

Clinical Study

Individualized functional restoration as an adjunct to advice for lumbar disc herniation with associated radiculopathy. A preplanned subgroup analysis of a randomized controlled trial

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Abstract

BACKGROUND CONTEXT: Physical therapy is commonly sought by people with lumbar disc herniation and associated radiculopathy. It is unclear whether physical therapy is effective for this population.

PURPOSE: To determine the effectiveness of physical therapist-delivered individualized functional restoration as an adjunct to guideline-based advice in people with lumbar disc herniation and associated radiculopathy.

STUDY DESIGN: This is a preplanned subgroup analysis of a multicenter parallel group randomized controlled trial.

PATIENT SAMPLE: The study included 54 participants with clinical features of radiculopathy (6-week to 6-month duration) and imaging showing a lumbar disc herniation.

OUTCOME MEASURES: Primary outcomes were activity limitation (Oswestry Disability Index) and separate 0–10 numerical pain rating scales for leg pain and back pain. Measures were taken at baseline and at 5, 10, 26, and 52 weeks.

METHODS: The participants were randomly allocated to receive either individualized functional restoration incorporating advice (10 sessions) or guideline-based advice alone (2 sessions) over a 10-week period. Treatment was administered by 11 physical therapists at private clinics in Melbourne, Australia.

Trial registration: ACTRN12609000205235 and ACTRN12609000834257.

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RESULTS: Between-group differences for activity limitation favored the addition of individualized functional restoration to advice alone at 10 weeks (7.7, 95% confidence interval [CI] 0.3–15.1) and 52 weeks (8.2, 95% CI 0.7–15.6), as well as back pain at 10 weeks (1.4, 95% CI 0.2–2.7). There were no significant differences between groups for leg pain at any follow-up. Several secondary outcomes also favored individualized functional restoration over advice.

CONCLUSIONS: In participants with lumbar disc herniation and associated radiculopathy, an individualized functional restoration program incorporating advice led to greater reduction in activity limitation at 10- and 52-week follow-ups compared with guideline-based advice alone. Although back pain was significantly reduced at 10 weeks with individualized functional restoration, this effect was not maintained at later timepoints, and there were no significant effects on leg pain, relative to guideline-based advice. © 2016 Elsevier Inc. All rights reserved.

Keywords: Intervertebral disc displacement; Low back pain; Physical therapy; Radiculopathy; Randomized controlled trial; Rehabilitation; Sciatica

Introduction

Lumbar disc herniation with associated radiculopathy (DHR) accounts for an estimated 5%–12% of all low back disorders [1,2]. This condition is associated with more severe symptoms, a poorer prognosis, and higher associated health-care costs than low back pain alone without radiculopathy [3–5]. Identifying effective treatments for DHR is therefore a high priority [6].

When DHR is severe, persists beyond 6 weeks, or has been unresponsive to conservative treatment, surgery is often advocated [6–8]. Discectomy provides faster improvement of leg pain and activity limitation compared with conservative management, although the benefits are not sustained at long-term follow-up [9–12]. Benefits of epidural steroid injections for DHR are small and are restricted to short-term follow-up [6,13]. For the majority of people with DHR, conservative treatments are attempted before consideration of surgery or injections [14–16].

Physical therapy is sought by 37%–65% of people with DHR [14–16]. The North American Spine Society guideline for the clinical management of DHR concluded that there was insufficient evidence (based on the limited number and quality of trials) to make a conclusive recommendation for or against the use of physical therapy or exercise therapy for people with DHR [6]. The guideline work group highlighted the need for more randomized controlled trials (RCTs) with long-term follow-up and validated outcome measures to determine which conservative treatment approaches (if any) are effective for people with DHR [6].

Patient advice is commonly recommended in clinical guidelines for managing low back disorders [17], including DHR [18]. Advice is effective for low back disorders [19,20]. Furthermore, in people with DHR, advice has been shown to be equivalent to discectomy at long-term follow-up in a meta-analysis of RCTs [9]. Given the higher symptom severity and poorer prognosis typically associated with DHR compared with low back pain [3,5], it is plausible that conservative interventions more complex than advice might have potential to offer improved outcomes. Functional restoration is a comprehensive treatment program, often delivered by physical

therapists, that involves structured exercise as well as strategies to address psychosocial factors [21]. Although case series have shown that people with DHR have achieved good outcomes with functional restoration [22,23], an RCT of functional restoration has never been completed in this population.

The Specific Treatment of Problems of the Spine (STOPS) trial evaluated the effectiveness of individualized physical therapy incorporating advice versus guideline-based advice alone in people with low back disorders [24,25]. The primary results of the trial showed that individualized physical therapy produced faster improvement in back pain and leg pain (5-, 10-, and 26-week follow-ups), as well as faster and sustained improvement in activity limitation (10-, 26-, and 52-week follow-ups) [25]. In that trial, participants meeting the criteria for classification into one of five low back disorder subgroups were recruited, with each participant in the individualized physical therapy group receiving treatment deemed suitable for their subgroup [24,25]. The subgroup with DHR was treated with individualized functional restoration [26,27]. The aim of this paper is to report the findings of a preplanned subgroup analysis to evaluate the effectiveness of individualized functional restoration incorporating advice versus guideline-based advice alone (advice) in people with clinically and radiologically confirmed DHR.

Methods

The present study was prospectively registered as a stand-alone, multicenter, parallel group RCT in people with DHR (ACTRN12609000205235). Ethical approval was obtained from La Trobe University. The trial was run concurrently with four other RCTs, each recruiting participants with a different low back disorder. After registration, a decision was made to merge all five trials into one, creating the STOPS trial (ACTRN12609000834257). The protocol [24] and results [25] for the STOPS trial have been reported previously. The present study reports for the first time the results obtained in the DHR subgroup as a preplanned subgroup analysis of the STOPS trial. LifeCare Health was an industry partner that provided in-kind contribution (facilities, personnel, and resources) to allow treatment of participants free of charge. The sponsors

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