# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effects of a combined exercise intervention program with cognitive physical therapy on pain, disability and postural sway on women with chronic non-specific low back pain

## Protocol summary

**Study aim**
Effects of a combined exercise intervention program with cognitive physical therapy on pain, disability and postural sway on women with chronic non-specific low back pain

**Design**
Randomized, clinical trial with control group , single blinded

**Settings and conduct**
The present study will be conducted in Arak city. 45 women with non-specific chronic back pain will participate in this study in the form of three groups of combined exercises, combined exercises with cognitive functional therapy and control. The exercises will be done for eight weeks and three sessions in each week.

**Participants/Inclusion and exclusion criteria**
The criteria for entering the study include suffering from non-specific chronic back pain (with a history of pain for at least 3 months) as diagnosed by a specialist doctor, not suffering from cardiorespiratory diseases, neuromuscular diseases and diabetes, not having a history of surgery, fractures, serious injuries in The spine includes disc herniation, no obvious structural abnormalities in the spine, not having a difference in the length of the legs, a disability score equal to or greater than 4 in the Roland Morris Disability Questionnaire, and a score of at least 3 on the visual pain measurement scale. Also, if the subjects do not participate regularly in the training sessions (two consecutive sessions and three non-consecutive sessions), they will be excluded from the study.

**Intervention groups**
Combined exercises that include aerobic, resistance, flexibility and strength exercises. Combined exercises with cognitive function therapy. Combined exercises that include aerobic, resistance, flexibility and strength exercises and cognitive function therapy target physical, lifestyle and psychological barriers to recovery. The control group will have the usual routine of life.

**Main outcome variables**
Pain, Disability, Postural sway, Kinesiophobia, Quality of life

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220722055522N1**
Registration date: **2022-12-03, 1401/09/12**
Registration timing: **prospective**

Last update: **2022-12-03, 1401/09/12**
Update count: **0**

**Registration date**
2022-12-03, 1401/09/12

**Registrant information**

**Name**
Mahsa Asgari

**Name of organization / entity**
The university of arak

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-12-11, 1401/09/20

**Expected recruitment end date**

2023-03-06, 1401/12/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effects of a combined exercise intervention program with cognitive physical therapy on pain, disability and postural sway on women with chronic non-specific low back pain

**Public title**
Effects of a combined exercise intervention program with cognitive physical therapy on women with chronic non-specific low back pain

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Suffering from non-specific chronic back pain (with a history of pain for at least 3 months) Absence of cardiorespiratory diseases Absence of neuromuscular diseases Not having diabetes No history of surgery No history of fracture Not having a history of serious injuries in the spine, including disc herniation Not having obvious structural abnormalities in the spine No difference in leg length Obtaining a disability score equal to or greater than 4 in the Roland Morris Disability Questionnaire Obtaining a score of at least 3 from the visual pain measurement scale

**Exclusion criteria:**
Having neuropathic pain, history of previous lumbar spine surgery history of previous lumbar spine surgery Mental disability Severe mental illness Illiteracy If the subjects do not regularly participate in the training sessions (two consecutive sessions and three non-consecutive sessions), they will be excluded from the study.

**Age**
From **20 years** old to **50 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **45**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this semi-experimental research, the sample size was calculated using Gpower software for the effect size (0.5), test power (0.8) and significance level (0.05) of 42 people and 14 people in each group. Considering the possibility of dropping out in the groups, 45 women with non-specific chronic back pain (n=15) will participate in this study voluntarily according to the inclusion and exclusion criteria. The subjects will be divided into three groups randomly using the Randlist software.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The data analyst will not have information about the grouping of the subjects and the data of the groups will be provided to her in the form of codes (1, 2 and 3).

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Arak University

**Street address**
Arak University, Basij Square, Arak, Iran

**City**
Arak

**Province**
Markazi

**Postal code**
3848177584

**Approval date**
2022-04-20, 1401/01/31

**Ethics committee reference number**
IR.ARAKU.REC.1401.020

## Health conditions studied

### 1

**Description of health condition studied**
Low Back Pain

**ICD-10 code**
M54.5

**ICD-10 code description**
Low back pain

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
Before and after intervention

**Method of measurement**
The visual analogue scale

**2**

**Description**
Disability
**Timepoint**
Before and after intervention
**Method of measurement**
The roland-morris disability questionnaire

## Secondary outcomes

**1**

**Description**
Postural sway
**Timepoint**
Before and after intervention
**Method of measurement**
Foor scan

**2**

**Description**
Quality of life
**Timepoint**
Before and after intervention
**Method of measurement**
SF-36questionnaire

**3**

**Description**
Kinesiophobia
**Timepoint**
Before and after intervention
**Method of measurement**
Kinesiophobia questionnaire

**4**

**Description**
The balance
**Timepoint**
Before and after intervention
**Method of measurement**
Y balance test

**5**

**Description**
walking
**Timepoint**
Before and after intervention
**Method of measurement**
Foot scan

**6**

**Description**
Muscular endurance
**Timepoint**
Before and after intervention
**Method of measurement**
Sorensen's test

## Intervention groups

**1**

**Description**
Intervention group 1: Performing combined exercises that include eight weeks of aerobic, endurance, strength, and flexibility exercises.
**Category**
Rehabilitation

**2**

**Description**
Intervention group 2: Conducting eight weeks of combined exercises with cognitive function therapy. The combined exercises that include aerobic, endurance, strength, and flexibility exercises. The cognitive function therapy targets lifestyle modification and psychological factors to help patients with chronic low back pain. The goals of this approach are to reconceptualize pain from a biopsychosocial perspective while eliminating unhelpful beliefs, overcoming barriers to functional participation related to relevant personal goals, and adopting a healthy lifestyle.
**Category**
Rehabilitation

**3**

**Description**
Control group: They will have their usual routine of life.
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Arak University
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

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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**
Arak 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**
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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**

Not applicable

**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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable