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Original article

The short-term effects of graded activity versus physiotherapy in patients with chronic low back pain: A randomized controlled trial

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ABSTRACT

Background: Chronic low back pain is one of the most common problematic health conditions worldwide and is highly associated with disability, quality of life, emotional changes, and work absenteeism. Graded activity programs, based on cognitive behavioral therapy, and exercises are common treatments for patients with low back pain. However, recent evidence has shown that there is no evidence to support graded activity for patients with chronic nonspecific low back pain.
Aim: to compare the effectiveness of graded activity and physiotherapy in patients with chronic nonspecific low back pain.
Methods: A total of 66 patients with chronic nonspecific low back pain were randomized to perform either graded activity (moderate intensity treadmill walking, brief education and strength exercises) or physiotherapy (strengthening, stretching and motor control). These patients received individual sessions twice a week for six weeks. The primary measures were intensity of pain (Pain Numerical Rating Scale) and disability (Rolland Morris Disability Questionnaire).
Results: After six weeks, significant improvements have been observed in all outcome measures of both groups, with a non-significant difference between the groups. For intensity of pain (mean difference = 0.1 points, 95% confidence interval [CI] = −1.1–1.3) and disability (mean difference = 0.8 points, 95% confidence interval [CI] = −2.6–4.2). No differences were found in the remaining outcomes.
Conclusion: The results of this study suggest that graded activity and physiotherapy showed to be effective and have similar effects for patients with chronic nonspecific low back pain.

1. Introduction

Chronic nonspecific low back pain is one of the most common problematic health conditions worldwide and is highly associated with disability, poor quality of life, emotional changes, and work absenteeism (Airaksinen et al., 2006; Delitto et al., 2012). Chronic nonspecific low back pain accounts for 95% of cases of low back pain and is characterized by a defined etiology and the presence of symptoms for at least 12 weeks (Airaksinen et al., 2006). A recent systematic review reports that 39% of adults will experience at least one episode of back pain during their lifetime (Hoy et al., 2012). The annual direct costs of chronic nonspecific low back pain in the United States range from $12.2 to $90.6 billion dollars, which represents only 14.5% of the total costs (Dagenais et al., 2008). In Brazil, as the second most frequent health complaint, it is estimated that 13.5% of the population suffers from chronic back problems (Barros et al., 2011).

In an attempt to reduce the impact associated with chronic nonspecific low back pain, certain treatments have been recommended by The European Guidelines for the Management of

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Chronic Low Back Pain as effective in the treatment of the condition, such as manipulation/mobilization, acupuncture, back school, and multidisciplinary treatment (Airaksinen et al., 2006). Moreover, studies show that exercise therapy associated with education can been effective in reducing low back pain and disability (van der Roer et al., 2008; van Middelkoop et al., 2011). Among the methods used in exercise therapy are exercise and cognitive behavioral therapy (Airaksinen et al., 2006).

Exercise programs may include the following types of exercise: aerobic, stretching, balance, motor control, coordination, and strengthening specific (e.g., the transversus, abdominis, or multifidus) or global (e.g., the trunk, abdomen, or back) muscles (van Middelkoop et al., 2010). Among these exercises, the practice of strengthening exercises, stretching, and motor control have shown good efficacy in reducing pain and disability in patients with chronic nonspecific low back pain (Airaksinen et al., 2006; Dufour et al., 2010; Smith and Grimmer-Somers, 2010). A recent systematic review (Macedo et al., 2009) shows that lumbar stabilization exercises are more effective than minimal intervention (booklet), yet the two have similar effects when compared to manual therapy or other types of exercises. A systematic review written by Macedo et al. (Macedo et al., 2009) recommends motor control exercises in conjunction with other types of exercise.

The cognitive behavioral therapy approach to low back pain uses interventions and counseling strategies to help change attitudes and inadequate beliefs that may negatively influence symptoms (Lamb et al., 2010; Rundell and Davenport, 2010). The cognitive behavioral model of treatment assumes that disability is determined not only by the underlying pathology, but also by social, cognitive, emotional, and behavioral factors. The graded activity program, based on the cognitive behavioral therapy, was developed based on studies suggesting that cognitive-behavioral aspects and operant conditioning principles can be used to reinforce healthy behaviors (Macedo et al., 2012). Moreover, the program was based on activities that each participant identified as problematic and that he or she could not perform or had difficulty performing because of back pain (Macedo et al., 2012). The program focuses on functional activities and progress in a time-contingent manner regardless of pain to achieve functional goals and increased activity. Quotas, pacing, and self-reinforcement are key features of the program (Macedo et al., 2010; Macedo et al., 2012). Graded activity aims to reduce pain and disability by addressing pain-related fear, kinesiophobia, and unhelpful beliefs and behaviors about back pain while correcting physical impairments such as reduced endurance, muscle strength, and balance (Leeuw et al., 2008).

A systematic review suggests that graded activity in the short-term and intermediate-term is slightly more effective than minimal intervention (i.e., usual care, waiting list, sham exercise, advice to stay active, or care by a general practitioner), yet is no more effective than other forms of exercise for persistent chronic nonspecific low back pain (Macedo et al., 2010). However, among trials that compared graded activity with other forms of exercise, two treated patients with sub-acute low back pain (Heymans et al., 2006; Anema et al., 2007), two others had poor methodological quality (Nicholas et al., 1991; Critchley et al., 2007), and one trial conducted only one treatment session per week, which is questionable in terms of the optimal way to implement an intervention (Nicholas et al., 1992). Although some studies show that graded activity are effective in reduce pain and disability in patients with chronic nonspecific low back pain (van der Roer et al., 2008; Macedo et al., 2012), recent systematic review has shown that, currently, there is insufficient evidence that graded activity is better for these outcomes in patients with non-specific LBP (van der Giessen et al., 2012). Therefrom, more studies are necessary to evaluate the benefits are graded activity in patients with chronic nonspecific low back pain.

Therefore, the purpose of this study was to compare the effectiveness of graded activity and physiotherapy in patients with chronic nonspecific low back pain.

2. Methods

2.1. Study design

This randomized controlled trial (RCT) recruited patients with chronic nonspecific low back pain. Patients were randomized into either Graded Activity (GA) Group or Physiotherapy Exercise (PE) Group. This study was approved by the ethics committee of the School of Medicine of the University of Sao Paulo (Protocol 393/12), and was registered at clinicaltrials.gov (registration number: NCT01719276). All participants gave their informed consent before participation.

2.2. Participants

Sixty-six patients with chronic nonspecific low back pain diagnosed by an orthopedist were recruited from Specialized Rehabilitation Services at Taboão da Serra in Sao Paulo, Brazil. The inclusion criteria were as follows: chronic nonspecific low back pain, age between 18 and 65 years, and a minimum pain intensity score of three in the 11-point Pain Numerical Rating Scale (Costa et al., 2008). Participants were excluded if they had any of the following criteria: known or suspected serious spinal pathology (e.g., fractures, tumors, inflammatory, rheumatologic disorders, or infective diseases of the spine), nerve root compromise, scheduled surgery, comorbid health conditions that would prevent active participation in the exercise programs, pregnancy, or cardiorespiratory illnesses.

In order to ensure the patients' safe participation in the study, the Physical Activity Readiness Questionnaire (PAR-Q) (Shephard, 1988) was used. Those answering “yes” to any of the questionnaire's questions were excluded from the study.

2.3. Randomization and blinding

Simple randomization was conducted using Microsoft Excel for Windows software (Microsoft Corporation, Redmond, Washington) by a researcher who was not involved in the recruitment of the participants. The allocation sequence was generated by one of the study's authors, who was not involved with participant recruitment or treatment. The allocation was concealed by using consecutively numbered, sealed, opaque envelopes. After the baseline assessment, eligible participants were referred to the physical therapist overseeing the treatment, who conducted their randomized allocation to the different treatments. The assessor was blind to the treatment allocation. Given the nature of the interventions, it was not possible for the therapist or the patients to be blinded.

2.4. Sample size

The study's sample size was designed in order to detect a two-point minimum difference between groups in terms of pain intensity outcome measured on the Pain Numerical Rating Scale, assuming a standard deviation of 1.9 points (Costa et al., 2008). The study also sought to detect a 4-point difference in functional disability measured on the Roland Morris Disability Questionnaire, with an estimated standard deviation of 4.9 points (Costa et al., 2007; Costa et al., 2008). Power was defined as 80% for an alpha