

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of eight-week water and land Pilates on pain, disability and balance in female college student with chronic non-specific low back pain

Protocol summary

Study aim

The aim of this study was to investigate the effect of eight weeks of Pilates exercise on the mat and in the water in female patients with chronic non-specific low back pain.

Design

Double-blind randomized clinical trial

Settings and conduct

The exercises were conducted in the pool and a gym at Bu Ali-Sina University.

Participants/Inclusion and exclusion criteria

Age between 20-30 years Existence of chronic non-specific low back pain at least 3 month No history of surgery or fracture in spine and lower limb

Intervention groups

Pilates exercise in the water Pilates exercise on the mat

Main outcome variables

Reduced pain; Reduced disability; Reduced postural sway

Arak University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-06, 1397/10/16

Expected recruitment end date

2019-01-13, 1397/10/23

Actual recruitment start date

2019-01-07, 1397/10/17

Actual recruitment end date

2019-01-14, 1397/10/24

Trial completion date

2019-03-17, 1397/12/26

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046368N1**

Registration date: **2020-03-04, 1398/12/14**

Registration timing: **retrospective**

Last update: **2020-03-04, 1398/12/14**

Update count: **0**

Registration date

2020-03-04, 1398/12/14

Registrant information

Name

Zahra Raeisi

Name of organization / entity

Scientific title

Effect of eight-week water and land Pilates on pain, disability and balance in female college student with chronic non-specific low back pain

Public title

Effect of eight-week water and land Pilates on female patients with chronic non-specific low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of chronic non-specific low back pain for at least three months

Exclusion criteria:

Structural dysfunction in the spine A history of surgery or fracture in spine and lower limb any other illness that can affect the research variables

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects randomized divided in two steps. At first each subject selected a number between the interval of 1 to 24 using the draw, then 12 random numbers were selected using Random number generator software from 24 to 1 numbers and then according to the numbers produced and the numbers selected, the subjects were divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in study and researcher that do laboratory tests were not aware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Science, in front of People's Garden, Shahid Fahmideh Street

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.UMSHA.REC.1397.762

Health conditions studied

1

Description of health condition studied

chronic non-specific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity

Timepoint

Before intervention (pre-test) and 8 weeks after intervention (post-test)

Method of measurement

The Visual Analogue Scale

2

Description

Functional disability

Timepoint

Before intervention (pre-test) and 8 weeks after intervention (post-test)

Method of measurement

The Oswestry Disability Questionnaire

3

Description

Balance

Timepoint

Before intervention (pre-test) and 8 weeks after intervention (post-test)

Method of measurement

Biodex Balance System

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: perform the Pilates exercises in the water for eight weeks (three session per week)

Category

Rehabilitation

2

Description

Second intervention group: perform the Pilates exercises on the mat for eight weeks (three session per week)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-ali Sina university

Full name of responsible person

Ali Yalfani

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu Ali-Sina University

Full name of responsible person

Gholamhossein Majzoubi

Street address

Vice Chancellery For Research Affairs, Bu Ali Sina University, Chahar Bagh Martyr Mustafa Ahmadi Roshan

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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

Bu Ali-Sina 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

Bu Ali-Sina University

Full name of responsible person

Ali Yalfani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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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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Person responsible for updating data

Contact

Name of organization / entity

Arak University

Full name of responsible person

Zahra Raeisi

Position

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Latest degree

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Other areas of specialty/work

Sport Medicine

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcomes of the study will be shared.

When the data will become available and for how long

Access period starting from 1398

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using information to help treat patients

From where data/document is obtainable

Ali Yalfani Email: Ali_yalfani@yahoo.com Tel: 00988138381422

What processes are involved for a request to access data/document

After receiving the e-mail if any possibility files to be shared.

Comments