

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Zahra Raeisi

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Arak university,Karbala Boulevard,Basij Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University

Full name of responsible person

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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

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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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