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Original article

Efficacy of classification-specific treatment and adherence on outcomes in people with chronic low back pain. A one-year follow-up, prospective, randomized, controlled clinical trial

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ABSTRACT

Background: It is unknown if low back pain (LBP) outcomes are enhanced by classification-specific treatment based on the Movement System Impairment classification system. The moderating effect of adherence to treatment also is unknown.
Objectives: Compare the efficacy of a classification-specific treatment (CS) and a non classification-specific (NCs) treatment and examine the moderating effect of adherence on outcomes.
Design: 2 center, 2 parallel group, prospective, randomized, clinical trial.
Method: Participants with chronic LBP were classified and randomized. Self-report data was obtained at baseline, post-treatment, and 6 and 12 months post-treatment. The primary outcome was the modified Oswestry Disability Index (mODI; 0–100%). Treatment effect modifiers were exercise adherence and performance training adherence. An intention to treat approach and hierarchical linear modeling were used.
Results: 47 people received CS treatment, 54 people received NCs treatment. Treatment groups did not differ in mODI scores ($p > 0.05$). For both groups, scores improved with treatment ($p < 0.05$), plateaued at 6 months ($p > 0.05$), and minimally regressed at 12 months ($p < 0.05$). Performance training adherence had a unique, independent effect on mODI scores above and beyond the effect of exercise adherence ($p < 0.05$). There were no treatment group effects on the relationship between mODI scores and the two types of adherence ($p < 0.05$).
Conclusions: There were no differences in function between the two treatment groups (CS and NCs). In both treatment groups, people with chronic LBP displayed clinically important long-term improvements in function. When both forms of adherence were considered, the improvements were uniquely related to adherence to performance training.

1. Introduction

At least 60%–80% of adults will experience mechanical low back pain (LBP) in their lifetime (Frymoyer, 1988) and almost 50% of them will have had an episode of LBP by age 30 (Papageorgiou et al., 1996). Recurrence rates within a year of LBP onset are as high as

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78% (Wahlgren et al., 1997) and recovery rates are poor (Croft et al., 1998; Pizzo and Clark, 2011). Chronic LBP is the most common type of chronic pain in adults (Pizzo and Clark, 2011) and its prevalence is increasing (Atkins et al., 2004; Sinnott and Wagner, 2009). Thus, for many people LBP is a long-term, function-limiting condition rather than a short-term, self-limiting condition (Von Korff, 1994; Croft et al., 1998; Hestbaek et al., 2003a, 2003b, 2006).

Currently exercise is one of the primary non-surgical approaches used for managing LBP (van Tulder et al., 2000; Hayden et al., 2005a; Van Middelkoop et al., 2010; Van Middelkoop et al., 2011). For chronic LBP exercise is as efficacious, if not more efficacious than (1) no treatment, (2) usual care, and (3) many other treatments such as massage or laser therapy (Hayden et al., 2005b; Rackwitz et al., 2006; Chou et al., 2007; Macedo et al., 2009; Van Middelkoop et al., 2010; Van Middelkoop et al., 2011). Despite the accumulating evidence for the beneficial effects of exercise in chronic LBP there is no evidence that any particular type of exercise is clearly and consistently more efficacious than any other, particularly with regard to long-term outcomes (Hayden et al., 2005a). Some have suggested that the lack of evidence for any one treatment is the result of investigators studying imprecisely defined groups of people with LBP (Spitzer et al., 1987a,b; Borkan and Cherkin, 1996; Croft et al., 1997; Bouter et al., 2003) and prescribing inadequate doses (Dimatteo et al., 2002; Hayden et al., 2005b; Jordan et al., 2010). The proposed solution is to focus on people with LBP who have been classified based on clinically-relevant variables (Spitzer et al., 1987a,b; Borkan and Cherkin, 1996; Bouter et al., 2003) and to provide effective doses of treatments.

One system that was developed to classify a person's LBP is the Movement System Impairment (MSI) classification system (Sahrmann, 2002; Van Dillen et al., 2003a). The premise underlying the classification system is that LBP develops because people repeatedly use direction-specific, stereotypic movement and alignment patterns of the lumbar spine across their day. The patterns are characterized by the lumbar spine moving more readily than other joints during performance of movements or assumption of postures. Use of the same patterns is proposed to contribute to sub-failure magnitude loading that, over time, contributes to LBP symptoms. Patterns are identified during a defined examination (Van Dillen et al., 1998; Van Dillen et al., 2003b; Van Dillen et al., 2009) as well as during performance of symptom-provoking functional activities. The findings are then used to classify the person's LBP (Van Dillen et al., 1998; Trudelle-Jackson et al., 2008; Harris-Hayes and Van Dillen, 2009; Henry et al., 2013). The LBP categories are named for the altered movements and alignments that are (1) displayed consistently across clinical tests, and (2) associated with symptoms (Sahrmann, 2002; Van Dillen et al., 2003a). Modification of the specific patterns associated with the person's LBP classification is addressed through exercises and training to change performance of direction-specific movements and alignments during functional activities. Reliability of examiners to classify using the system has been documented (Norton et al., 2004; Trudelle-Jackson et al., 2008; Harris-Hayes and Van Dillen, 2009; Henry et al., 2013; Kim et al., 2013). Various aspects of the validity of the system also have been tested (Van Dillen et al., 2003a; Norton et al., 2004; Gombatto et al., 2007; Van Dillen et al., 2007; Kim et al., 2013). The system is used widely but there is no evidence that outcomes are enhanced by classifying and providing classification-specific treatment.

One factor that affects the dose of treatment in people with chronic LBP is treatment adherence (World Health Organization, 2003). There is evidence that emphasizing adherence to activity-based treatments results in higher doses of treatment and better outcomes than are achieved without an emphasis on adherence (Liddle et al., 2004; Hayden et al., 2005b). Despite improved outcomes and recommendations to examine the effects of adherence on outcomes (Hayden et al., 2005b; Rackwitz et al., 2006; Liddle et al., 2008; Van Middelkoop et al., 2010; Jordan et al., 2010) examination of the moderating effects of adherence on outcomes in people with chronic LBP is rarely examined.

The purpose of this study was to (1) compare the efficacy of Classification-Specific (CS) treatment and Non Classification-Specific (NCs) treatment, and (2) examine the moderating effects of adherence on outcomes in people with chronic LBP. We hypothesized that the (1) CS group would demonstrate greater improvement in function than the NCs group, (2) the classification subgroups receiving CS treatment would demonstrate greater improvement in function than the classification subgroups receiving NCS treatment, and (3) adherence would moderate the effect of treatment on outcomes.

2. Methods

2.1. Study design

Our study was a 2-parallel group, 2-center, prospective, single blind, randomized clinical trial in people with chronic LBP. Duration of treatment was 6 weeks; data were collected before and immediately after treatment, and 6 and 12 months later. Recruitment spanned February 2007 through August 2009. Final follow-up outcomes were collected in October 2011. The study events are in Fig. 1. The trial was funded by grant R01 HD047709 from the National Institute of Child Health and Human Development. The protocol used for the trial was approved by the Human Research Protection Office at Washington University School of Medicint (IRB #: 201107034). The trial ended upon attainment of all of the 12 month outcomes. There were no changes to the trial design after commencement of the study. The trial was registered on Clinicaltrials.gov (NCT00802724).

2.2. Setting and participants

Recruitment strategies included placing flyers in the local community and in physician offices, and placing ads in local media. Testing was conducted in the Musculoskeletal Analysis Laboratory. Data were collected using self-report measures, laboratory instruments, and a defined clinical exam (Van Dillen et al., 1998; Van Dillen et al., 2003b; Van Dillen et al., 2009). When treatment visits were completed, self-report data were collected via electronic mail 6 and 12 months later.

People included were between 18 and 60 years, had chronic LBP for at least 12 months, were able to (1) stand and walk without assistance, (2) understand and read English, and (3) understand and sign a consent form. People excluded were in an acute flare-up (Von Korff, 1994), had a history or diagnosis of spinal deformity, disc herniation, pain or paresthesia below the knee (Deyo et al., 1992; van der Windt et al., 2010), systemic inflammatory condition, primary hip problem, other serious medical condition, reported any spinal fracture or surgery, displayed magnified symptom behavior (Waddell et al., 1980), were pregnant, receiving worker's compensation or disability benefits, were involved in pending litigation for their LBP, or referred from a specialized pain clinic.

2.3. Classification of low back pain

The MSI LBP categories that could be included were lumbar flexion, lumbar extension, lumbar rotation, lumbar flexion-rotation, and lumbar extension-rotation (Sahrmann, 2002). Each