Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Hamedan

Province
Hamadan

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

City
Hamedan

Province
Hamadan

Postal code
6517833131

Phone
+98 81 3838 1601

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

City
Hamedan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 1422

Email
ali_yalfani@yahoo.com

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
Rehabilitation management

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

City
Hamedan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 1422

Email
ali_yalfani@yahoo.com

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

Street address
Arak University, Basij Square

City
Arak

Province
Markazi

Postal code
3848177584

Phone
+98 86 3417 3492

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