Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Six Weeks of Water-based Stretching and Pilates Exercises on Pain, Function, Spine Posture, and Foot Pressure Distribution in Patients with Ankylosing Spondylitis

Protocol summary

Study aim

Comparing the effectiveness of Pilates exercises and stretching exercise in water on pain, pulmonary function, spine posture, quality of life, and distribution of plantar pressure in patients with ankylosing spondylitis.

Design

The study had three groups parallel to the control group and pre-test and post-test design, assessors blind, randomized phase 2 and, 45 patients. Random number allocation software is used for randomization

Settings and conduct

This study will be conducted at Razi university. evaluators will be blinded in the study The method of blinding will be done by randomization process by a person not involved in the study and placed the subjects' numbers in a sealed envelope.

Participants/Inclusion and exclusion criteria

no progression of the bamboo spine on radiographical scans,(2) Bath Ankylosing Spondylitis Disease Activity Index (BAS-DAI) of 4.0 points or lower, (3)lack of regular exercise for the last 6 months; (4) use of medication for the last 6 months. Those with uncontrolled chronic diseases or psychiatric history and currently on psychiatric medication were excluded

Intervention groups

water-based Pilates exercise group stretch-based exercise group control

Main outcome variables

pain, spin posture, spine range of motion, foot pressure distribution.

General information

Reason for update

This study was conducted during the COVID pandemic time; We were at the beginning of a new peak of COVID, and according to the research supervisor, the number of weeks of interventions was decreased to six weeks, but the number of sessions per week increased to four. However, we reduced the number of weeks and increased the number of sessions per week recommended by the research supervisor to prevent encountering COVID pike and contamination of participants. Second, we removed the lung function based on the project supervisor because we had to use a spirometer mouth to measure lung function, and again the participants were likely to get coronavirus, so we removed the lung function. The mentioned changes were reported to the university research committee and the project supervisor, but we were not informed about the update of the RCT site.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190426043377N3**
Registration date: **2021-05-22, 1400/03/01**
Registration timing: **prospective**

Last update: **2022-06-16, 1401/03/26**
Update count: **1**

Registration date

2021-05-22, 1400/03/01

Registrant information

Name
Farzaneh Gandomi

Name of organization / entity
دانشگاه رازی

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-07-06, 1400/04/15
Expected recruitment end date
2021-08-06, 1400/05/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Six Weeks of Water-based Stretching and Pilates Exercises on Pain, Function, Spine Posture, and Foot Pressure Distribution in Patients with Ankylosing Spondylitis

Public title
The Effect of Water-based Stretching and Pilates Exercises on Ankylosing Spondylitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No progression of the bamboo spine on radiographical scan Bath Ankylosing Spondylitis Disease Activity Index (BAS-DAI) of 4.0 points or lower Lack of regular exercise for the last 6 months Use of medication for the last 6 months
Exclusion criteria:
Those with uncontrolled chronic diseases or psychiatric history and currently on psychiatric medication
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple individual randomization using Random Number Allocation software was used. The assignment sequence is hidden by the numbered envelopes, which are numbered sequentially, and the envelopes are opened only after all the initial and basic assessments of the participants have been made. The random assignment sequence is performed by one of the study partners who is not involved in the evaluations and remains secret from the evaluators and other research colleagues.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome assessors do not know the assigned group of subjects; Because the assignment of individuals to groups is done by a person outside the research and after evaluating the pre-test, he introduces the assigned group to him.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Center No. 2, Shahid Beheshti Blvd.
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Kermanshah
Postal code
6715663137
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.KUMS.REC.1399.1137

Health conditions studied

1

Description of health condition studied
Ankylosing Spondylitis
ICD-10 code
M45
ICD-10 code description
Ankylosing spondylitis

Primary outcomes

1

Description
Primary outcome: pain
Timepoint
Before and after 8-week
Method of measurement
Pain by the visual analog scale (VAS)

2

Description
Spine range of motion (ROM)
Timepoint

Before and after 8-week

Method of measurement

Spine range of motion by inclinometer

Secondary outcomes

1

Description

Spine posture

Timepoint

Before and after 8-week intervention

Method of measurement

Spine posture by Spinal mouse

2

Description

Foot pressure distribution

Timepoint

Before and after 8-week intervention

Method of measurement

Foot pressure distribution by PT scan

3

Description

Pulmonary Function

Timepoint

Before and after 8-week intervention

Method of measurement

Spirometry device

Intervention groups

1

Description

Intervention group: Pilates in water: Pilates in water training program includes 12 sessions in the shallow, semi-deep and deep part of Azadi pool in Kermanshah on even days, 3 sessions per week with water temperature of 28 to 29 degrees Celsius. Each training session is 60 minutes and includes the following: The correct way of abdominal breathing and the basic principles of the sessions, including the main physical exercises in different positions (standing, floating in two positions, arch and back) and with resistance bands (TheraBand Elastic Band Hygienic Corporation, Akron, OH, USA) Combines training balls, rims, clamps attached to bars around the pool, steppe and wood.

Category

Rehabilitation

2

Description

Control group: medication; NSAIDs & Anti TNF (weekly, two weekly, and monthly)

Category

Treatment - Drugs

3

Description

Intervention group: Stretching exercise in water: The stretching program in water in this study includes 24 sessions of water exercise activity in the shallow part of Azadi pool in Kermanshah on even days, 3 sessions per week with water temperature of 33 to 30 degrees Celsius and intensity of exercise 50 Up to 75% of the maximum heart rate is performed. Each training session is 60 minutes, which is divided into 3 parts: 10 to 15 minutes of warm-up and 35-45 minutes of the main exercises. In general, the movements performed in this stage include a series of stretching movements, walking in directions. Jogging in water, upper limb movements while the lower limbs are immobile, lower limb movements while the upper limbs are fixed, and upper and lower limb movements will be performed simultaneously by the exercise instructor. The water is designed according to the condition and ability of patients according to the instructions of the American Physical Medicine Association.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Research Development Center, Imam Reza Hospital

Full name of responsible person

Fatemeh Vafaei

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Imam Reza Hospital, Bage-e- Abrisham Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah 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
Kermanshah 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
Razi Univesity
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Farzaneh Gandomi
Position
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available