3

Description

Control group: Participants in the control group did not receive any structured exercise intervention. They were instructed to continue their usual daily routines and activities without engaging in any additional exercise programs during the study period. To maintain fairness, participants in this group were offered general guidance on safe physical activity after completing the trial.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Pardisan Noor Sports Complex

Full name of responsible person
Fatemeh Mousavi

Street address
Noor 2 & 3, Moj Square, South Jangolban Blvd, After Azadegan Exit, Hemmat Gharb, Tehran

City
Tehran

Province
Tehran

Postal code
1494956641

Phone
+98 21 4471 3219

Email
Pardisannoor98@gmail.com

Web page address
https://www.pardisanpool.ir/contactUs

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Payame Noor University

Full name of responsible person
Dr. Majid Zamahni

Street address
Payame Noor University, Nakhl St, Artesh Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
193954697

Phone
+98 21 2332 0000

Email
zamahani@pnu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Payame Noor 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
Payame Noor University

Full name of responsible person
Afshin Moghadasi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sports Injury and Corrective Exercises

Street address
Payame Noor University, Nakhl St, Artesh Blvd, Tehran, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
193954697

Phone
+98 21 2332 0000

Email
moghadasi@pnu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Payame Noor University

Full name of responsible person
Afshin Moghadasi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sports Injury and Corrective Exercises

Street address
Payame Noor University, Nakhl St, Artesh Blvd, Tehran, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
193954697

Phone
+98 21 2332 0000

Email
moghadasi@pnu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Payame Noor University

Full name of responsible person
Afshin Moghadasi

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports Injury and Corrective Exercises
Street address
Payame Noor University, Nakhl St, Artesh Blvd, Tehran, Tehran Province, Iran
City
Tehran
Province
Tehran
Postal code
193954697
Phone
+98 21 2332 0000
Email
moghadasi@pnu.ac.ir

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
itle of Data/Documents: Individual Participant Data (IPD) – Women with Mild to Moderate Lumbar Disc Herniation Details: Includes clinical and questionnaire data (pain, mobility, functional disability, quality of life) and physical/laboratory measurements All data are de-identified; no personally identifiable information will be shared All collected data, including primary and secondary outcomes, are potentially shareable for research purposes after de-identification Additional documents: study protocol and statistical analysis plan
When the data will become available and for how long
The study data and documents will be available to interested researchers six months after the publication of the main study article and will remain accessible for five years from the start of access.
To whom data/document is available
The study data and documents will be available to interested researchers affiliated with academic and research institutions, as well as independent investigators. Applicants from industry or commercial organizations may also request access, provided that their purpose is strictly scientific research and independent analysis, and they sign a confidentiality agreement and commit to ethical research practices.
Under which criteria data/document could be used
Data and documents are to be used strictly for scientific research and independent analysis. Permitted types of analysis: Any statistical analysis, modeling, or review related to the study topic, provided confidentiality is maintained. Use of documents: Study protocol and statistical analysis plan may be used to understand methodology and conduct independent analyses. Request procedure: Submit a formal request via the study team's email Complete the data access request form Sign a confidentiality agreement and commit to ethical research practices Request reviewed and approved by the study team and ethics committee prior to access
From where data/document is obtainable
Applicants interested in accessing study data and documents may proceed as follows: 1. Send a formal email to the corresponding author Email: moghadasi@pnu.ac.ir Contact person: Dr. Afshin Moghadasi 2. Send a postal letter: Department of Sports Injury and Corrective Exercises, Payame Noor University, Nakhl St, Artesh Blvd, Tehran, Iran. Recipient: Dr. Afshin Moghadasi, Corresponding Author 3. Phone for inquiries: Number: +98 918 943 2264 All requests will be reviewed by the corresponding author, and access will be granted after approval and signing of a confidentiality agreement and commitment to ethical research practices.
What processes are involved for a request to access data/document
Request process for data/documents: 1. Submit a formal request: The applicant sends a written or email request to the corresponding author. 2. Complete the access form: The applicant fills out the data/documents access request form. 3. Review of the request: The study team and corresponding author review the request to ensure compliance with usage conditions. 4. Ethics committee approval (if required): The ethics committee reviews and approves the request if necessary. 5. Sign confidentiality agreement: The applicant signs a confidentiality agreement and commits to ethical research practices. 6. Access granted: After completing the above steps, access to the data/documents is provided. 7. Follow-up and support: The applicant can contact the corresponding author for guidance or additional information during the process.
Comments