Movement Patterns in Patients with Chronic Low Back Pain during Lifting and Walking and its relation to Central Sensitization.

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1. to test differences in movement patterns during a standardized lifting task and gait between patients with chronic low back pain with high central sensitization (CS+), low back pain with low/moderate central sensitization (CS-) and healthy…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49892

Source
ToetsingOnline

Brief title
Movement pattern in Patients with low back pain

Condition

- Other condition

Synonym
Back Pain, spinal pain

Health condition

A-specifieke chronische lage rugpijn

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomechanics, Chronic pain, Functional capacity, sensitization

Outcome measures

Primary outcome

The patients with chronic low back pain will be categorized into two subgroups between CS+ and CS-. This will be carried out with the central sensitization inventory (CSI) based on standardized cut-off scores. Main endpoints will be tested in the movement laboratories of both the UMCG-Beatrixoord (patients) and Saxion university of applied sciences (healthy controls). Movement analyses will be performed using Vicon movement analysis system. To test differences in motor control between the groups, we will apply Principal Component Analyses to measure and compare their loadings using motion capture data.

Secondary outcome

1. Quantitative Sensory Testing: QST is a psychophysical method that is used to assess the somatosensory function. In this study, the assessment will consist three sensory tests, 1) Cuff-algometry (CA), 2) Temporal Summation of Pain (TSP), and 3) activation of Conditioned Pain Modulation (CPM). These tests will be used in all the three groups.

2. Nummeric Rating Scale for Pain: A pain rating scale will be administered to

rate current pain intensity by giving a number between 0 and 10 (0 = no pain, and 10 = maximum pain imaginable). This scale will be used just in the patients groups.

3. Surface Electromyography derived from m. biceps and quadriceps femoris in both lower limbs with 4 EMG sensors. Two EMG sensors are placed at the erector spinae bilaterally. Finally, another 3 EMG sensors at the trapezius descendens, pectoralis major, and anterior deltoid muscules will be placed. all placements will be carried out following SENIAM methods.

4. Ground reaction forces during lifting and gait.

Study description

Background summary

Increasing evidence suggests that in prolonged Low Back Pain, pain processing alters as a consequence of central sensitization (CS). It is unknown how CS is related to the ability to perform functional tasks (in this case lifting and gait).

Study objective

1. to test differences in movement patterns during a standardized lifting task and gait between patients with chronic low back pain with high central sensitization (CS+), low back pain with low/moderate central sensitization (CS-) and healthy controls.
2.to test differences in movement patterns during a standardized lifting task overtime during the course of a rehabilitation program.

Study design

1st research question: a cross sectional case-control.

2nd research question: a within-subject prospective study design

Study burden and risks

This study can only be done using these patients* groups. There are negligible injury risks and/or burdens and safety of the lifting test has previously been tested on safety in patients with low back pain and healthy controls. Quantified Sensory Testing, a secondary measure, is applied worldwide and considered a safe technique to quantify pain processing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age >=18

2. Have to experienced back pain more than 3 months
3. Non-specific CLBP confirmed by a physiatrist of UMCG Pain Rehabilitation.Admitted to a 12 week pain rehabilitation program
4. Have reported a minimal pain level of 3 on the 0-10 pain numerical rating scale (NRS)
5. Signed informed consent

Exclusion criteria

1.. Spinal pathologies, such as fractures, tumours or inflammatory diseases, such as ankylosing spondylitis, nerve root compromise will be confirmed by clinical neurological tests (disk herniation and spondylolisthesis with neurological involvement, infection, malignancy, rheumatic, narrowing of spinal canal and other conditions) or severe cardiorespiratory diseases
2. Diseases affecting sensory processing (eg. diabetes, alcohol or substance abuse, neuropathy)
3. Back surgery in the past 2 years
4. Patients using neuroleptics, benzodiazepines or regular / strong opioids

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2024
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-01-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78448.042.21