Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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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
۹۸۱۶۷۴۵۷۸۵
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
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Sistan-va-Balouchestan
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9816847154
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Dr. Noor Mohammad Yaqoubi
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9816745845
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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

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

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Person responsible for updating data

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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