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## ORIGINAL RESEARCH

### Effectiveness of graded activity versus physiotherapy in patients with chronic nonspecific low back pain: midterm follow up results of a randomized controlled trial<sup>☆</sup>

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#### KEYWORDS

Q2 Low back pain;  
Physical therapy;  
Rehabilitation;  
Exercise

#### Abstract

*Background:* Low back pain (LBP) is a major health and economic problem worldwide. Graded activity and physiotherapy are commonly used interventions for nonspecific low back pain. However, there is currently little evidence to support the use of one intervention over the other in the medium-term.

*Objective:* To compare the effectiveness of graded activity exercises to physiotherapy-based exercises at mid-term (three and six months' post intervention) in patients with chronic nonspecific LBP.

*Methods:* Sixty-six patients were randomly allocated to two groups: graded activity group ( $n = 33$ ) and physiotherapy group ( $n = 33$ ). These patients received individual sessions twice a week for six weeks. Follow-up measurements were taken at three and six months. The main outcome measurements were intensity pain (Pain Numerical Rating Scale) and disability (Rolland Morris Disability Questionnaire).

*Results:* No significant differences between groups after three and six month-follow ups were observed. Both groups showed similar outcomes for pain intensity at three months [between group differences:  $-0.1$  (95% confidence interval [CI] =  $-1.5$  to  $1.2$ )] and six months [ $0.1$  (95% CI =  $-1.1$  to  $1.5$ )], disability at three months was [ $-0.6$  (95% CI =  $-3.4$  to  $2.2$ )] and six months [ $0.0$  (95% CI =  $-2.9$  to  $3.0$ )].

<sup>☆</sup> The trials register number NCT01719276 clinicaltrials.gov.

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**Conclusion:** The results of this study suggest that graded activity and physiotherapy have similar effects in the medium-term for patients with chronic nonspecific low back pain.  
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## Introduction

Low back pain is the highest contributor to disability in the world and the average lifetime prevalence of LBP is 39% in adults with LBP in the world.<sup>1</sup> However, less than 60% of people with low back pain actually seek treatment.<sup>2</sup> In Brazil, LBP is the second most frequent health complaint while it is estimated that 11.9% of the population suffers from chronic back problems at any given time.<sup>1</sup> The duration of symptoms is highly associated with the prognosis of LBP<sup>3</sup> with patients with acute LBP having a better prognosis compared with those with chronic symptoms.

According to the guidelines on management of LBP,<sup>4</sup> there is a wide variety of approaches recommended for chronic LBP such as supervised exercises and cognitive behavioral therapy. Supervised exercises incorporated in physical therapy treatment (strengthening, stretching and motor control exercises) and graded activity exercises under the principles of cognitive-behavioral therapy have been shown to be no more effective than other forms of exercise in reducing intensity of pain and disability in patients with chronic LBP. However, these reviews included patients with acute and subacute pain, whereas the current review focused on chronic, nonspecific conditions.<sup>5</sup> Moreover, stretching, strengthening and motor control exercise are among the most commonly used interventions provided by physical therapists in the management of patients with chronic LBP.<sup>6</sup>

Graded activity exercises use a cognitive-behavioral approach to increase activity tolerance by addressing pain-related fear, kinesiophobia, and unhelpful beliefs and behaviors concerning back pain while addressing physical impairments such as impaired endurance, muscle strength, and balance.<sup>7,8</sup> Then, Graded activity consists of three phases: measuring functional capacity, educating in the workplace and providing an individual program of sub-maximal exercise that is gradually increased.<sup>7</sup> Then, once a week physiotherapist and patient's interaction to discussing important point about booklet to help patients to minimize risk about unhelpful beliefs and behaviors about pain. Additionally, a graded activity program focuses on identifying specific activities the patients have difficulty performing due to LBP and goals were formulated to serve as references.<sup>9</sup> The treatment principle was guided by the patient's feedback with respect to functional abilities. The key features of the program are the use of pacing, exercise quotas, and patients 'self-reinforcement of healthy behavior. Quotas were set for frequencies, loads, repetitions, and duration for each activity was establish to each patient.<sup>9</sup>

The efficacy of graded activity exercises for LBP is conflicting with a recent systematic review showing that while this approach is effective for pain, disability and

return to work compared to control interventions (e.g. waiting lists), they tend to be equally effective compared to other forms of exercise such as motor control exercises in the short term.<sup>5</sup> Potential limitations in previous trials that used graded activity in patients with chronic LBP are the low methodological quality, the use of low dosage of treatment (e.g. one treatment session per week)<sup>10</sup> and the use of heterogeneous patient populations with acute, sub-acute, and chronic low back pain.<sup>5,11</sup>

There is a paucity of studies that compared graded activity exercises to physical therapy exercises in patients with chronic nonspecific LBP. We have previously showed that graded activity exercises offer similar effects in terms of pain intensity and disability when compared with physiotherapy exercises (strengthening, stretching and motor control exercises).<sup>6</sup> However, our previous publication only reported results for short-term, i.e. immediate post intervention. Therefore, the aim of this study was to compare the effectiveness of graded activity exercises to physiotherapy-based exercises at mid-term (three and six-month post intervention) in patients with chronic nonspecific LBP.

## Methods

This was a two-arm, single-blinded, randomized controlled trial. The study was approved a priori by the local ethics committee at the Universidade de Sao Paulo (USP), São Paulo, SP, Brazil (Protocol 393/12), prospectively registered at clinicaltrial.gov (registration number: NCT01719276) with a published protocol outlining trial procedures.<sup>12</sup> The study was conducted in a Rehabilitation setting affiliated with a public hospital in the city of Sao Paulo, Brazil. Patients seeking treatment for LBP from both genders were recruited.

A physiotherapist who was blinded to treatment allocation, screened patients in order to confirm eligibility criteria, collect demographic and anthropometric data and assess outcomes. Patients were included in the trial if they were suffering with chronic nonspecific LBP (triaged and diagnosed by an orthopedic specialist), aged between 18 and 65 years, and presenting with a minimum pain intensity score of three in the 11-point Pain Numerical Rating Scale.<sup>13</sup> 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 (diagnosed by a radiologist through magnetic resonance imaging), scheduled or a history of previous spinal surgery, and comorbid health conditions that could prevent active participation in the exercise programs such as high blood pressure, pregnancy, or cardio-respiratory illnesses.

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