

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

#### 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

Arak University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3492

##### Email address

z\_raisi13@yahoo.com

##### 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

##### 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

**City**

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**Province**

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**Postal code**

6517833131

**Phone**

+98 81 3838 1422

**Email**

Ali\_yalfani@yahoo.com

## 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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**Phone**

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**Email**

sakhai@basu.ac.ir

**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

**Street address**

Bu Ali Sina University, Chahar Bagh of martyr Mustafa Ahmadi Roshan

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## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University

**Full name of responsible person**

Zahra Raeisi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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**Phone**

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**Fax**

**Email**

Z\_raisi13@yahoo.com

## 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**