Movement System Impairment–Based Classification Versus General Exercise for Chronic Low Back Pain: Protocol of a Randomized Controlled Trial

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Background. Low back pain (LBP) is an important health problem in all developed countries and is associated with high levels of disability. Evidence-based clinical practice guidelines usually recommend different physical therapy interventions to manage this condition. However, those interventions usually result in small to moderate clinical effects. Recent studies suggest that interventions based on subgroup classifications may improve the effect sizes compared with rehabilitation programs where the same interventions were applied to all patients.

Objective. This study will investigate the efficacy of treatment based on a Movement System Impairment (MSI)–based classification model for patients with chronic LBP compared with general exercise. The primary outcomes will be pain intensity and disability at 2 months after randomization.

Design. The study is a 2-arm, prospectively registered, randomized controlled trial with a blinded assessor.

Setting. The study setting will be a university physical therapy clinic in Brazil.

Participants. A total of 148 individuals with chronic LBP will participate in the study.

Intervention. Included individuals will be randomly allocated to participate in an 8-week treatment program based on the MSI-based classification or a general exercise program of stretching and strengthening exercises.

Measurements. Pain intensity, disability, and global impression of recovery will be assessed by a blinded assessor at baseline and at follow-up appointments after treatment (2 months) and 4 and 6 months after randomization.

Limitations. Therapists will not be blinded.

Conclusions. The results of this study may contribute to a better understanding of the efficacy of treatments based on classification of participants with chronic LBP into subgroups.
Chronic low back pain (CLBP) has reached epidemic proportions. The 1-year prevalence of an episode of low back pain (LBP) is 38% in the general population. Low back pain has been recorded in 17.1% of all patients diagnosed with any musculoskeletal condition. Estimates of recurrence at 1 year range from 24% to 80%. Low back pain is the world’s major cause of disability. In Brazil, this condition is the second most prevalent health problem. In the United States, patients with LBP had total medical care costs that were $1,320 greater than those without LBP ($3,498 versus $2,178, respectively). The total costs related to LBP in the United States is estimated at $84.1 billion to $624.8 billion.

Low back pain is usually classified as acute (when the duration of the episode is less than 6 weeks), subacute (when the duration of the episode ranges from 6 to 12 weeks), and chronic (when the duration of the episode is longer than 3 months). When looking at the clinical course of persistent LBP, although most patients show a marked reduction in mean pain and disability in the first 6 weeks, they could present persistent pain, with moderate levels of pain and disability between 6 and 52 weeks. Most guidelines and systematic reviews for CLBP treatment recommend active physical therapy interventions (eg, exercise). Specifically, manual therapy, trunk coordination, strengthening, endurance, and directional preference exercises are recommended based on strong evidence.

Some studies have compared the effectiveness of different physical therapy strategies in patients with CLBP. Other studies have shown that the strategies usually result in small-to-moderate clinical effects and that no treatment strategies are clearly superior in the long term. A major issue in these studies could be related to sample heterogeneity, as most people with CLBP are often labeled with the diagnosis of nonspecific LBP. Usually, LBP is classified as specific or nonspecific LBP. Specific LBP is defined as symptoms caused by a specific pathophysiological mechanism, such as hernia nuclei pulposi (with nerve root compromise), inflammatory diseases (eg, ankylosing spondylitis), infection, osteoporosis, rheumatoid arthritis, fracture, or tumor. Nonspecific LBP is defined as symptoms without a clear specific cause. The nonspecific classification includes 90% of all patients with LBP and is based on exclusion of specific pathology. Several authors have suggested that the classification of nonspecific LBP into more homogeneous subgroups will lead to specific interventions for those subgroups that could enhance treatment effects. A few studies have already shown that using specific classification rules to guide treatment of patients with acute LBP and CLBP can improve the short-term treatment effects. Recommendations for future research in LBP include investigations on the effect of treatment strategies based on subgrouping.

Different models for classification and diagnosis have been described to guide LBP treatment. Classification using the Movement System Impairment (MSI)–based classification model involves interpreting data from a standardized examination to assign a patient to an LBP subgroup. The clinician identifies mechanically based impairments and associated symptoms across a series of tests of movements and positions to decide on the patient’s LBP classification. One of the differences between the MSI model and other classification systems is the assessment of the patient’s ability to maintain a stable lumbopelvic region when performing lower and upper limb movement tests. During each movement test, the examiner makes a judgment about the timing and magnitude of lumbopelvic region movement. The effect of the movement test on LBP symptoms also is assessed. Tests that are symptom provoking are immediately followed by standardized modifications to determine the role of lumbopelvic movement on the patient’s symptoms. Overall, the modification involves minimizing or restricting lumbar movement during the test movement and encouraging movement in other joints to accomplish the movement goal. An improvement in LBP symptoms with the modification indicates that the initially identified lumbopelvic movement is an important contributor to the person’s LBP symptoms.

Some studies have demonstrated that it is possible to discriminate specific LBP subgroups from healthy people using the MSI-based classification. Scholtes et al reported that patients with LBP involved in sports that require trunk rotation may move their lumbopelvic region earlier and to a greater extent during lower limb movement tests compared with people with healthy backs. Increased lumbopelvic movement could be related both to the increased demand on lumbar spine structures and to the symptoms.

The validity of MSI-based classification model for LBP has been previously determined. It also has been shown that the MSI classification model can be reliably applied by trained clinicians, even if those clinicians have limited clinical experience. Several case reports have shown promising findings when the MSI model was used to guide LBP treatment. However, the efficacy of this model in a high-
quality randomized controlled trial design still needs to be tested.

The objective of this study will be to investigate the efficacy of a treatment based on the MSI model for patients with CLBP in a randomized controlled trial with blinded assessors.

**Method**

**Study Design**
The study will be a 2-arm, prospectively registered randomized controlled trial with a blinded assessor.

**Study Setting**
The study setting will be a university physical therapy clinic in Brazil.

**Eligibility Criteria**
Individuals of both sexes, between 18 and 65 years of age, with chronic (pain for more than 3 months) non-specific LBP with a pain intensity of at least 3 points measured using a 0-to-10-point verbal numeric pain rating scale will participate in the study. Participants should be able to stand and walk independently and be literate in Portuguese. The exclusion criteria include any contraindications to physical exercise according to the guidelines of the American College of Sports Medicine, major depression (ie, scored >21 points on the Depression, Anxiety and Stress Scale [DASS]69,70), serious spinal pathologies (fractures, tumors, and inflammatory pathologies such as ankylosing spondylitis), nerve root compromise (disk herniation, spinal stenosis, spondylolisthesis, and other diagnoses associated with nerve compromise), serious cardio-respiratory diseases, previous back surgery or pregnancy, and cannot be classified into any of the 5 categories of the MSI model on initial assessment.77

**Procedure**
The participants will be recruited from orthopedic outpatient clinics and by advertising in radio media. The blinded assessor will screen the eligibility of each participant based on the previously described eligibility criteria. All eligible participants will receive information about the study and will sign an informed consent form before participation. The assessor will collect the baseline data prior to randomization and at 2, 4, and 6 months after randomization. With the exception of the baseline assessment, data for all other assessments will be collected over the telephone. All data entry will be coded, and data will be entered onto an Excel (Microsoft Corp, Redmond, Washington) spreadsheet and doubled-checked prior to the analysis.

**Outcome Measures**
Each participant’s assessment will include the following instruments: (1) a questionnaire of participant characteristics (age, sex, history of LBP, factors that alleviate or aggravate symptoms, location and duration of symptoms), (2) a physical examination using the MSI-based classification model for people with LBP, (3) a verbal numeric pain rating scale (0–10 points), (4) the 24-item Roland-Morris Disability Questionnaire, and (5) the 11-item Global Perceived Effect Scale. The primary outcome measures will be pain intensity and disability at 2 months after randomization. The secondary outcome measures will be pain intensity and disability at 4 and 6 months after randomization and global impression of recovery at 2, 4, and 6 months after randomization. All scales and questionnaires have been translated and cross-culturally adapted into Brazilian Portuguese, and their respective measurement properties have been described.77,58 A detailed description of each of the instruments is given below.

**Physical examination using the MSI–based classification model for patients with LBP.** The physical examination for classification based on the MSI model includes: (1) reports of symptoms associated with various positions and movements and (2) judgments of movements and postures during clinical tests performed in different positions. For each of the tests (posture or movement) that provoked symptoms, the participant either assumes a modified posture or performs a corrected movement (spinal or lower extremity) and then reports a possible change in his or her LBP symptoms.62 After the examination, the examiner will classify each participant into 1 of 5 possible categories (flexion, extension, rotation, flexion with rotation, or extension with rotation syndromes) based on the rules described by Harris-Hayes and Van Dillen.67 All participants will be classified before randomization by the main author using the MSI model.

**Numeric pain rating scale.** The numeric pain rating scale assesses the pain intensity levels perceived by the participant in the past 7 days using an 11-point scale ranging from 0 (“no pain”) to 10 (“worst possible pain”).77,58

**Roland-Morris Disability Questionnaire.** The Roland-Morris Disability Questionnaire assesses disability associated with LBP.63 It has 24 questions that describe daily tasks that participants have difficulty performing due to their LBP.77,58,64 The total score ranges from 0 to 24 points and is the sum of the points obtained. Higher scores indicate higher disability.

**Global Perceived Effect Scale.** The Global Perceived Effect Scale assesses an individual’s global impression of recovery, comparing the onset of symptoms with the last few days. It is an 11-point numeric
scale ranging from $-5$ (“vastly worse”) to 0 (“unchanged”) to $+5$ (“completely recovered”). Participants will respond to the following question: “Compared with when this episode first started, how would you describe your back these days?” Higher scores indicate better recovery.

**Random Allocation**

The participants will be randomly allocated to 1 of 2 groups (treatment based on MSI model or general exercise) using a computer-generated randomization conducted by a researcher who has no contact with the participants. Participants’ concealed allocations will be kept in sealed, opaque envelopes using a random numerical sequence. The examiner responsible for the treatment will open each envelope in front of the participant and tell the participant to which treatment group he or she has been randomly assigned.

**Blinding**

Because of the study design, only the assessor will be blinded to treatment group assignment. The Figure depicts the study design.

**Interventions**

The therapists responsible for the treatment (MSI model or general exercise) will be trained by the first author, who has 16 years of experience in orthopedic physical therapy and has been using the MSI model in practice for 11 years. Training will consist of a 16-hour course (lecture) and the opportunity to practice both treatment protocols over a 1-month period with supervision from the principal investigator. The principal investigator also will periodically audit the interventions through revision of patient home exercise charts and direct oversight during treatment sessions.

**Treatment Based on the MSI Model**

Treatment based on the MSI model will consist of 12 treatment sessions with an estimated duration between 45 and 60 minutes per session (2 sessions per week for the first 4 weeks and 1 session per week in the last 4 weeks). Treatment based on the MSI model includes: (1) patient education, (2) analysis and modification of performance of daily activities, and (3) prescription of specific exercises.

Patient education will involve teaching each participant how performance of daily activities is related to his or her LBP symptoms. One assumption of the MSI model is that the development and course of a person’s LBP is related to the repetition of altered movements and maintenance of prolonged postures associated with a specific direction (e.g., flexion, extension, rotation). Participants also will receive information about the importance of controlling the postures and movements on a
daily basis. The principles will be taught to participants in the first treatment session.

Modification of daily activities will begin with analysis of the activities that the participant reports as symptom-provoking. During the analysis, the examiner will observe the individual performing the specific activities limited by his or her LBP. Participants will be taught how to modify the movements and postures that are associated with their symptoms and that are proposed to contribute to accumulation of stress concentrations in the lumbar region. The analysis of daily activities is driven by the person’s LBP classification. For example, a person classified as having a lumbar flexion syndrome might be taught how to assume a sitting position and to move from a sitting to a standing position without flexing the lumbar spine and without an increase in LBP. Modification of daily activities will be initiated in the first treatment session. During the follow-up sessions, the examiner will revise the instructions according to patient progress.

The prescription of specific exercises also will be directed by each participant’s LBP classification. The exercises consist of practicing the movement tests performed during the initial assessment. However, now the movements will be modified to emphasize control of lumbar spine movement and to increase movement of the adjacent joints. Movement tests that were pain-free but during which a participant displayed an altered movement pattern also may be prescribed. During each treatment session, participants will perform the exercises while being monitored for any increase in symptoms. They also will be advised to perform the exercises at home at least once a day. To facilitate the execution of the home exercises, each participant will receive pictures of the exercises with written instructions. The participant’s ability to perform his or her home exercise program will be assessed during each treatment session. The assessment is an adaptation of that used in the study by Harris-Hayes et al. and includes judgments about the person’s cognition (knowledge of key concept of the exercise or activity prescribed by the physical therapist) and psychomotor skill (performance of the exercise or activity prescribed by the physical therapist). The assessment does not result in additional time in treatment and standardizes the progression of the home program. Participants will register their home exercise in an exercise diary and will be monitored for any exacerbation of symptoms in each treatment session.

### Treatment Based on General Exercise

The general exercise program consists of 12 treatment sessions with an estimated duration between 45 and 60 minutes per session (2 sessions per week for the first 4 weeks and 1 session per week in the last 4 weeks). Each session will be conducted by a trained physical therapist. The participants will perform an exercise program that starts with pedaling a stationary bicycle or walking for 5 minutes to warm up, followed by stretching exercises. The stretching exercises will address the lumbar and abdominal muscles (lumbar flexors, extensors, lateral flexors and rotators) and the lower limb muscles (hip flexors, extensors, rotators, adductors and abductors, hamstrings, quadriceps, and calves). Each participant also will perform strengthening exercises for the abdominal and paraspinous muscles. The participant may progress through increased load to keep inducing muscle fatigue after completion of 10 repetitions per set. Participants also will be advised to perform the exercises at home (3 times a week) and will receive figures of the exercises with written instructions. Their ability to perform the home exercise program also will be assessed during each treatment session. The exercise program will be prescribed according to American College of Sports Medicine recommendations. The participants will register their home exercise in an exercise diary and will be monitored for any exacerbation in symptoms in each treatment session.

### Statistical Methods

#### Sample size calculation.

Seventy-four participants are needed per treatment condition based on a sample size calculation considering a statistical power of 80%, an alpha of 5%, and a 15% dropout rate. The calculation was based on the detection of a 1-point between-group difference for the 11-item numeric pain rating scale (estimated standard deviation of 1.84) outcome and a 4-point between-group difference for the Roland-Morris Disability Questionnaire (estimated standard deviation of 4.9 points) outcome.

### Analysis of effects of treatment.

Descriptive statistics will be calculated to check for data normality. The between-group comparisons to obtain the effects of the treatments will be conducted by means of interaction terms (group versus time interactions) using a linear mixed model. We also will perform subgroup analyses using the MSI classification as a potential treatment effect modifier. All data will be given to the examiner, who will perform the statistical analysis using a coded form. The statistical analysis will be performed according to an intention-to-treat approach. The IBM SPSS 19 statistic package (IBM Corp, Armonk, New York) will be used for these analyses.
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Ethics
Participants will be informed about the study and will sign an informed consent form before participating in the trial. This study was approved by Ethics Committee of Pontifícia Universidade Católica de Minas Gerais, Brazil (17660913.0.0000.5137) and was prospectively registered at ClinicalTrials.gov (NCT02221609). Possible protocol modifications will be registered with the Ethics Committee as well as in the trial registry. Data will be stored at Universidade Cidade de São Paulo, Brazil.

Discussion
Potential Impact and Significance of the Study
The wide variability in CLBP clinical presentations poses a challenge to physical therapist diagnosis and treatment. In response to this challenge, various classification systems aiming at identifying common patterns of symptoms behavior, cognitive characteristics, or musculoskeletal dysfunctions have emerged.25,35–40 It is expected that classifying individuals with CLBP into more homogeneous subgroups may enhance treatment effects. Other classification systems used to guide conservative treatment in LBP have been shown to improve treatment effects compared with manual therapy and general exercise.32 treatment based on electrophysical agents,31 or back school.50

Although the reliability and validity of the MSI-based classification model for patients with LBP have been evaluated, the efficacy of the model in a high-quality randomized controlled trial design still needs to be assessed. The current study will compare a treatment based on the MSI classification model with general exercise that is recommended in most clinical practice guidelines.1,11 Recommendations for studies involving LBP highlight the need for assessment of treatment effects based on subgrouping.1,33,34 The results of this study, therefore, will contribute to advancing the LBP research agenda in high-priority areas. If positive, our findings will inform physical therapists’ decision making on exercise prescriptions more tailored to patient-specific musculoskeletal impairments. Although some other classification systems also involve movement-related criteria,25,35,36,40 none of these systems approach the concept of directional susceptibility to movement more centrally and systematically than the MSI system.41–43

Contribution to the Physical Therapy Profession and to Patients
The MSI-based classification model allows physical therapists with different levels of experience to reliably classify people with LBP into subgroups.47,48,50–52 The LBP treatment provided is based on each patient’s classification and includes education about how the individual’s daily activities may contribute to his or her LBP. Participants also are taught how to modify their daily activities by modifying the movements and postures that appear to increase lumbar spine stress and LBP symptoms. The participants also receive a series of exercises to be performed at home. It is expected that patients will become independent and more empowered in controlling movements and postures associated with their LBP.53–55 We expect that patients receiving treatment based on the MSI model will have a better outcome compared with those in the general exercise group. These findings might help therapists, healthcare providers, and people with CLBP in their choice between a general exercise program or a treatment based on the MSI model.

Future Research
The results of this study might contribute to future trials comparing the effects of different classification systems25,35–40 used to guide LBP treatment. It also is possible that different treatment effects would be found when comparing different subgroups in the MSI group. Although this study might not be powered to detect those differences, our results may inform future studies on the topic.

Strengths and Weaknesses of the Study
The strength of the current study is that it is a randomized controlled trial that has been prospectively registered. The study also includes concealed allocation and an intention-to-treat approach. The sample size has been calculated to provide appropriate statistical power to detect differences in the primary outcome between the 2 treatment conditions. The assessor responsible for collecting outcome data will be blinded to treatment group assignment. Physical therapists responsible for treatment have similar clinical experience and have been trained by the main author of the study. Our study has some limitations. Participants and examiners responsible for treatments cannot be blinded. Both exercise programs include home exercises, which depend on each participant’s motivation. It is not possible to predict the amount of home exercises that will be performed by each group.

Mr Azevedo, Dr Van Dillen, Dr Ferreira, and Dr Costa provided concept/idea/research design. Mr Azevedo, Dr Van Dillen, Mr Santos, Mr Oliveira, and Dr Costa provided writing. Mr Azevedo, Mr Van Dillen, Mr Santos, and Mr Oliveira provided data collection and analysis. Dr Costa provided fund procurement. Mr Azevedo provided facilities/equipment. Mr Azevedo, Dr Van Dillen, Mr Santos, Mr Oliveira, and Dr Ferreira provided consultation (including review of manuscript before submission).

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