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SINGLE COHORT STUDY

Exploration of clinical changes following a novel mobilisation technique for treatment of chronic low back pain: A single cohort design

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Summary To explore clinical changes following a novel manual mobilisation technique, 24 participants who experienced 'moderate' to 'severe' chronic low back pain were recruited from new patients attending a suburban osteopathy clinic. The intervention was a previously undescribed side-lying mobilisation technique targeting the lumbosacral spine (median of 6 treatment sessions). After 8 weeks reductions were shown in Oswestry Disability Index of 15 points (95% CI: 9.3, 22.7; $p < 0.0001$ for overall ANOVA); Quadruple Visual Analogue Scale of 2.0 points (95% CI: 1.0, 3.0; $p < 0.0001$); and Patient Specific Functional Scale of 3.1 points (95% CI: 1.9, 4.3; $p < 0.0001$). The results indicate that pain intensity, disability and function improved in most participants following treatment. Further investigation is indicated using more robust research designs to compare this approach with other treatment approaches and usual care for the treatment of chronic low back pain.

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Introduction

Low back pain (LBP) is one of the most common musculoskeletal conditions, with estimates of point prevalence ranging from 14 to 39% in most Western countries, and from 20 to 56% for 12-month prevalence (Hoy et al., 2012). Though a small proportion of people develop chronic LBP (>3 months duration), they account for a relatively large proportion of the economic burden, mainly because of the number of work days lost (Maetzel and Li, 2002). The importance of broad adverse functional and psychosocial effects of chronic LBP are well recognized (Duquesnoy et al., 1998; Froud et al., 2014). In New Zealand, a 54% 12-month prevalence has been reported amongst adults of working age (Widanarko et al., 2011). Annual economic losses directly resulting from back pain amount to $1.5 billion (NZD), approximately 1% of gross national product, before taking into account personal expenditure on medications and other therapies (National Health Committee, 2007).

Non-surgical, pharmacological approaches to LBP management include oral non-steroidal anti-inflammatories, muscle relaxants and injected corticosteroids (Shen et al., 2006). Other options include manual therapy, exercise, cognitive behavioural therapy, electrotherapy, thermotherapy, and pharmacotherapy (Garcia et al., 2011), with multidisciplinary interventions combining exercise or functional restoration with cognitive behavioural and/or educational elements regarded as having the greatest efficacy for chronic low back pain (Garcia et al., 2011; Guzmán et al., 2001; Shen et al., 2006). The evidence for the role of spinal manipulation/mobilisation is less clear. Systematic reviews have variously shown clinically small, but statistically significant effects (Ferreira et al., 2002; Kuczynski et al., 2012) or no effect (Rubinstein et al., 2011) on chronic non-specific LBP. Heterogeneity of participants in many trials has been suggested as an explanation for differing conclusions (Slater et al., 2012), and several reviews have found beneficial effects of these techniques for subgroups of participants with less severe and shorter duration LBP (Bronfort et al., 2008; Hidalgo et al., 2014; Slater et al., 2012).

Another possible explanation for different findings of manipulation/mobilisation trials are differences in the spinal level at which these techniques are applied. The sacroiliac joint (SIJ) is considered an important source of LBP (Rupert et al., 2009), and has been implicated as the primary source of LBP in 10–27% of patients utilising controlled comparative local anaesthetic blocks (Hansen et al., 2012). SIJ dysfunction can mimic discogenic or radicular LBP and is frequently overlooked as a cause of LBP (Weksler et al., 2007). Although a recent systematic review showed lack of efficacy of SIJ injection therapies (Hansen et al., 2012), very few studies exist that investigate manual therapies directed to this region. Two previous studies showed reductions in pain and disability measures following four high velocity, low amplitude thrust treatments to the SIJ region (Shearar et al., 2005), or a single session of lumbar-sacral manipulative techniques (Kamali and Shokri, 2012). Participants in the earlier trial reported LBP lasting at least 2 weeks, and were thus a heterogeneous mix of patients with acute, subacute and chronic pain. Those in the later trial had acute LBP of 6 ± 4 (mean ± SD) week's duration. The effects of similar manual therapy in patients with chronic low back pain is unknown.

According to Bialosky et al.'s (2009) proposed model to explain the mechanisms of manual therapy, the mechanical forces associated with manual therapy provide a mechanical stimulus that initiates neurophysiological responses in the peripheral and central nervous system that contribute to clinical improvement. The 'Bruce Jones technique' (BJT) is a novel, previously undescribed, mobilisation technique that involves a mechanical stimulus applied to the lumbosacral region that may modulate low back pain. Based on anecdotal reports of clinical success associated with this technique, coupled with the absence of any previous investigation, the aim of this study was to explore changes in pain and disability following treatment of people experiencing chronic LBP with this technique.

Methods

Design and setting

A single cohort design was used as this pilot study is an observational design that reports on data from a single group without a control group (Leon, 2004; von Elm et al., 2007), and was deemed best suited for pragmatic application in a private practice setting. Institutional ethical approval was obtained (UREC 2008-850) and all participants gave written informed consent to participate. The study was registered with the Australia New Zealand Clinical Trials Registry (ACTRN ACTRN12614001062617).

Sample size

G*Power software (v3.0.1) (Faul et al., 2007) was used to calculate the *a priori* sample size for a two-tailed t-test for the difference between two means. Based on α error probability of 0.05, a power (1-β error probability) of 0.80 the minimum required sample was 24 participants to detect an effect size of $d = 0.6$. An effect size of this magnitude would equate to a change of 7 units for Oswestry Disability Index (ODI), 0.86 mm for Visual Analogue Scale (Hägg et al., 2003) and 1.1 for Patient Specific Functional Scale (PSFS) (Pengel et al., 2004).

Participant recruitment and eligibility

Participants were recruited by convenience sampling of new patients from a clinical practice operated by the developer of the intervention and from an article placed in a local newspaper. Prospective participants were briefed by a researcher, not the practitioner delivering treatment, and then provided with a written information sheet. To determine eligibility for study enrolment, the ODI Questionnaire and a medical screening questionnaire were administered.

For inclusion in the study participants were aged between 18 and 65 years, had experienced chronic LBP for