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Strengthening and targeted rehabilitation in patients with chronic low back pain

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
10/11/2025

Overall study status
Ongoing

Last Edited
10/11/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Low back pain (LBP) is the leading cause of disability worldwide. While exercise therapy is the most recommended treatment for chronic LBP, its effectiveness remains modest, likely due to the differences in patient presentations. Evidence suggests that matching individuals to the most appropriate exercise type could improve outcomes. The primary aim of this study is to evaluate the effect of a targeted exercise program versus general resistance exercise program on disability in individuals with chronic low back pain. A secondary aim is to determine whether each intervention can improve back muscle health (size and composition) and function (strength), pain, quality of life, sleep quality, physical activity levels, satisfaction and perceived recovery in individuals with chronic LBP.

Who can participate?
Patients aged between 18 and 60 years with non-specific chronic LBP, i.e., pain of unspecified origin

What does the study involve?
Participants will be assigned to one of the following groups:
Group 1: Targeted exercise program
Group 2: General exercise program
The exercise program will include either a targeted exercise for the back such as motor control and isolated lumbar extensor exercises, or a general muscle strengthening program. All exercises of both groups will aim to improve disability and increase muscle function and strength.
This research project is randomized, which means that participants will be divided into one or the other of two groups. The assignment to one or the other of these treatment groups is random, so participants will not be able to choose their group. Thus, 1 in 2 (50%) will be included in group 1 and 1 in 2 (50%) will be included in group 2.
Participants will be asked throughout the duration of of their participation in this project to continue to follow their normal rhythm of life and usual physical activities. During the first visit, participants be asked to complete some questionnaires regarding the intensity of their low back pain, and how their pain interferes with their daily life. They will also be asked to fill out a sociodemographic questionnaire. The completion of these questionnaires will take around 30

minutes. They will also be introduced to the application “Manage My Pain” by ManagingLife.
Subsequently, in order to measure participants back muscles’ morphology and function, participants will undergo a:
1. An MRI evaluation of their spine, glute muscles and hips for a duration time of around 45 minutes.
2. A back and glute muscles strength test, for a duration time of around 30 minutes
Participants will then begin a 16-week exercise program, with a frequency of three sessions a week. Each session will last between 45-60 minutes and will take place at the School of Health. A certified athletic therapist or kinesiologist will supervise the exercise program. During the course of the intervention, participants will be asked to use the “Manage My Pain” app to track their disability, pain, quality of life, sleep quality and physical activity levels. Pain ratings will be collected weekly throughout the program duration using the mobile app.
At the end of the 16-week program, in order to evaluate possible changes in back musculature and symptoms, participants will be requested to complete the same examination as performed during the first step and to complete the same questionnaires.
Some of participants will be invited to do an individual interview to ask about prior experiences with exercise for low back pain and expectations before the exercise program. In addition, we will ask participants some questions regarding their experience and satisfaction after the exercise program.
These interviews will take place either in person or via a video conference and will last approximately 40 minutes. The conversation will be recorded and transcribed for data analysis. Any identifiable information will be removed from the transcripts, and your data will be stored securely.

What are the possible benefits and risks of participating?
There are potential personal benefits from participating in this research project. In addition, the results obtained will contribute to the advancement of scientific knowledge in this field of research. This trial will provide a unique opportunity to evaluate the effectiveness of MC+ILEX as compared to free-weight resistance training in a homogeneous sample of participants with primary nociceptive chronic LBP. The findings will provide robust scientific evidence to support a targeted LBP intervention. These results will have important implications for clinical practice, offering cost-effective and personalized treatment strategies. Furthermore, the study will contribute to the advancement of knowledge in musculoskeletal rehabilitation and inform future research directions in the field.
Besides the time required for participation in this research project, there are no other disadvantages associated with participation in this research project. According to current knowledge, undergoing MRI examinations for the purpose of this research project will not put participants at any risk, if they have no contraindications.
Due to the strength of the magnetic field emitted by the device, it is necessary to take certain precautions. This is why participants must complete a detailed questionnaire in order to detect any contraindication, for example, the presence of a pacemaker, an aneurysm clip, a metal prosthesis, a prosthesis or cardiac valve clip, presence of metal in the eye or on the body, tattoo, piercing, dental braces or if they suffer from claustrophobia. The rigorous verification of the presence of contraindication will be assumed by the medical imaging technologist.
In addition, the conditions imposed by the use of the apparatus may result in discomfort from having to stand still and discomfort could also be associated with the noise which is generated by the operation of the apparatus. Participants might also feel some stress.
It is possible that participants feel some muscular stiffness after completing an exercise session, which is quite normal following a muscle strengthening program. The pain should disappear quickly in 1 or 2 days. All exercises will be adapted to their condition and physical level.

Where is the study run from?
Concordia University (Canada)

When is the study starting and how long is it expected to run for?
December 2025 to August 2028

Who is funding the study?
Canadian Institutes of Health Research

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CCER 25-26-14

Study information

Scientific Title
Strengthening and Targeted Rehabilitation for Optimal Neuromuscular Gains for Chronic BACK Pain (STRONG-BACK): a randomized controlled trial in participants with primary nociceptive pain drivers

Acronym

STRONG-BACK

Study objectives
The goal of this randomized controlled trial is to test a targeted-care approach based on the Pain and Disability Drivers Management model to identify and establish the best type of exercise to improve disability (primary outcome) and overall paraspinal dysfunction (secondary outcome) in a homogenous group of patients suffering from chronic low back pain (LBP).

The trial will answer the following research questions:
1. To investigate which 16-week exercise intervention, motor control+isolated lumbar strengthening exercises (MC+ILEX) or free-weight resistance training, is more effective to improve disability (most important outcome for patients) with predominant nociceptive chronic LBP?
2. To investigate if changes in multifidus muscle composition mediate improvements in disability?
3. To investigate which 16-week exercise intervention, MC+ILEX or free-weight resistance training, is more effective to improve multifidus muscle quality and lumbar strength in patients with predominant nociceptive chronic LBP?
4. To explore if baseline score on the Lumbar Spinal Instability Questionnaire can moderate the response to MC+ILEX or free-weight resistance training in chronic LBP at 16 weeks?
5. To explore participants' prior experiences and expectations regarding exercise therapy for chronic LBP before starting a 16-week MC+ILEX or free weight resistance training intervention
6. To explore participants' satisfaction and experience of exercise therapy for chronic LBP after completion of a 16-week MC+ILEX or free weight resistance training intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/09/2025, Central Ethics Committee of Health and Social Services from the Ministry of Quebec (500, rue Sherbrooke Ouest, bureau 800, Montréal, H3A 3C6, Canada; +1 (0)514 873 2114; johane.de.champlain.ccer@msss.gouv.qc.ca), ref: CCER 25-26-14

Study design
Single-center interventional single-blinded (outcome assessor) randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nociceptive chronic low back pain

Interventions
Randomization:
Participants will be randomized into treatment groups using RedCap software. A statistician outside of the research team will generate the randomization sequence and upload it on RedCap. Randomization sequence will be blocked and stratified by the score obtained on the LSIQ questionnaire (high >9, and low < 9). Randomization will occur at the time of the first

treatment sessions by the treating therapists, who will log into RedCap and randomize participants, ensuring allocation concealment.

Blinding:
This trial will be randomized with concealed allocation and assessor blinding. True blinding of therapists and patients is not possible within an exercise trial. However, the therapists and participants will be blinded to the results of the LSIQ.

Arm 1 - Experimental:
Motor control + isolated lumbar extension exercise (MC+ILEX). Targeted motor control and isolated lumbar extensor strengthening exercises. Supervised 16-week program, 3 times a week. This experimental intervention group is called motor control as it uses principles of motor learning such as segmentation, simplification, and task-specific practice to retrain control of trunk muscles activation, alignment and movement. The intervention is based on assessment of the individual patient's motor control impairments and the patient's individual treatment goals (set collaboratively with the therapist). MC will be combined with ILEX exercise to maximize the stimulus and induce adaption of the lumbar extensors. ILEX training will be performed on the MedX Lumbar Extension Machine (MedX, Ocala, FL). Each training session (60 minutes) will be individually supervised by certified athletic therapists. The intervention will last 16 weeks and will take place in the Concordia University School of Health.

Arm 2 - Experimental: Free-weight resistance training
Free-weight resistance training program to address impairments in muscle strength, muscle quality and endurance. Supervised 16-week program, 3 times a week.
This experimental intervention group will receive free-weight resistance training, or compound exercise. The exercises will be delivered across two sessions. Session 1 will include single leg gluteus raise, goblet squats, split squats, planks and standing over row. Session 2 will include a standardized warm up (gluteus myofascial release, glute raise, multi-direction lunge, standing hamstring stretch to overhead squat, assisted squat), deadlift, step-ups, lat pulldown, side bridge, press up. Sessions will be alternated between 2 x session 1 and 1 x session 2 in one week, and 1x session 1 and 2 x session 2 in the following week. Each training session (60 minutes) will be individually supervised by certified kinesiologists. The intervention will last 16 weeks and will take place in the Concordia University School of Health conditioning floor.

Intervention Type
Behavioural

Primary outcome(s)
Level of disability in relation to LBP measured using the Oswestry Low Back Pain Disability Index (ODI) score at baseline and 16 weeks

Key secondary outcome(s))
1. Multifidus muscle fatty infiltration (composition) measurements obtained from magnetic resonance imaging (MRI) from L1 to L5 spinal levels, which will be measured automatically using convolutional neural networks (CNNs). Timepoints: Baseline, 16 weeks.
2. Multifidus cross-sectional area and cumulative 3D volume from magnetic resonance imaging (MRI) slices from L1 to L5 spinal levels (bilaterally) measured automatically using convolutional neural networks (CNNs). Timepoints: Baseline, 16 weeks.
3. Lumbar extensor muscle strength assessed using a MedX Lumbar Extension Machine. Timepoints: Baseline, 16 weeks.
4. Gluteal muscle strength assessed using a handheld dynamometer VALD DynaMo. Timepoints:

Baseline, 16 weeks.
5. Hip range of motion in flexion and extension measured using a handheld dynamometer VALD DynaMo. Timepoints: Baseline, 16 weeks.
6. Pain and how it interferes with physical and mental function, measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)-29 v2.0 score. Timepoints: Baseline, 16 weeks.
7. Pain measured using the visual numerical pain rating scale (NPR) and the “Manage My Pain” app. Timepoints: Baseline, 16 weeks.
8. Health-related quality of life measured using the 12-item Short Form Health Survey (SF-12). Timepoints: Baseline, 16 weeks.
9. Perceived recovery and satisfaction measured using the Satisfaction and Recovery Index (SRI). Timepoints: Baseline, 16 weeks.
10. Sleep quality. Participants will be sent a wrist-worn actigraph (AX3, Axivity) in order to further evaluate sleep disturbance. Participants will be asked to use the actigraph for 7 days at home for objective estimation of average sleep latency, wake after sleep onset, total sleep time and sleep efficiency, and asked to complete a sleep diary. Timepoints: Baseline, 16 weeks.
11. Physical activity measured using the International Physical Activity Questionnaire (IPAQ). Timepoints: Baseline, 16 weeks.
12. Qualitative inquiry. Potential participants will be invited to take part in a one-on-one in-depth semi-structured interview either before the start of the intervention or after completing the intervention. Semi-structured interviews will take place in a private room at Concordia University. Conversations will be audio-recorded and transcribed verbatim. Pre-intervention interviews will be carried out after screening and within 5 days before the first session. An interview guide containing questions and prompts will be used to elicit information about prior experiences with exercise therapy and expectations. The guide will be piloted with three participants to adjust and refine questions before recruiting more participants. Post-intervention interviews will be carried out within 7 days after the final session. Both completers and non-completers may be invited to participate. Similarly, an interview guide will be used to elicit information about satisfaction and experience regarding the intervention received. Timepoints: Baseline, 16 weeks.

Completion date
01/08/2028

Eligibility

Key inclusion criteria
1. Chronic non-specific LBP (>3 months) defined based on the NIH task force recommendations
2. Between 18 and 60 years of age
3. Speak English or French (to allow response to questionnaires and communication with therapist)
4. Present with predominant nociceptive chronic LBP, namely, score Category A for nociceptive drivers, Category 0 for nervous system dysfunction (absence of neurological involvement), Category 0 for comorbidity drivers (absence of comorbidity), and Category 0 for cognitive-emotional factors and Category 0 or A contextual for drivers on the Pain and Disability Drivers Management (PDDM).

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Previous spinal surgery or vertebral fractures
2. Radiculopathy
3. Other major lumbar spine structural abnormalities (e.g., spondylolysis, spondylolisthesis, or lumbar scoliosis >10°)
4. Health conditions that would prevent active participation in exercise (e.g. systemic inflammation)
5. Institutional contraindications for undergoing an MRI exam (e.g., pregnancy)

Date of first enrolment
01/12/2025

Date of final enrolment
01/04/2028

Locations

Countries of recruitment
Canada

Study participating centre
Concordia University
School of Health
7200 Sherbrooke St. West
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Sponsor information

Organisation

Concordia University

ROR
https://ror.org/0420zvk78

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from.
Contact: maryse.fortin@concordia.ca
Type of data: De-identified participant level data, including clinical outcomes, imaging-derived quality metrics, and functional assessment scores.
Availability: Data will be available upon reasonable request starting after publication and for a minimum of 5 years.
Access criteria: Data will be shared with qualified researchers for scientifically sound secondary analyses, subject to approval of data access request and, if application, data sharing agreement.
Consent: Participants provided informed consent for anonymized data sharing.
Anonymization: All shared data will be fully de-identified in accordance with institutional and ethical guidelines.
Restrictions: Data sharing is subject to approval by the Concordia University Human Research Ethics Committee and compliance with Canadian privacy laws.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes