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The effect of regular exercise on the clinical status and paraspinal muscles of patients with chronic non-specific low back pain

Submission date
21/07/2025

Recruitment status
No longer recruiting

Registration date
23/07/2025

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain is a common health problem that affects people all over the world, especially those aged 40 to 69, and more often women. When this pain lasts for more than 12 weeks and has no clear cause, it's called chronic non-specific low back pain (CNLBP). Around 23% of people experience this type of pain. This study aimed to find out whether regular exercise could help reduce pain and disability, improve muscle strength and endurance, and change the structure of certain back muscles, as seen on MRI scans.

Who can participate?
The study focused on people diagnosed with chronic non-specific low back pain.

What does the study involve?
Participants first had a neurological check-up, a physical assessment by a physiotherapist, and an MRI scan of their lower back. They then followed a specially designed 18-week exercise programme that they could do at home. After completing the programme, they were assessed again to see how their pain, physical function, muscle condition, and satisfaction had changed.

What are the possible benefits and risks of participating?
Participants may benefit from a personalised exercise plan that could help reduce their back pain and improve their mobility. As with any physical activity, there may be minor risks such as temporary discomfort or muscle soreness, but the programme was designed to be safe and manageable at home.

Where is the study run from?
The study was carried out at University Hospital Brno in Brno, Czech Republic.

When is the study starting and how long is it expected to run for?
October 2019 to November 2023

Who is funding the study?
The study was supported by the Ministry of Health of the Czech Republic and Masaryk University in Brno.

Who is the main contact?
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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Functional and quantitative magnetic resonance imaging parameters of the lumbar paraspinal muscles in patients with chronic non-specific low back pain and the effect of exercise

Study objectives
The project evaluated the effect of regular exercise aimed at activating the deep spinal stabilisation system and strengthening the lumbar paraspinal muscles in patients with chronic non-specific low back pain. The study analysed whether regular exercise improved clinical condition (pain and disability) and whether it led to changes in muscle strength and endurance and structural parameters of the lumbar paraspinal muscles (as assessed by MRI).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/02/2020, Multicentric Ethics Committee of the University Hospital Brno (Jihlavska 20, Brno, 62500, Czech Republic; +420 532 232 798; etickakomise@fnbrno.cz), ref: 02-120220/EK

Study design
Single-centre prospective interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic non-specific low back pain

Interventions
This study had only one arm, namely for patients with chronic non-specific low back pain.

At the beginning of the trial, each patient underwent a detailed neurological clinical evaluation, including medical history and patient-oriented measures, functional assessment of the trunk muscles and MRI of lumbar spine and lumbar paraspinal muscles. The intervention (HBRP) itself was led by two other physiotherapists and lasted 18 weeks. After this period of time, the assessment (neurological, functional and MRI) was repeated.

Neurological clinical evaluation and patient-oriented outcomes
Each subject was interviewed and examined by an experienced neurologist and the medical history was taken to evaluate the presence of exclusion criteria and comorbidities and the current intake of analgesics or muscle relaxants. Subjects underwent a comprehensive neurological examination. LBP was deeply analysed in terms of the intensity. Pain intensity was quantified using an 11-step numerical rating scale (NRS: 0-10). Current pain intensity together

with average and maximum pain intensity in the previous 4 weeks were recorded. Disability in relation to LBP was evaluated using the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMQ).
After completing the 18-week rehabilitation programme, patient satisfaction with the rehabilitation programme and changes in patient beliefs (whether the patient believed that the rehabilitation programme helped with their LBP) were assessed using a semiquantitative scale with five levels (fully satisfied/ rather satisfied/ neither satisfied nor dissatisfied/ rather dissatisfied/ fully dissatisfied).

Functional assessment of trunk muscles
To assess trunk muscle function, a battery of simple tests including strength and endurance measurements specific for core muscles with an emphasis on examining the back extensors was used. Maximal isometric lower back extensor strength was examined using a handheld dynamometer MicroFET 2 (Hoggan Scientific, LLC.). To evaluate trunk and hip extensor endurance, the Biering-Sørensen test was used.

MRI of lumbar spine and lumbar paraspinal muscles
The Philips Ingenia 3T MRI system with anterior and posterior receiving coils was used for the morphological evaluation. The examination included standard MRI sequences (turbo spin echo T2, T1, and STIR in the sagittal plane, and T2 in the axial and coronal planes). Furthermore, an axial 6-point Dixon gradient echo sequence with multi-fat-peak compensation (seven) was utilised as well as eddy current correction (labelled mDixon Quant by the Philips company) for creating water, fat, in-phase, out-phase images, and fat fraction maps with resolution 1.2*1.2*5 mm3.
The sequences covered LPM from intervertebral disc Th12/L1 to L5/S1. An experienced radiologist assessed all MRI images to exclude pathology. Manual segmentation of the bilateral multifidus muscle (MF) and erector spinae muscle (ES) was performed using ITK-SNAP software without any interpolation methods. LPM represented MF and ES combined. Segmentation masks were utilised to extract muscle FF (fat fraction) and TMV (total muscle volume) of individual muscles. FF represented an average of FF in all muscle voxels bilaterally, expressed as a percentage. TMV were estimated as a sum of TMV from right and left-sided muscles. FMV (functional muscle volume) was calculated as FMV=TMV*(1-FF).

Home-based rehabilitation programme
The therapy combined back school, respiratory training, and sensorimotor exercise engaging the lower back muscles as a part of the core system by activating and coordinating deep trunk muscles and reducing the overactivation of the superficial back muscles. For the purposes of this study, three sets of increasingly difficult exercises were created. Patients were asked to exercise at home for 15 minutes twice a day for 18 weeks. Each patient received seven regular physiotherapy sessions over 18 weeks; all the other trainings were done at home. Patient compliance was monitored via telemonitoring or an exercise diary if the patient was unwilling or unable to use the mobile application.

Compliance and telemonitoring
Telemonitoring was used to monitor patient compliance using a special mobile application adapted for this purpose. In this application, the patient was asked to record the frequency of exercise (whether they had done the exercise and how many times a day). With telemonitoring, investigators were able to contact the patient immediately via email or phone if it seemed that the patient was not following the programme and then discuss the potential problem. However, if the patient did not want/was not able to use this modern technology, there was an option to use an exercise diary in which they recorded information about the frequency of exercise. The diary was handed in at every check-up visit and any problems that arose were discussed in

person. The mobile application and exercise diary served as feedback for patients and investigators.

Intervention Type
Behavioural

Primary outcome(s)
Before and after the exercise programme:
1. Morphological parameters of the lumbar paraspinal muscles using magnetic resonance imaging (MRI) with a 6-point Dixon gradient-echo sequence. We evaluated the quantitative MRI parameters, including fat fraction and total and functional muscle volume (FMV).
2. Functional parameters of lumbar paraspinal muscles - maximal isometric lumbar extensor strength (MILEMS) and the lumbar extensor endurance (LEME). MILEMS (in kilograms) was examined with the subject seated in a purpose-designed chair using a handheld dynamometer MicroFET 2. LEME was assessed using the Biering-Sørensen test (in seconds).
3. Pain assessed using an 11-point Pain Numerical Rating Scale (NRS: 0-10)
4. Disability assessed using the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMQ).

Key secondary outcome(s))
At the end of the exercise programme:
1. Satisfaction with the exercise programme was assessed using a semiquantitative scale with five levels (fully satisfied/rather satisfied/neither satisfied nor dissatisfied/rather dissatisfied /fully dissatisfied).
2. Adherence to exercise was analysed based on how much of the mobile application was completed, as this was designed to monitor compliance.

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Age between 18 and 70 years
2. Chronic non-specific low back pain (pain localised in the lumbar spine area and without radiation below the knee; pain duration over 12 weeks). Discontinuation of analgesics was not be required at study entry.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. General MRI contraindications
2. Presence of any metal material in the lumbar spine
3. Previous lumbar spine involvement:
- Vertebral fracture
- Tumour
- Spine infection
- Surgery
4. Scoliosis
5. Presence of lumbar spinal stenosis (Schizas classification above A4)
6. Lumbar disc herniation
7. Comorbid conditions affecting overall mobility
8. Pregnancy
9. Presence of lumbosacral radicular pain in the medical history with residual clinical signs of nerve root dysfunction
10. Presence of myopathy

Date of first enrolment
12/03/2020

Date of final enrolment
17/04/2023

Locations

Countries of recruitment
Czech Republic

Study participating centre
The University Hospital Brno
Jihlavska 20
Brno
Czech Republic
62500

Sponsor information

Organisation
University Hospital Brno

ROR
https://ror.org/00qq1fp34

Organisation
Masaryk University

ROR
https://ror.org/02j46qs45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Brno

Funder Name
Lékařská fakulta, Masarykova univerzita

Alternative Name(s)
Lékarská fakulta Masarykovy univerzity, Lékarská fakulta Masarykovy univerzity, Faculty of Medicine at Masaryk University, Faculty of Medicine of Masaryk University, Faculty of Medicine, Masaryk University, LF MU, LF MU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Czech Republic

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study are available upon request from Blanka Adamova (adamova.blanka@fnbrno.cz).
Data is in pseudonymised form.
Patients agreed in their informed consent that pseudonymised data may be passed on to other entities (collaborating professionals and institutions), but only for the purpose of scientific research.
Data will be provided and/or used until it is useful for this research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2025	30/12/2025	Yes	No
Other publications	Pilot study	13/01/2023	22/07/2025	Yes	No
Participant information sheet	in Czech		22/07/2025	No	Yes