Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of adding pain neuroscience education on the clinical results of core muscle training using pressure biofeedback in people with chronic low back pain diagnosed with functional instability

Protocol summary

Study aim

investigating the effect of adding pain neuroscience education on the clinical results of core muscle training using pressure biofeedback in people with chronic low back pain diagnosed with functional instability

Design

Randomized two arm parallel group trial with single blinded assessor,48 patient.

Settings and conduct

In Rofaydeh Hospital, Tehran, by using two explicit training methods, which include the addition of pain neuroscience education to core muscle training along with pressure biofeedback in people with chronic back pain, we aim to improve both the subjective aspects of back pain by using We will examine the changes in brain waves recorded by neurofeedback and analyze the biological dimensions of the morphological changes of the transverse abdominal muscle using musculoskeletal ultrasound, and finally we will examine pain, disability and fear of movement.All criteria are performed by an blind evaluator . After the initial evaluation, the participants are randomly divided into two groups during the block.the measurement is done in the first treatment sessions and immediately after 15th session and in order to follow up the participants, three months after the end of the treatment, again the primary evaluation criteria are measured by the evaluator. during the three-month follow-up , the participant will not receive anytreatment .

Participants/Inclusion and exclusion criteria

People with chronic back pain diagnosed with functional instability who do not suffer from nerve and muscle pain with a specific cause

Intervention groups

core muscle training with pressure biofeedback device,core muscle training with pressure biofeedback device plus pain neuroscience education

Main outcome variables

brain wave with neurofeedback,transverse abdominal muscle with sonography, pain in the visual analogous scale,disability in Oswestry disability index,and fear of movement with a Tampa scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240916063057N1**
Registration date: **2024-10-20, 1403/07/29**
Registration timing: **prospective**

Last update: **2024-10-20, 1403/07/29**
Update count: **0**

Registration date

2024-10-20, 1403/07/29

Registrant information

Name

Golnaz Sadria

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 5198

Email address

gl.sdr9019@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-17, 1403/08/27

Expected recruitment end date

2025-08-18, 1404/05/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding pain neuroscience education on the clinical results of core muscle training using pressure biofeedback in people with chronic low back pain diagnosed with functional instability

Public title

the effect of education in treatment of chronic low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

age range 18-40 at least education level is diploma prone instability test is positive Gower’s sign is positive at least 3 month patient have continuous pain in lumbago there is no obvious symptom in lumbar region (patients rule out when have these disorder: decrease sensation in specific dermatome , decrease strength in specific myotome of lumbar region , disc herniation ,sacroiliac joint dysfunction) at least patient have 3times low back pain during last year intensity of patient's pain during Gower’s test in Visual Analogous Scale should be 3to7 Oswestry disability index more than 12% patient can stand and walk without any supportive aid such as cane patient don't have Rheumatoid and central nervous system disorder patient don't have any history of tumor, malignancy and spinal malposture patient don't have any history of abdominal surgery at least score of MMSE for measuring cognition state should be 27 BMI not more than 30 patient don't get any medications and exercise therapy during last 3 month

Exclusion criteria:

pregnancy sitting more than 2 hours a day

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

People referring to the Physiotherapy Department of ROFAYDEH Hospital, Department of Low Back Pain School are first examined by the senior researcher (NOT BLIND) according to the Inclusion criteria. If they meet the Inclusion criteria, they are included in the study.) Using the www.sealed envelope.com website with a block size of 4 (block size n=4) a random sequence is made Then, one of the 6 modes AABB, ABAB, ABBA, BBAA, BABA, BAAB will be randomly selected, where A represents the first group and B represents the second group. Then the blind assessor seals using non-transparent envelopes the random sequences generated by the site are placed in envelopes for every 48 people, and people take one of the 48 envelopes without putting them in the order of arrival and enter the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

Therapist doesn't blind to type of treatment and assessment and both groups Assessor blind to type of treatment and assessment and both groups Patient don't blind to type of treatment and groups Statistics analyzer blind to treatment and assessment and both groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of social welfare and rehabilitation science

Street address

Koodakyar End, Shahid Shahriari Square,Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2024-09-28, 1403/07/07

Ethics committee reference number

IR.USWR.REC.1403.134

Health conditions studied

1

Description of health condition studied

chronic low back pain diagnosed with functional instability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

pre treatment,immediate after fifteen session,Three months after the end of treatment

Method of measurement

visual analogous scale

Secondary outcomes

1

Description

disability

Timepoint

pre treatment, immediate after fifteen sessions , Three months after the end of treatment

Method of measurement

Oswestry disability index

2

Description

fear of movement

Timepoint

pre treatment, immediate after fifteen sessions , Three months after the end of treatment

Method of measurement

tampa scale

3

Description

thickness of transverse abdominis muscle

Timepoint

pre treatment, immediate after fifteen sessions , Three months after the end of treatment

Method of measurement

sonography

4

Description

brain wave

Timepoint

pre treatment, immediate after fifteen sessions , Three months after the end of treatment

Method of measurement

neurofeedback

Intervention groups

1

Description

Intervention group: core muscle training using pressure biofeedback device along with pain neuroscience education

Category

Rehabilitation

2

Description

Control group: core muscle training using pressure biofeedback device

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofaydeh hospital

Full name of responsible person

Golnaz Sadria

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nemati Alley,south salimi Ave,gheytarieh

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1935973476

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rofeideh.hospital@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

mohammad saeed khanjani

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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

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Golnaz Sadria
Position
Phd candidate
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is 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
All ethical forms and documents and informed consent in the process of receiving the code of ethics are registered in the proposal
When the data will become available and for how long
8 months after the publication of the results of the thesis and the publication of the article extracted from the thesis
To whom data/document is available
Senior Researcher (Golnaz Sadria) Ethics Committee of the University of social welfare and Rehabilitation Sciences
Under which criteria data/document could be used
It can be retrieved only if the patient's physical condition becomes problematic and for a detailed examination of the information and the treatment process
From where data/document is obtainable
In order to receive the results of the research, the

contact numbers of the patients and their communication channels are included in the informed consent form, and after the review and analysis of the data by the senior researcher, the results will be provided to the participants via email or face-to-face meeting.

What processes are involved for a request to access data/document

First, according to the informed consent form, in which the number of the senior researcher (Golnaz Sadria) is mentioned, contact is made with that number, then after explaining the reason for receiving the documents to the senior researcher and presenting it to the ethics committee of the University of social welfare and rehabilitation science, information After unlocking, the code will be provided to the participant.

Comments