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Preliminary development of a tool allowing to predict which patients with low back pain who would best benefit from a specific exercise program

Submission date
07/11/2016

Recruitment status
No longer recruiting

Registration date
14/11/2016

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Lower back pain (LBP) is a common and costly problem, which affects most people at some point in their lives. Around 70% of people suffering from LBP naturally recover within 3-4 weeks, the so-called acute phase of LBP. However, the remaining 30% (non-acute LBP) will account for most of the costs because 10% will develop long-term (chronic) disabling LBP. Physical exercise can reduce pain and disability in patients with non-acute LBP, but these effects are relatively modest on the whole. To enhance the effectiveness of this type of treatment, it is necessary to appropriately match different patient groups to different types of exercise programs, so that patients can obtain maximum benefit. The researchers intend to develop a tool that would make this match for a specific exercise program that is gaining credibility and popularity: lumbar stabilization exercises. This tool is a clinical prediction rule (CPR) that would target, during the initial clinical examination, the patients that would likely best respond to this exercise program. The overall aim of this study is to begin the development of a tool allowing clinicians, at the initial exam, to identify which patients would benefit or not benefit of a lumbar stabilization exercise program, and find out why some patients benefit more than others to this exercise program.

Who can participate?
Sixty adults with low back pain and thirty healthy people of the same age.

What does the study involve?
The 60 patients take part in an 8 week lumbar stabilization exercise program, which is led by trained physiotherapists. This involves taking part in two, 30-minute sessions per week of completing a range of exercises designed to better control and strengthen abdominal and lower back muscles. After the program ends, patients review the exercises they have learned with the physiotherapists and encouraged to continue practicing them at home. At the start of the study, half way through and at the end of the exercise program, as well as six months later, participants complete a number of questionnaires in order to assess different psychological characteristics as

well as their disability and pain levels to find out how effective the treatment is. A physical exam is also performed at the start and end of the exercise program. The psychological and physical measures collected at the start of the exercise program will be used to predict who has benefited and who has not benefited from this exercise program. The measures that will show predictive value will then be retained in clinical prediction rules of treatment success and failure. Once these rules will be fully developed, they will be used by the clinicians as decision tools to help them determine if a lumbar stabilization program is likely to benefit (or not) to their patients. The 30 healthy patients are assessed twice (8 weeks apart) in a laboratory setting to evaluate the control of their trunk (torso) muscles with the use of 6 tests. The non-obese patients are also asked to perform the same laboratory assessments.

What are the possible benefits and risks of participating?
Patients may benefit from taking part in the exercise program. The risk of participating to the exercise program is minimal, although it can temporarily make low back pain feel worse. There are no direct benefits or risks to the healthy people taking part.

Where is the study run from?
The study is run from PhysioExtra and the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal (Canada)

When is the study starting and how long is it expected to run for?
July 2012 to August 2016

Who is funding the study?
Occupational Health and Safety Research Institute Robert-Sauvé (Canada)

Who is the main contact?
Dr Christian Lariviere

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010-0022

Study information

Scientific Title
Preliminary development of a clinical prediction rule for identifying patients with non-acute low back pain who respond best to a lumbar stabilization exercise program

Study objectives
The overall aim of this study is to:
1. Initiate the development of a clinical prediction rule allowing clinicians, at the initial exam, to identify which patients would benefit or not benefit of a lumbar stabilization exercise program
2. Research to understand why some patients benefit more than others to this exercise program

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), 26/07/2012, ref: CRIR-638-0512

Study design
Prospective non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Low-back pain

Interventions

All patients will take part in an 8-week lumbar stabilization exercise program, which consists of two 30 minute sessions per week, in local physiotherapy clinics without any co-intervention allowed. Physiotherapists will be involved in the preliminary identification of patients (inclusion and exclusion criteria will be strictly applied by a research assistant) and will supervise the exercise program. Patients will also be recruited through newspaper advertisements. Six to eight physiotherapists will be trained to deliver this intervention. A two-days training session will be provided by a researcher (JPD) and another expert (physical therapist) trained in this approach. They will perform their own initial clinical assessment, independently of the clinical and laboratory assessments carried out by the research assistant, to apply their clinical judgment (adjustment of the dosage of the exercise program). In order to standardize the information given to the patients about their condition the pamphlet entitled ''Back Book'' will be handed out to the patients as the first visit. The patients will be encouraged to do the exercises at home. The exercise program will focus on motor control of the deep trunk muscles, followed by gradual inclusion of overloading exercises designed to improve endurance and strength of the paraspinal and abdominal muscles.

During the last appointment, the physiotherapist will review the home exercise program with the patient to ensure that they know and understand the expected exercise and frequency, so that they can continue the exercises once the treatment ended at 8 weeks.

Participants will be followed up at 6 months by a research assistant who will send questionnaires by mail.

Intervention Type
Other

Primary outcome measure
1. Perceived disability is measured using the Oswestry disability questionnaire (OSW) at baseline, 4 weeks, 8 weeks and 6 months
2. Pain intensity, measured using an 11-point (0 to 10) numeric pain rating scale (NPRS) to assess the current, best and worst levels of pain intensity during the last week, so as to average the three ratings and obtain a more reliable composite score at baseline, 4 weeks, 8 weeks and 6 months
3. Patient satisfaction is measured using the Physical Therapy Patient Satisfaction (PTPS) questionnaire at 8 weeks

Secondary outcome measures
Clinical assessment:
Outcomes will be measured at baseline and 8 weeks
1. Posture (pelvic tilt, lordosis, kyphosis) and range of motion is measured using one or two inclinometers
2. Aberrant movements are measured using observations during flexion – extension
3. Lumbar instability is measured using the prone instability test
4. Ligamentous laxity is measured using the Beighton Scale
5. Lumbar instability is measured using painful arc in flexion
6. Lumbar instability is measured using painful arc in return from flexion
7. Posterior chain flexibility is measured using the passive straight leg rising test
8. Load transfer of lumbo-pelvic area is measured using the active straight leg rising test
9. Muscle testing is measured using three brief tests: side support, active set-up, extensor

endurance
10. Physical performance is measured using repeated sit-to-stand, repeated trunk flexions, loaded reach and 360 degree rollover

Psychological assessment:
Outcomes will be measured at at baseline, 4 weeks, 8 weeks and 6 months, unless stated otherwise
1. Fear-avoidance beliefs are measured using the Fear-avoidance beliefs questionnaire (FABQ)
2. Pain catastrophizing is measured using the Pain Catastrophizing Scale (PCS)
3. Psychological distress is measured using the Psychological distress Inventory
4. Activity-related pain is measured by asking participant "Do you experience increased pain during general activity or exercise?"
5. The physical activity level is measured using the Baecke physical activity questionnaire (last month recall)
6. Self-efficacy for exercise is measured using the Self-efficacy for exercise Scale (SEES)
7. Barriers to exercise is measured using the Barriers Efficacy Scale (BES)
8. Social/Family support to exercise is measured using Exercise-specific Items (n = 12/50) of the Friend/Peer Support-Health Eating Physical Activity Scale – FPS-HEPAS
9. Illness perceptions are measured using the Brief Illness Perception Questionnaire (Brief-IPQ)
10. Risk of poor prognosis is measured using the StarT Back screening tool.
11. Expectations about exercise are measured using the Outcome expectation for exercise scale (OEES)
12. Treatment credibility is measured using the Credibility/Expectancy Questionnaire (CEQ). This outcome was measured at 1 week (instead of baseline) as well as mid-treatment (4 weeks) and end of treatment (8 weeks), to allow the patients understand the basic elements of the exercise program.
13. Quality of patient/therapist relationship is measured using the Short form of the Working Alliance Inventory (WAI). This outcome was measured at 1 week (instead of baseline) as well as mid-treatment (4 weeks) and end of treatment (8 weeks) because a minimum of three meetings are required before it is administered.
14. Readiness to exercise is measured using the Stages of Change Questionnaire
15. Home exercise adherence (HEA) is evaluated with two questions asked at the end of treatment (8 weeks) and six-month follow-up:
(1) How many times have you done your exercises as prescribed in the last week?
(2) On average during the last month, how many times a week did you do your exercises as prescribed?
These questions were developed for this study. The frequency is divided by the physiotherapist's recommendation to obtain a ratio, in accordance with the most common definition of adherence. The ratio may vary between 0 and 1, 1 meaning that the frequency will be equal or higher than prescribed.

Neuromuscular assessment:
Outcomes will be measured at baseline and 8 weeks
1. Deep trunk muscle motor control of abdominal and lumbar multifidus muscles is measured using ultrasound imaging
2. Lumbar proprioception (motion perception threshold) is measured using a custom built motorized apparatus allowing to passively rotate the lumbar spine in the transverse plane (trunk rotation) by rotating the lower body (seat) at a very slow steady rate. As soon as motion is perceived, participants (eyes closed) stop the rotation by pressing a switch.
3. Trunk postural stability during unstable sitting is measured using a wobble chair and an inertial sensor measuring its angular position
4. Lumbar stiffness is measured using a custom built motorized apparatus generating series of

pseudorandom position-controlled trunk perturbations and measuring forces and displacements at the harness surrounding the thorax, allowing to estimate the intrinsic and reflexive contributions to lumbar stiffness
5. Anticipatory postural adjustments to a rapid arm flexion movement is measured using surface electromyographic measures of 12 trunk muscles (6 abdominals + 6 back) and the angular kinematics of the lumbar spine
6. Trunk muscle coordination during maximal trunk flexion/extension movements is measured using surface electromyographic measures of 6 back muscles and the angular kinematics of the pelvis, lumbar spine and thoracic spine

Overall study start date
03/07/2012

Completion date
01/08/2016

Eligibility

Key inclusion criteria
Patients with low-back pain:
1. Aged between 18 and 65
2. Fluency in either French or English
3. Experiencing LBP for at least four weeks, with or without leg pain
4. Scoring above 12% on the Oswestry disability questionnaire (OSW) [minimum clinically important change is 10 points]

Healthy controls:
1. Aged between 18 and 65
2. Fluency in either French or English

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Objective 1: N = 60 (30 men and 30 women) patients with non-specific chronic low-back pain; Objectives 2 and 3: N = 30 healthy controls (15 men and 15 women)

Total final enrolment
62

Key exclusion criteria

Patients with low-back pain:
1. Specific lumbar pathology (fracture, infection or tumor) or scoliosis
2. One positive neurological sign in two test categories (knee and ankle reflexes, myotomes, dermatomes)
3. Having previously undergone back surgery
4. Systemic disease
5. Having begun an exercise program in the last six months and (6) pregnancy.

Healthy controls:
1. Back pain in the preceding year or back pain exceeding one week in the years before
2. Surgery of the pelvis or spinal column
3. Systemic disease
4. Having begun an exercise program in the last three months
5. Pregnancy
6. Obesity (body mass index > 30 kg/m2)

Date of first enrolment
17/10/2012

Date of final enrolment
27/06/2014

Locations

Countries of recruitment
Canada

Study participating centre
PhysioExtra
2171 Fleury East
Montreal
Canada
H2B 1J9

Study participating centre
Center for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR)
Institut de réadaptation Gingras-Lindsay-de-Montréal
6300 avenue Darlington
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Sponsor information

Organisation
Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST)

Sponsor details
505, Boul De Maisonneuve Ouest
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Sponsor type
Research organisation

Website
http://www.irsst.qc.ca

ROR
https://ror.org/04e4jbv10

Funder(s)

Funder type
Research organisation

Funder Name
Occupational Health and Safety Research Institute Robert-Sauvé (Institut de Recherche Robert-Sauvé en Santé et en Sécurité du Travail)

Alternative Name(s)
Robert-Sauvé Institute for Workplace Health and Wefare, IRSST

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Publication and dissemination plan
Since this is a preliminary study, only the results corresponding to the neuromuscular assessment (reliability study and between-group comparisons) will be published, which would lead to approximately eight articles in peer-reviewed journals related to biomechanics, motor

control and physical therapy. These articles should be published 2-3 years after the trial end date. All results corresponding to objective 1 (clinical prediction rule) will not be published until the required sample size has been obtained (need funding to continue the data collection).

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The participant level data will not be made available for this pilot study. Funding is being sought to pursue the data collection (n = 50 additional patients according to the new sample size estimation) and reach the required sample size (n = 98) to derive robust (stable) clinical prediction rules of success and failure. Then, the complete data set will be made available.
All personal information collected during the study will be codified to insure confidentiality. Only the research team members will have access to that information. However, for research projects controls, the study file could be consulted by a mandated person from the ethic committee of the CRIR establishments or the Ethic Unit of the Health and Social Services ministry, which adhere to a strict confidentiality politic. The data will be kept locked in a cabinet (questionnaires and electronic files on a backup support) at the Center for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR), Institut de réadaptation Gingras-Lindsay-de-Montréal, Montréal, by the study leader.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/12/2016	15/12/2016	No	No
Basic results		12/12/2016	15/12/2016	No	No
Results article		31/10/2017	01/12/2022	Yes	No