Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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
Zahra Raeisi
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Sponsors / Funding sources

1

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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
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Arak University
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Assistant professor
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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