

Clinical Study

# Dose-response and efficacy of spinal manipulation for care of chronic low back pain: a randomized controlled trial

Mitchell Haas, DC<sup>a,\*</sup>, Darcy Vavrek, ND<sup>a</sup>, David Peterson, DC<sup>b</sup>, Nayak Polissar, PhD<sup>c</sup>,  
Moni B. Neradilek, MS<sup>c</sup>

<sup>a</sup>Center for Outcomes Studies, University of Western States, 2700 NE 132nd Ave., Portland, OR 97230, USA

<sup>b</sup>Division of Chiropractic Sciences, University of Western States, 2700 NE 132nd Ave., Portland, OR 97230, USA

<sup>c</sup>The Mountain-Whisper-Light Statistics, 1827 23rd Ave. E., Seattle, WA 98122, USA

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## Abstract

**BACKGROUND CONTEXT:** There have been no full-scale trials of the optimal number of visits for the care of any condition with spinal manipulation.

**PURPOSE:** To identify the dose-response relationship between visits to a chiropractor for spinal manipulation and chronic low back pain (cLBP) outcomes and to determine the efficacy of manipulation by comparison with a light massage control.

**STUDY DESIGN/SETTING:** Practice-based randomized controlled trial.

**PATIENT SAMPLE:** Four hundred participants with cLBP.

**OUTCOME MEASURES:** The primary cLBP outcomes were the 100-point modified Von Korff pain intensity and functional disability scales evaluated at the 12- and 24-week primary end points. Secondary outcomes included days with pain and functional disability, pain unpleasantness, global perceived improvement, medication use, and general health status.

**METHODS:** One hundred participants with cLBP were randomized to each of four dose levels of care: 0, 6, 12, or 18 sessions of spinal manipulation from a chiropractor. Participants were treated three times per week for 6 weeks. At sessions when manipulation was not assigned, they received a focused light massage control. Covariate-adjusted linear dose effects and comparisons with the no-manipulation control group were evaluated at 6, 12, 18, 24, 39, and 52 weeks.

**RESULTS:** For the primary outcomes, mean pain and disability improvement in the manipulation groups were 20 points by 12 weeks and sustainable to 52 weeks. Linear dose-response effects were small, reaching about two points per six manipulation sessions at 12 and 52 weeks for both variables ( $p < .025$ ). At 12 weeks, the greatest differences from the no-manipulation control were found for 12 sessions (8.6 pain and 7.6 disability points,  $p < .025$ ); at 24 weeks, differences were negligible; and at 52 weeks, the greatest group differences were seen for 18 visits (5.9 pain and 8.8 disability points,  $p < .025$ ).

**CONCLUSIONS:** The number of spinal manipulation visits had modest effects on cLBP outcomes above those of 18 hands-on visits to a chiropractor. Overall, 12 visits yielded the most favorable results but was not well distinguished from other dose levels.

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## Keywords:

Chronic low back pain; Dose-response; Spinal manipulation; Chiropractic; Randomized controlled trial

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The disclosure key can be found on the Table of Contents and at [www.TheSpineJournalOnline.com](http://www.TheSpineJournalOnline.com).

The trial was registered at ClinicalTrials.gov NCT00376350.

\* Corresponding author. Center for Outcomes Studies, University of Western States, 2700 NE 132nd Ave., Portland, OR 97230, USA. Tel.: (503) 251-5728; fax: (503) 251-2832.

E-mail address: [haasmitch@comcast.net](mailto:haasmitch@comcast.net) (M. Haas)

## Introduction

It has long been known that low back pain (LBP) is a prevalent and costly condition [1,2] and that chiropractors provide the vast majority of spinal manipulation [3] and treat a large proportion of LBP in the United States [4]. It is therefore important to determine the optimal quantity of spinal manipulative therapy (SMT), particularly for chronic low back pain (cLBP) [5].

Recommendations for duration and frequency of SMT/chiropractic care for cLBP have varied widely and have long been based on the clinical experience and opinion [6]. In the early 1990s, a multidisciplinary RAND panel found that opinion was too varied to come to a formal evidence-based consensus (2–24 weeks of care, 1–5 visits per week), but on average, members expected the typical patient to improve in 4 to 6 weeks with three visits per week [7]. In contrast, an all-chiropractic RAND expert panel recommended 30 visits over 14 weeks [8]. Shekelle et al. [3] noted a range of 1 to 19 visits in the published studies of chiropractic care. Later, Nyiendo et al. [9] found a mean of 6.7 visits (standard deviation [SD]=7.5, range=1–56) in a practice-based cohort of 526 nonspecific cLBP patients.

To this day, there is no consensus on the efficacy of SMT and its role in the care of cLBP. Some systematic reviews have reported quality evidence in support of SMT [10,11], whereas others including the latest Cochrane review found SMT to be no better than other interventions [12]. Results of systematic reviews, whether meta-analysis or best-evidence synthesis, may depend on the quantity of care used in the trials included in the reviews. Investigators have had virtually no evidence from dose-response trials to inform the number of SMT sessions provided.

Because of the dearth of evidence for duration and frequency of care, we conducted the first pilot randomized trial evaluating dose-response of SMT (n=72) [5]. We found a clinically important association between number of visits to a chiropractor (1–4 weekly visits for 3 weeks) and short-term pain and disability relief showing that a higher number of visits yielded more favorable results. We have subsequently conducted the current 5-year study, the first full-scale dose-response trial with the aim of identifying optimal care of cLBP with SMT and informing the design of comparative effectiveness studies. We also evaluated the efficacy of the SMT dose levels by testing the hypothesis of no difference between SMT and a hands-on control. The trial evaluated the unique contribution of SMT to outcomes beyond the effects of a light massage to control attention (quantity of visits) and touching the patient, history, and context [13].

## Methods

### Design

In a prospective open-label randomized controlled trial, 400 participants with nonspecific cLBP were randomized to

## EVIDENCE & METHODS

### Context

The impact of spinal manipulation on chronic low back pain compared to light massage, serving as a control, is assessed by the authors.

### Contribution

In this well-performed RCT, spinal manipulation for 18 visits was found to result in modestly improved outcomes relative to light massage, but such improvements may not be clinically significant. They also found that the best treatment effects for manipulation were at 12 sessions versus the control and no additional benefit was afforded at 18 sessions.

### Implications

This study provides some guidance where there is currently little. Twelve chiropractic sessions are reasonable, manipulation may be modestly better than light massage at this endpoint, but not at 24 weeks. As important, the study serves as a reasonable model for the design of a practice-based randomized trial.

—The Editors

receive a dose of 0, 6, 12, or 18 SMT sessions from a chiropractor. All participants were assigned 18 treatment visits, 3 per week for 6 weeks. Spinal manipulative therapy was performed at the assigned number of visits, and a brief light massage control was performed at non-SMT visits to control provider attention and touching the participants [14]. For example, those receiving 12 visits for SMT received 6 visits for light massage from the chiropractor (Fig. 1). Follow-up evaluation was by mailed questionnaire or blinded phone interview at 6, 12, 18, 24, 39, and 52 weeks after randomization. The primary outcomes were prespecified as self-reported pain intensity and functional disability at the 12- and 24-week end points. The primary end points were chosen to emphasize a short- and a long-term post-treatment time point.

Randomization was conducted using computer-generated design-adaptive allocation [15,16] to balance six baseline variables across groups: pain and disability scores, age, gender, relative confidence in SMT and massage, and any previous SMT or massage care. Allocation to study groups was hence concealed from all study personnel and participants by requiring entry of data into the computer program collected immediately before randomization (pain, disability, and confidence in treatment success). Patient coordinators called in the allocation variables over the phone to research staff who entered the data into the allocation computer program. The patient coordinator then assigned the participant to group by placing an unmarked sealed envelope identifying care in the patient's clinic file. Participants and treating

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