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Study Protocol

The addition of neurodynamic exercises to extension-oriented exercises among patients with chronic back-related leg pain: A study protocol

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ABSTRACT

Background: Patients with back-related leg pain exhibit nociceptive and neuropathic characteristics. Few studies have investigated the combination of interventions considering these characteristics.
Objectives: To investigate if the addition of neurodynamic exercises (EEN) to extension-oriented exercises (EE) promotes additional benefits in individuals with back-related leg pain and a directional preference.
Methods: Patients will be randomized to either EE or EEN. Patients from both groups will receive 7 sessions over 3 weeks. Low back and leg pain, function, quality of life, disability, and global perceived effect will be evaluated at baseline, 3 weeks after randomization and 1-month follow-up. A linear mixed model will be used for outcomes analysis.

1. Introduction

Low back pain is the leading cause of disability worldwide (GBD, 2015). Approximately 60% of patients with low back pain also have leg pain (Hill et al., 2011). Patients with back-related leg pain have a worse clinical prognosis than those with low back pain alone, especially when patient symptoms do not centralize (Aina et al., 2004; Hider et al., 2015; Hill et al., 2011). Given the negative impact on health, management of these conditions are extensively studied. Current guidelines have recommended the use of exercise in the treatment of back-related leg pain (Bernstein et al., 2017).

Extension-oriented exercises (EE) and neurodynamic exercises have been used in the management of patients with low back and leg pain (Tambekar et al., 2016). Extension-oriented exercises are used to obtain a centralization response though repetitive or sustained extension movements and postures (Browder et al., 2007). Previous studies regarding the management of low back pain show positive effects of specific exercises, such as extension exercises, to patients with a directional preference (Delitto et al., 2012; Long et al., 2008; Surkitt et al., 2012). EE have been shown to be more effective than manipulation, trunk strengthening, and electrophysical agents in people with low back pain (Browder et al., 2007; Murtezani et al., 2015; Petersen et al., 2011).

Centralization response is defined as the process where the most distal symptoms are progressively abolished from specifics movements, postures, or directions (Albert et al., 2012). This concept was described by Mckenzie and has become more widespread over the years (Mckenzie, 1981). The presence of centralization response contributes to the prognosis and treatment of low back and leg pain (Berthelot et al., 2007). According to Albert et al. (2012), centralization is associated with better outcomes in activity limitation and leg pain. Furthermore, patients who do not have a centralization response are 6 times more likely to undergo surgery (Skytte et al., 2005).

Neurodynamic exercises have already been shown to centralize the symptoms of people with low back and leg pain in a pilot trial (Cleland et al., 2006). These exercises are used for treatment of adverse neural tension. Neurodynamic exercises can produce sliding or tensioning movements between neural structures and nonneural tissues (Coppieters and Butler, 2008). A previous meta-

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analysis showed significant improvements in pain and disability after neurodynamic exercises in people with low back pain (Neto et al., 2017; Basson et al., 2017). However, high-quality studies are necessary to support these findings (Efstathiou et al., 2015).

The combination of interventions can provide additional effects in patients with low back pain. Previously, the addition of neurodynamic exercises to other treatment approachs was more effective in improving pain and disability for patients with low back pain (Nagrale et al., 2012). Therefore, this study has the following research questions: (1) Does adding neurodynamic exercises to extension-oriented exercises improve leg pain and function? (2) Does it improve low back pain, disability, quality of life, and global perceived effect? (3) Are any possible effects maintained at the 4-weekfollow-up?

2. Methods

2.1. Trial design

This study is a parallel design, single-blind, randomized clinical trial (1:1 allocation ratio) among patients with low back and leg pain. The protocol was approved by the Ethics Research Committee of the Federal University of Sergipe (protocol number: 2.321.252) and it will be carried out according to The International Code of Ethics of The World Medical Association. The study has been prospectively registered with the Brazilian Clinical Trials Registry (ReBEC number: RBR-4fr2gf).

2.2. Participants

Participants will be recruited from waitlist of the ambulatory of Federal University of Sergipe Hospital, Brazil. Potential patients may also be referred to the clinical trial from physiotherapists and clinicians. All participants will be asked to sign informed consent prior to admission. The flow of participants is illustrated in Fig. 1.

Eligible patients will meet all of the following criteria: age between 18 and 65 years, low back pain radiating below the buttock for at least 12 weeks, leg pain intensity of at least 3 points (measured on an 11-point Numerical Pain Rating Scale), positive SLR test, directional preference for extension, and sufficient understanding of the Portuguese language.

Active movement testing will be used to identify the directional preference for extension as described by Browder et al. (2007). First, the patient will perform a single active movement of lumbar extension and the pain location and intensity will be observed. Then, repeated extension movements will be performed in prone and standing positions. Directional preference for extension will be present if extension movements to reduce or to abolish pain and/or to move the symptoms from an area more distal to an area closer to the lumbar spine.

Patients with any condition making exercise impossible, serious spinal pathology (e.g., the cauda equine syndrome, spondylolysis, spondylolisthesis), history of lumbar surgery, severe metabolic or cardiovascular pathology, and pregnant women will be excluded.

2.3. Randomization, allocation, and blinding

Prior to enrollment, a research assistant not involved in eligibility will carry out the randomization process. Eligible patients will be randomized via computer-generated random sequence (http://www.randomization.com) using sequentially numbered opaque sealed envelopes in a 1:1 allocation ratio. The outcomes assessor will be blinded to group assignments. Given the nature of the interventions, the patient and therapist will not be blinded.

2.4. Enrollment and baseline measures

Baseline characteristics will be collected in the initial assessment by a physiotherapist. In this assessment, a clinical physical exam will be performed. In accordance with suggested measures for the assessment of patients with low back pain, the following will be evaluated: demographic/medical history (age, sex, education, socioeconomic status, medical history and comorbidities), low back and leg pain (Numeric Rating Pain Scale), disability (Roland Morris Disability Questionnaire), quality of life (36-Item Short Form Survey), fear avoidance beliefs (Fear-Avoidance Beliefs Questionnaire), catastrophizing (Pain Catastrophizing Scale), sleep quality (Pittsburgh Sleep Quality Index), health behaviors (alcohol and tobacco use), anxiety, depression, and social isolation (brief screening questions).

2.5. Interventions

The interventions will be conducted by a physiotherapist. Following baseline assessment, participants will be randomly assigned into one of two exercise groups: Extension-oriented exercises (EE) or Extension-oriented plus Neurodynamic exercises (EEN). Each participant will receive seven sessions of active treatmenttwice per week during three weeks. In the first week, treatment frequency will be three times per week.

Extension-oriented exercises (EE) will be based on the principles of McKenzie method (McKenzie, 2003). Participants will be treated according to directional preference with extension active exercises in prone and standing positions (see Fig. 2). Exercises will be progressed according to patient tolerance starting with 5 minutes in prone position and progressing to end range prone and standing exercise. The aim of these exercises is to reduce pain and to promote centralizing of symptoms. The exercises will be performed 5 sets of 10 repetitions for each exercise in all session. Patients will be instructed to perform these exercises 3–5x/day every day at home.

Neurodynamic exercises will be added to specific exercises on EEN group. These exercises will be based on David Butler principles (Butler, 1991). In our protocol, only active exercises will be included. Patients will receive sliding and tensioning exercises (see Fig. 3). During the treatment session, discomfort can be perceived. However, if the pain becomes worse (>2 points), exercise may be discontinued.

2.6. Outcomes

Leg pain intensity and function at 3 weeks after enrollment will be the primary outcomes. Low back pain intensity, health-related quality of life (HRQoL), disability and global perceived effect at 3 weeks and 1 month after the enrollment will be the secondary outcomes. All outcomes will be assessed at the baseline, 3 weeks, and 1-month follow-up. All instruments used have good validity and they are recommended for assessing patients with low back pain (Chiarotto et al., 2016).

2.7. Pain intensity

Pain intensity (leg and low back) will be measured using a 0–10 Numeric Pain Rating Scale (NPRS). This scale is responsive in patients with chronic low back pain (Childs et al., 2005). Patients will be asked to rate their current pain intensity from 0 to 10, 1 being no pain and 10 being the worst pain imaginable. A change of 2.0 points in the NPRS corresponds to minimal clinically important difference (MCID) in patients with chronic back-related leg pain (Lauridsen et al., 2006).

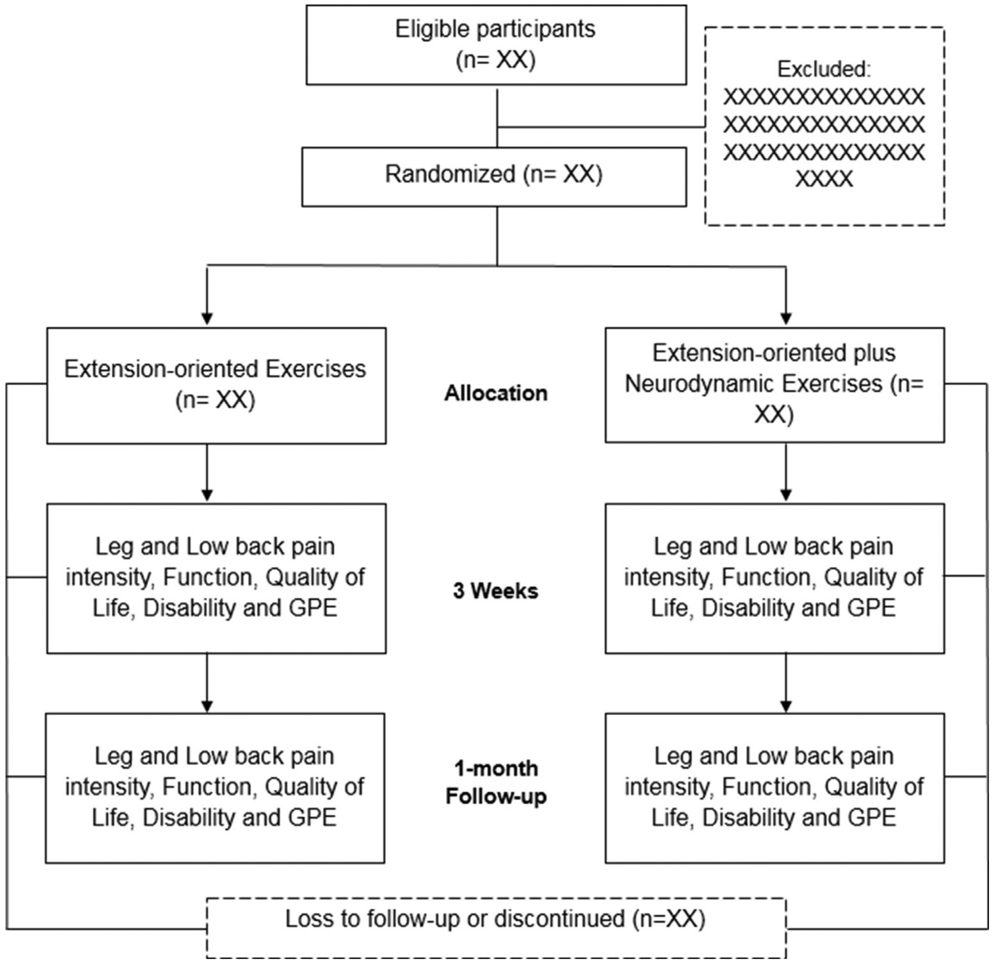

Fig. 1. Flow of participants.

Fig. 2. Extension-oriented exercises. A, B extension exercise in prone position. A, patient is asked to maintain this position for 5 min without increase in symptoms. B, patient gradually bends backward performing repeated extension movements. C, D repeated extension exercise in standing position. C, initial position of extension movement. D, end range position of extension movement.

2.8. Function

Patient Specific Functional Scale (PSFS) will be used to assess functional change. This self-reported scale is reliable and responsive for low back pain patients (Horn et al., 2012). The patients may report three activities they have difficulty performing. Each activity

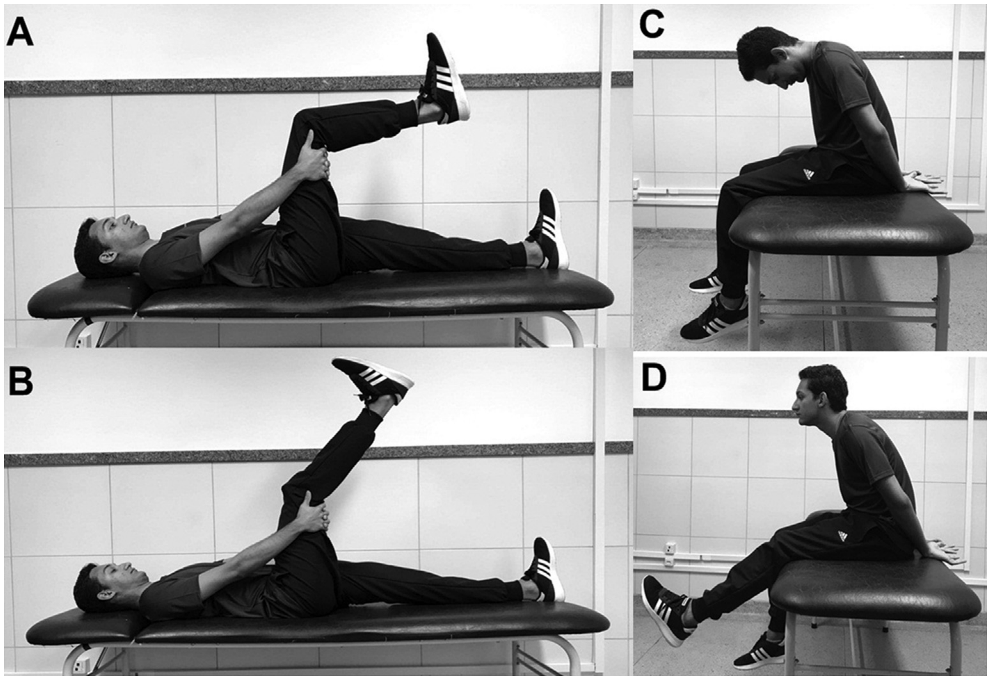

Fig. 3. Neurodynamic exercises. A, B tensioning exercise. A, initial position of exercise with knee flexion. B, final position of exercise with knee extension. C, D sliding exercise in slump sitting. C, initial position of the exercise. D, sliding nerve exercise alternating neck and knee extension.

will be scored between 0 (unable to perform) and 10 (able to perform at preinjury level). Higher scores indicate better functioning. PSFS is adapted to Brazilian individuals (Costa et al., 2008).

2.9. Health-related quality of life (HRQoL)

Health-related quality of life (HRQoL) will be assessed using 36-Item Short Form Survey. This questionnaire measures eight health dimensions: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. The scores range from 0 to 100, with higher scores indicating higher quality of life. SF-36 is a valid and reliable measure to assess the HRQoL in Brazilian citizens (Ciconelli et al., 1999).

2.10. Disability

Roland Morris Disability Questionnaire (RMDQ) will be used to evaluate disability. This questionnaire contains 24 items related to back pain perceptions and disability. RMDQ shows high levels of internal consistency and reproducibility to Brazilian individuals (Costa et al., 2008). The instrument has good test-retest reliability and moderate-to-large correlation with other disability outcome measures (Smeets et al., 2011).

2.11. Global perceived effect

Global Perceived Effect scale (GPE) measures the transition of health status. This 11-point scale ranges from −5 (vastly worse) to +5 (completely recovered). The patients will be asked “How do you describe your symptoms today compared to the first episode?” Higher scores indicate higher recovery from the condition. GPE shows excellent reliability when used in people with musculoskeletal disorders (Kamper et al., 2010).

2.12. Statistical methods

Baseline characteristics of participants will be presented using descriptive statistical tests and summarized by group allocation. Descriptive statistics with central tendency (mean and median) and variability (standard deviation and confidence interval) will be related for continuous variables. For categorical variables, frequency and percentage will be calculated. The alpha level will be set at 0.05. All analyses will be performed using SPSS software version 22.0 (IBM Corporation, NY, USA).

Primary and secondary outcomes will be analyzed by a repeated measures linear mixed model adjusted for baseline values using interaction between groups (EE and EEN) and time (baseline, 3-week , and 1-month follow up). The between-group differences and their 95% confidence intervals will be calculated for all outcome measures. In order to increase the efficiency of the analysis and to avoid conditional bias, age (continuous variable), baseline low back and leg pain intensity (continuous variable), baseline disability score (continuous variable), presence of pain below the knee (dichotomous variable), and pain catastrophizing score (continuous variable) will be included *a priori* as covariates. These variables were chosen based on their association with the primary outcomes and their predictive value, as shown in previous studies (Jensen et al., 2010; Konstantinou et al 2015, 2018; Garcia et al., 2016). A multiple regression model will be used to verify the association among these potential covariates and the primary outcomes. In the final model, only variables judged to be at least moderately correlated ($r \geq 0.5$) with the primary outcomes will be analyzed.

Sample size calculation was based on minimal detectable change (MDC). MDC for individuals with back-related leg pain was 2 points (SD 2.6) on the numeric pain rating scale. An overall sample of 68 patients will provide 80% power to detect a difference of 2 points in pain intensity measured by NPRS assuming alpha level set at 0.05 and possible loss to follow-up of 20%.

3. Discussion

In this study, extension-oriented and neurodynamic exercises will be performed in individuals with back-related leg pain who have a directional preference (DP) for extension. Managing low back and leg pain with a treatment that is based on the directional preference of the patient is thought to be effective (Surkitt et al., 2012). However, few studies have investigated the effects of interventions in individuals with a directional preference.

The mechanisms of back-related leg pain are varied, involving nociceptive and neuropathic components (Harrisson et al., 2017). Nevertheless, randomized clinical trials (RCTs) investigating back-related leg pain generally consider a single component to address the management. This study is attempting to fill this gap in scientific acknowledge. If the combination of extension-oriented exercises and neurodynamic exercises shows additional therapeutic effectiveness to only extension exercises, it will be suggested that both nociceptive and neuropathic components may be considered when developing a treatment program for individuals with back-related leg pain and a directional preference. It is important to note that limiting the sample of this study to people with a directional preference will not allow a generalization of the findings to the overall low back pain population.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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