Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of central stability exercises and cognitive tasks compared to general exercises and cognitive tasks on pain, disability and postural control of people with non-specific chronic low back pain.

Protocol summary

Study aim

Determining the effect of core stability exercises and cognitive tasks compared to general exercises and cognitive tasks on pain, disability and postural control of people with non-specific chronic low back pain.

Design

Two-arm parallel-group randomized control trial, single-blind (assessor), Randomization using random blocks method was used for randomization on 34 patients with non-specific chronic back pain, Rand function of Excel software.

Settings and conduct

In many clinical guidelines, exercise therapy is a recommended treatment for low back pain. First, the assessment of the pain intensity and the disability level, as well as postural control using the force plate device, the quality of life, the fear of movement, and the fear-avoidance beliefs, in people with Chronic non-specific back pain will be done in the movement analysis laboratory of the rehabilitation faculty of the Iran University. Finally, the participants will go to the physiotherapy clinic of the rehabilitation faculty of Iran University and will be randomly divided into two groups and will be treated for 16 sessions (3 days a week). At the end of the treatment, the above evaluations will be done again. This study is single-blind (blinding of the assessor).

Participants/Inclusion and exclusion criteria

Non-specific chronic low back pain that has lasted at least 3 months since its onset Pain score of 3 or more on a visual analog scale Not having radicular pain and any neurological symptoms Uncorrected vision impairment Hearing problems Vestibular dysfunctions Previous spinal surgery

Intervention groups

Experimental group: core stability exercises with cognitive tasks Control group: general exercises with cognitive tasks

Main outcome variables

1- Visual analog scale: Questionnaire evaluating pain intensity. Range from 0-10. 2- Oswestry Disability Index: Questionnaire evaluating the level of disability. Range from 0-100

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039470N2**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Reza Salehi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-02, 1402/02/12

Expected recruitment end date

2024-01-30, 1402/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of central stability exercises and cognitive tasks compared to general exercises and cognitive tasks on pain, disability and postural control of people with non-specific chronic low back pain.

Public title

Effects of Core Stability Exercises and Cognitive Tasks on Chronic Non-specific Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Orthopedist-confirmed diagnosis of chronic nonspecific low back pain that has lasted at least three months since its onset. Pain score of 3 or more on a visual analog scale. Pain during quiet standing. Cognitive level above 24 based on mini-mental state examination (MMSE).

Exclusion criteria:

Radicular pain and any neurological signs. Uncorrected vision impairment. Hearing problems. Vestibular dysfunctions. Cognitive deficit. Previous spinal surgery. Severe deformity or injury to the lower extremities.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done by the method of variable blocks, which will include four-letter blocks consisting of letters A and B. After that, according to the fact that 34 people are needed in the study and the blocks are four components, 9 random numbers will be prepared, which will determine the arrangement of the four component blocks. Then, the random treatment list will be placed in sealed and numbered envelopes in the form of letters A and B. Letter A will represent CSE exercises with cognitive task and letter B will represent GE exercises with cognitive task. Then, an envelope will be assigned to each patient in the order of entering the study and his group will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the dissimilarity of the treatment and control groups, there is no possibility of blinding the participants and the therapist. Therefore, in the present study, only for objective evaluations, including assessment of postural stability and postural control strategies, the blinding of the evaluator will be done with respect to the grouping of the subjects under study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Clinical trials.gov

Secondary trial Id

NCT05832918

Registration date

2023-05-01, 1402/02/11

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Faculty of Rehabilitation Sciences, Madad karan St., Shah Nazari St., Mader Square, Mirdamad

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1545913487

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.IUMS.REC.1401.838

Health conditions studied

1

Description of health condition studied

Non-specific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks ", "change from baseline at three months "
Method of measurement
Visual analog scale

2

Description
Disability level
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks ", "change from baseline at three months "
Method of measurement
Oswestry disability index questionnaire

Secondary outcomes

1

Description
Center of pressure (COP) sway range for anteroposterior (AP range)
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

2

Description
COP sway range for mediolateral (MA range)
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

3

Description
COP sway velocity
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

4

Description
Sway area
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

5

Description
Short-term diffusion coefficient of stabilogram diffusion plot
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

6

Description
Long-term diffusion coefficient of stabilogram diffusion plot
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

7

Description
Critical point coordinates
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Force plate device

8

Description
Quality of life
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
12-item short form health survey

9

Description
kinesiophobia
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Tampa scale for kinesiophobia

10

Description
Fear-avoidance beliefs
Timepoint
"Baseline (pre-intervention)", "change from baseline immediately after the intervention at five weeks "
Method of measurement
Fear-avoidance beliefs questionnaire

Intervention groups

1

Description
Intervention group: core stability exercises with cognitive tasks (16 sessions, three times a week of local muscle exercises)
Category
Rehabilitation

2

Description
Control group: general exercises with cognitive tasks (16 sessions, three times a week of global muscle exercises)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Clinic, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
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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
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

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

Title and more details about the data/document
Effects of Core Stability Exercises and Cognitive Tasks on Chronic Non-specific Back Pain

When the data will become available and for how long
Starting after publication

To whom data/document is available
This is only available for people working in academic institutions.

Under which criteria data/document could be used
It can be used for advanced analysis and with new topics while maintaining ownership of university data.

From where data/document is obtainable
Salehi.re@iums.ac.ir

What processes are involved for a request to access data/document
It will be done through the email registered in the protocol.

Comments