

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effect of adding breathing exercises to core stability exercises on pain, function, balance and fear of movement in pre-elderly women with non-specific chronic back pain

#### Protocol summary

##### Study aim

The effect of adding breathing exercises to core stability exercises on pain, function, balance and fear of movement in pre-elderly women with non-specific chronic back pain

##### Design

A controlled, parallel-group, single-blind, randomized clinical trial on 30 patients.

##### Settings and conduct

The study will be conducted in the exercise therapy department of Dr. Shakeri's Pain Clinic in Zahedan. The study population will be selected from among those who refer to this clinic with chronic non-specific low back pain and, after conducting the tests, will be divided into intervention and control groups according to the entry and exit criteria. The study will be single-blinded, so that the samples will not be aware of the details of the tests and exercise groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included: reporting pain in the lower back, lumbosacral region, and buttocks that worsened after physical activity; age range 48 to 58 years; back pain for more than 3 months; full awareness of the aspects related to the study and possible benefits and harms; and signing an informed consent form. Exclusion criteria included: participating in regular physical activity in the past 6 months; receiving treatment for chronic non-specific low back pain in the past month; presence of lumbar disc herniation or fracture leading to back pain; osteoporosis or cancer or cardiorespiratory diseases and diabetes; any surgery in the abdomen or chest, back pain following trauma, smoking, any respiratory problems, having associated structural changes in the tissues of the back. Pregnant women

##### Intervention groups

Intervention group: breathing exercises and core stability exercises, control group: core stability exercises

#### Main outcome variables

Pain, function, balance, fear of movement, Endurance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250219064774N1**

Registration date: **2025-06-03, 1404/03/13**

Registration timing: **retrospective**

Last update: **2025-06-03, 1404/03/13**

Update count: **0**

##### Registration date

2025-06-03, 1404/03/13

##### Registrant information

##### Name

Zahra Kashefi Nezhad

##### Name of organization / entity

University of Sistan&Baluchestan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3435 4644

##### Email address

zahrakashefi4665@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-09, 1404/01/20

##### Expected recruitment end date

2025-04-25, 1404/02/05

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of adding breathing exercises to core stability exercises on pain, function, balance and fear of movement in pre-elderly women with non-specific chronic back pain

**Public title**

The effect of breathing exercises and center stability exercises in pre-elderly women with non-specific chronic back pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Reports of pain in the lower back, lumbosacral region, and buttocks that is worse after physical activity Age range 48 to 58 years Back pain for more than 3 months Full knowledge of aspects related to the study and possible benefits and losses and signing the informed consent form.

**Exclusion criteria:**

Participation in regular physical activity in the past 6 months Received non-specific chronic back pain treatment in the last month Lumbar disc protrusion or fracture that leads to back pain Osteoporosis or cancer or cardiorespiratory diseases and diabetes Any surgery in the abdomen or chest, back pain following trauma, smoking, any breathing problems, having accompanying structural changes in the back tissues. pregnant women

**Age**

From **48 years** old to **58 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Through a lottery and in the presence of the individuals themselves, each person will be given a number from 1 to 30. The numbers are written on paper and the papers are folded and placed in a container (container number 1). Then in another container, the names of the groups (each group has 15 sheets) are folded and placed in the container (container number 2). Then a lottery will be held in the presence of the participants. One person will draw the lottery number and group and one person will record and write the lottery numbers (one sheet will be taken from container number 1, one sheet from container number 2. For example, number 10 is the control group, number 13 is the training group, etc.) All individuals will be grouped in the same way.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, outcome assessors (laboratory technicians) are asked to take the desired tests from the patients. These individuals will be unaware of the purpose of the study, the assignment to study groups, and the reason for their presence in the laboratory, and will only assess the variables and record their observations.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of the University of Sistan and Baluchestan

**Street address**

University Boulevard

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745780

**Approval date**

2024-11-09, 1403/08/19

**Ethics committee reference number**

IR.USB.REC.1403.032

**Health conditions studied****1****Description of health condition studied**

Chronic nonspecific low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Pain level

**Timepoint**

Before the intervention, one day after the intervention

**Method of measurement**

Visual Pain Scale

## 2

### **Description**

Assessment of functional limitations

### **Timepoint**

Before the intervention, one day after the intervention

### **Method of measurement**

Roland Morris Disability Questionnaire and Oswestry Disability Index

## 3

### **Description**

Balance

### **Timepoint**

Before the intervention, one day after the intervention

### **Method of measurement**

5 times standing and sitting test. Static balance: One-legged standing test with eyes closed. Dynamic balance: Through Y test.

## 4

### **Description**

Fear of movement

### **Timepoint**

Before the intervention, one day after the intervention

### **Method of measurement**

Fear of movement questionnaire

## 5

### **Description**

Endurance

### **Timepoint**

Before the intervention, one day after the intervention

### **Method of measurement**

Sorensen test, Trunk flexor test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Breathing exercises and core stability exercises for improving low back pain. The exercises will be performed three sessions per week for 8 weeks.

#### **Category**

Rehabilitation

### 2

#### **Description**

Stability exercises at the center. The exercises will be three sessions per week for 8 weeks.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Dr. Shakeri Pain Clinic

##### **Full name of responsible person**

Asadollah Shakeri

##### **Street address**

Khayyam Street

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816847154

##### **Phone**

+98 992 190 2556

##### **Email**

drashakeri@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

University of Sistan and Baluchestan

##### **Full name of responsible person**

Dr. Noor Mohammad Yaqoubi

##### **Street address**

University Street

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816745845

##### **Phone**

+98 54 3113 6245

##### **Email**

yaghoubi@mgmt.usb.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

University of Sistan and Baluchestan

#### **Proportion provided by this source**

20

#### **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

zahrakashefi4665@gmail.com

### Contact

**Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Zahra Kashefi Nezhad

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports pathology and corrective exercises

**Street address**

University Street

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Phone**

+98 914 032 4665

**Email**

zahrakashefi4665@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Zahra Kashefi Nezhad

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports pathology and corrective exercises

**Street address**

University Street

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816745845

**Phone**

+98 914 032 4665

**Email**

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Zahra Kashefi Nezhad

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports pathology and corrective exercises

**Street address**

University Street

**City**

Zahedan

**Province**

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9816745845

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+98 914 032 4665

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zahrakashefi4665@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**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