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Original Article

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Pain and functional recovery from chronic low back pain over 12 months: implications for osteopathic medicine

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Abstract

Context: Although low back pain is a common medical condition that often progresses to become a chronic problem, little is known about the likelihood of recovery from chronic low back pain (CLBP).

Objectives: This study aimed to measure the risk of recovery from CLBP based on low back pain intensity and back-related functioning measures reported by participants within a pain research registry over 12 months of observation and to consider the implications for osteopathic medicine.

Methods: A total of 740 participants with CLBP in the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation in the United States were studied between April 2016 and October 2021. Inception cohorts for pain recovery and functional recovery were assembled from the participants who did not meet the recovery criteria at registry enrollment. The pain recovery criterion was having a score of ≤1/10 on a numerical rating scale for low back pain intensity, and the functional recovery criterion was having a score of ≤4/24 on the Roland-Morris Disability Questionnaire. A total of 737 and 692 participants were included in the inception cohorts for pain recovery and functional recovery, respectively. Participants provided follow-up data at quarterly encounters over 12 months to determine if they achieved and maintained a pain or functional recovery from CLBP over the entire period of observation. Logistic regression was utilized to identify factors associated with recovery.

Results: The mean age of the participants at baseline was 52.9 years (SD, 13.1 years) and 551 (74.5%) were female. No participant reported a pain recovery that was maintained over all four quarterly encounters, whereas 16 participants (2.3%; 95% CI, 1.2–3.4%) maintained a functional recovery. Having high levels of pain self-efficacy (OR, 17.50; 95% CI, 2.30–133.23; p=0.006) and being Hispanic (OR, 3.55; 95% CI, 1.11–11.37; p=0.03) were associated with functional recovery, and high levels of pain catastrophizing (OR, 0.15; 95% CI, 0.03–0.65; p=0.01) and having chronic widespread pain (OR, 0.23; 95% CI, 0.08–0.66; p=0.007) were inversely associated with functional recovery. The findings for pain self-efficacy and Hispanic ethnicity remained significant in the multivariate analysis that adjusted for potential confounders.

Conclusions: The absence of pain recovery and the low likelihood of functional recovery observed in our study suggests that osteopathic physicians should embrace a biopsychosocial approach to CLBP management and work with patients to set realistic expectations based on more pragmatic outcome measures, such as those that address health-related quality of life. The findings also suggest the potential importance of patient education and counseling to enhance pain self-efficacy.

Keywords: chronic low back pain; pain research registry; physical function; recovery.

The Global Burden of Disease Study found that low back pain is both prevalent (632 million persons, or 9.17% of the worldwide population) and the leading cause of years lived with disability [1]. Progression from acute to chronic low back pain (CLBP) is associated with adverse health-related quality of life and greater risk of disability. However, once it occurs, relatively little is known about the likelihood of recovery from CLBP over time. Pain intensity and physical functioning have been utilized to measure CLBP recovery, with a numerical rating scale and the Roland-Morris Disability Questionnaire for back-related functioning [2] embodying the research instruments most often utilized. Indeed, recovery criteria from CLBP based on these two measures have been proposed, and receiver operating characteristic curves suggest their utility when viewed with

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reference to patients' global perception of recovery [3]. However, questions have arisen in recent years about the appropriateness of utilizing pain intensity to assess chronic pain management programs in the United States [4], and some have even advocated rejection of the dependence on numerical pain scales [5]. Unintended consequences of the "pain-as-the-fifth-vital-sign" campaign in the United States were manifest as the opioid crisis. The Centers for Disease Control and Prevention reported that the nation was experiencing an epidemic of drug-overdose deaths, driven by increasing mortality rates attributable to the use of opioid pain relievers and heroin over two decades [6]. Striving to eliminate chronic pain has not only led to iatrogenic injury, but it also obscures a critical focus on health-related quality of life [7].

Osteopathic physicians provide about one-fifth of the patient visits for low back pain in the United States [8]. Thus, it is important to better understand how osteopathic principles and practice may relate to CLBP recovery, both in terms of general medical care and the use of osteopathic manipulative treatment (OMT). The four key principles of osteopathic philosophy are that the human body is a dynamic unit of function, that it possesses self-regulatory mechanisms that are healing in nature, that structure and function are interrelated at all levels, and that rational treatment is based on these principles [9]. Osteopathic manipulative treatment is utilized to alleviate somatic dysfunction, which is defined as impaired or altered function of related components of the body framework system: skeletal, arthrodial, and myofascial structures, and their related vascular, lymphatic, and neural elements [9]. Such dysfunction is characterized by positional asymmetry, restricted range of motion, tissue texture abnormalities, or tenderness. Thus, unlike the reduction or elimination of chronic pain, improved physical functioning is fundamentally aligned with osteopathic philosophy and practice. The aims of this study were to measure the risk of pain and functional recovery from CLBP based on low back pain intensity and back-related functioning measures reported by participants within a pain research registry over 12 months of observation and to consider the implications for osteopathic medicine.

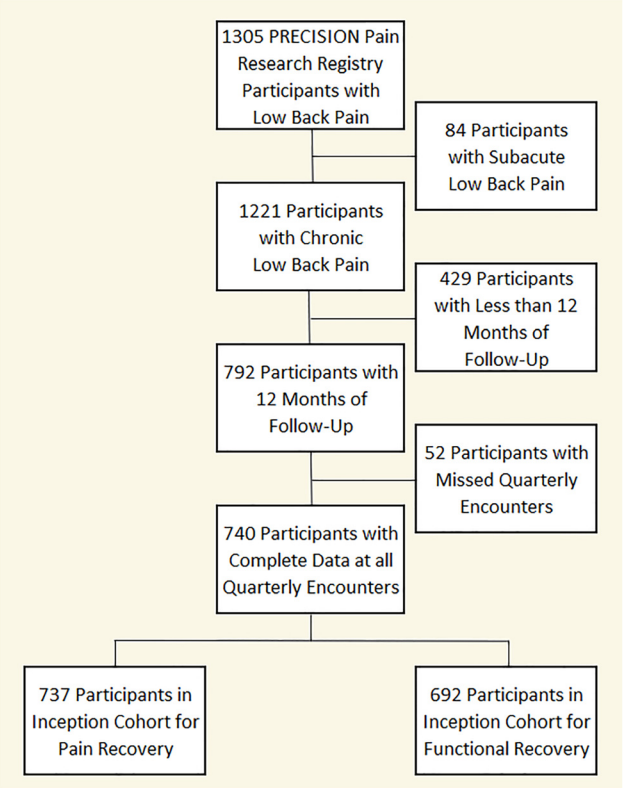

Figure 1: The flow of participants through the study.

Methods

Participant recruitment

The Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) enrolls participants with CLBP from the 48 contiguous states and the District of Columbia. It collects longitudinal participant-reported data on sociodemographic, clinical, and psychological aspects of CLBP, and on its treatment and outcomes, utilizing a digital research platform. Registry participants were considered for inclusion in the present study if they reported CLBP at the time of registry enrollment utilizing diagnostic criteria established by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [10]. These criteria involve having low back pain for at least 3–6 months, with a frequency of at least half of the days in the past 6 months. Participants who completed the registry baseline encounter during the period from April 2016 to October 2020 were identified, and those who completed all four subsequent quarterly encounters at 3, 6, 9, and 12 months by October 2021 were included in the study. Participants with limited English language proficiency that precluded their completing case report forms (either independently or with assistance from registry staff), those residing at institutional facilities, and pregnant women were excluded from the study. Registry and study procedures were approved by the North Texas Institutional Review Board (protocol 2015–169), and all participants provided informed consent prior to entering the study.

Data collection

A summary of registry data collection procedures and related instruments is available at ClinicalTrials.gov [11]. Sociodemographic, clinical, and psychological measures were collected at registry enrollment. Participants self-identified their preferred race and ethnicity on the two respective survey items that included traditional

Table 1: Baseline characteristics of participants (n=740).[a]

Variable	No.	%
Age, yr (range, mean, SD)	21–79	
	52.9 ± 13.1	
Gender		
Male	189	25.5
Female	551	74.5
Race		
White	578	78.1
Black	141	19.1
Other	21	2.8
Ethnicity		
Non hispanic	673	90.9
Hispanic	67	9.1
Educational level		
High school diploma or lower	146	19.7
Some post-high school education	312	42.2
College degree or higher	282	38.1
Current cigarette smoking status		
Non-smoker	625	84.5
Smoker	115	15.5
Body mass index (mean, SD)	32.6 ± 8.2	
Chronic low back pain duration		
≤5 yr	233	31.5
>5 yr	507	68.5
History of low back surgery		
No	603	81.5
Yes	137	18.5
Presence of chronic widespread pain		
No	265	35.8
Yes	475	64.2
Pain catastrophizing (mean PCS score, SD)	19.1 ± 13.4	
Pain self-efficacy (mean PSEQ score, SD)	34.0 ± 14.9	
History of comorbidities		
Herniated disc		
No	451	60.9
Yes	289	39.1
Sciatica		
No	399	53.9
Yes	341	46.1
Osteoarthritis		
No	416	56.2
Yes	324	43.8
Osteoporosis		
No	629	85.0
Yes	111	15.0
Hypertension		
No	430	58.1
Yes	310	41.9
Heart disease		
No	667	90.1
Yes	73	9.9
Diabetes		
No	597	80.7
Yes	143	19.3
Asthma		
No	531	71.8
Yes	209	28.2
Depression		
No	343	46.4
Yes	397	53.6
No. of comorbidities (mean, SD)	3.0 ± 1.9	
Type of physician		
Allopathic	565	77.0
Osteopathic	169	23.0
Current opioid use for low back pain		
No	478	64.6
Yes	262	35.4
Low back pain intensity (mean NRS score, SD)	6.0 ± 1.9	
Back-related disability (mean RMDQ score, SD)	14.3 ± 5.7	

[a]Table entries are no, (%) unless otherwise indicated. Participants were classified as having chronic widespread pain if they were bothered "a little" or "a lot" by it. NRS denotes numerical rating scale; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; RMDQ, Roland-Morris Disability Questionnaire.

category descriptors for these variables. These were then utilized to characterize the study sample from which the pain recovery and functional recovery inception cohorts were assembled for 12 months of follow-up. These inception cohorts of non-recovered participants with CLBP were assembled utilizing their baseline levels of pain intensity and back-related functioning. Pain intensity was measured with an 11-point numerical rating scale (0–10) for average low back pain intensity over the past 7 days. Back-related functioning was measured with the Roland-Morris Disability Questionnaire, wherein scores may range from 0 to 24 [2]. Higher scores represent greater back-related disability on this measure. Participants then reported follow-up data at quarterly encounters. Pain recovery was defined as a numerical rating scale score ≤1 at all four quarterly encounters over 12 months. Correspondingly, functional recovery was defined as a Roland-Morris Disability Questionnaire score ≤4 at all four quarterly encounters. Both criteria were based on thresholds for global perception of CLBP recovery at 12 months as reported in the literature [3]. The Pain Catastrophizing Scale [12] and the Pain Self-Efficacy Questionnaire [13] were utilized to measure the exaggerated negative mindset and coping mechanisms, respectively, relating to CLBP. Higher scores on each measure were indicative of greater pain catastrophizing and greater pain self-efficacy, respectively.

Statistical analyses

The number (%) and mean (SD) were initially utilized to describe the study sample from which participants in the pain recovery and functional recovery inception cohorts were derived. The OR and 95% CIs were initially utilized to identify significant predictors of recovery in a series of univariate analyses involving sociodemographic, clinical, and psychological variables. Subsequently, a multiple logistic regression model was utilized to measure ORs and 95% CIs while simultaneously adjusting for potential confounders. In these logistic regression analyses, measures of pain catastrophizing and pain self-efficacy were dichotomized based on a median split of participant data

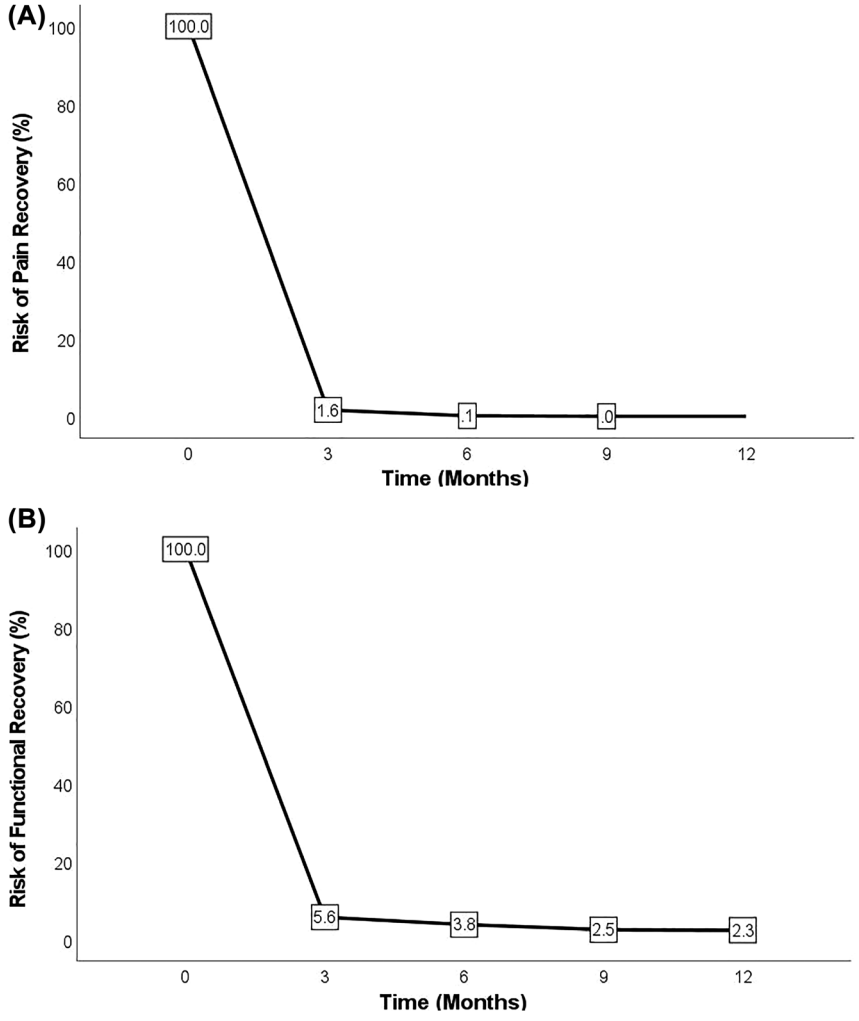

Figure 2: The risk of recovery over 12 months. The risk of recovery was 100% at the time that the inception cohort was assembled, and it declined over time based on reported outcomesat each subsequent quarterly encounter. (A) The risk of pain recovery. (B) The risk of functional recovery.

reported on the Pain Catastrophizing Scale and Pain Self-Efficacy Questionnaire, respectively. Data management and statistical analyses were performed with the IBM SPSS Statistics software package (Version 28). Two-sided tests and significance thresholds of $p \leq 0.05$ were utilized for all statistical analyses.

Results

The 740 (93.4%) of 792 participants with CLBP who completed all four quarterly encounters following enrollment in the registry formed the basis for this study, including assembly of the inception cohorts for pain and functional recovery (Figure 1). These participants ranged from 21 to 79 years of age at baseline (mean, 52.9 years; SD, 13.1 years) and 551 (74.5%) were female (Table 1). A total of 507 (68.5%) participants had CLBP for more than 5 years, and 262 (35.4%) were utilizing opioids for their low back pain. There were 737 non-recovered participants in the inception cohort for pain recovery and 692 non-recovered participants in the inception cohort for functional recovery. The sociodemographic, clinical, and psychological characteristics of participants in these two inception cohorts were similar to those of the population from which they were derived and to each other.

No participant reported a pain recovery that was maintained over all four quarterly encounters, whereas 16 participants (2.3%; 95% CI, 1.2–3.4%) maintained a functional recovery (Figure 2). In univariate analyses, having high levels of pain self-efficacy (OR, 17.50; 95% CI, 2.30–133.23; p=0.006) and being Hispanic (OR, 3.55; 95% CI, 1.11–11.37; p=0.03) were associated with functional recovery, and high levels of pain catastrophizing (OR, 0.15; 95% CI, 0.03–0.65; p=0.01) and having chronic widespread pain (OR, 0.23; 95% CI, 0.08–0.66; p=0.007) were inversely associated with functional recovery (Table 2). High levels of pain self-efficacy (OR, 19.81; 95% CI, 1.83–214.04; p=0.01) and being Hispanic (OR, 9.25; 95% CI, 1.71–50.09; p=0.01) both remained as significant predictors of functional recovery in the multivariate model that adjusted for potential confounders. Although pain catastrophizing and chronic widespread pain were no longer

Table 2: Risk of functional recovery over 12 months.[a]

Variable	Unadjusted			Adjusted		
	OR	95% CI	p-Value	OR	95% CI	p-Value
Age category, yr						
21–49	1			1		
50–64	1.14	0.36–3.62	0.83	1.26	0.30–5.32	0.75
65–79	1.40	0.37–5.29	0.62	0.59	0.08–4.58	0.61
Gender						
Male	1			1		
Female	0.53	0.19–1.49	0.23	0.56	0.15–2.04	0.38
Race						
White	1			1		
Non-white	0.49	0.11–2.19	0.35	0.59	0.10–3.34	0.55
Ethnicity						
Non hispanic	1			1		
Hispanic	3.55	1.11–11.37	0.03	9.25	1.71–50.09	0.01
Educational level						
High school diploma or lower	1			1		
Some post-high school education	0.97	0.18–5.37	0.97	1.16	0.15–8.72	0.89
College degree or higher	2.99	0.65–13.85	0.16	2.81	0.40–19.77	0.30
Current cigarette smoking status						
Non-smoker	1			1		
Smoker	0.34	0.04–2.57	0.29	0.64	0.06–6.98	0.72
Body mass index (n=683)						
Normal or underweight (<25.0)	1			1		
Overweight (25.0–29.9)	1.06	0.29–3.83	0.93	0.60	0.12–3.12	0.55
Obese (≥30.0)	0.39	0.11–1.42	0.15	0.32	0.06–1.67	0.17
Chronic low back pain duration						
≤5 yr	1			1		
>5 yr	0.55	0.20–1.50	0.24	0.59	0.17–2.01	0.40
Presence of chronic widespread pain						
No	1			1		
Yes	0.23	0.08–0.66	0.007	0.33	0.10–1.13	0.08
History of low back surgery						
No	1			1		
Yes	0.58	0.13–2.60	0.48	1.02	0.16–6.56	0.98
Pain catastrophizing						
Low	1			1		
High	0.15	0.03–0.65	0.01	0.23	0.04–1.38	0.11
Pain self-efficacy						
Low	1			1		
High	17.50	2.30–133.23	0.006	19.81	1.83–214.04	0.01
History of comorbidities						
Herniated disc						
No	1			1		
Yes	0.33	0.09–1.16	0.08	0.25	0.05–1.36	0.11
Sciatica						
No	1			1		
Yes	0.50	0.17–1.45	0.20	1.06	0.27–4.12	0.94
Osteoarthritis						
No	1			1		
Yes	0.39	0.12–1.21	0.10	0.41	0.10–1.77	0.23
Osteoporosis						
No	1			1		
Yes	1.85	0.59–5.86	0.29	8.68	1.44–52.35	0.02
Hypertension						
No	1			1		
Yes	1.01	0.37–2.75	0.98	1.25	0.34–4.58	0.74

Table 2: (continued)

Variable	Unadjusted			Adjusted		
	OR	95% CI	p-Value	OR	95% CI	p-Value
Heart disease						
No	1			1		
Yes	0.58	0.08–4.44	0.60	0.68	0.07–6.60	0.74
Diabetes						
No	1			1		
Yes	0.57	0.13–2.53	0.46	2.81	0.41–19.53	0.30
Asthma						
No	1			1		
Yes	0.57	0.16–2.02	0.38	0.47	0.09–2.33	0.36
Depression						
No	1			1		
Yes	0.46	0.17–1.29	0.14	2.36	0.56–9.87	0.24
Type of physician (n=686)						
Allopathic	1			1		
Osteopathic	0.79	0.22–2.82	0.72	0.42	0.10–1.78	0.24
Current opioid use for low back pain						
No	1			1		
Yes	0.56	0.18–1.75	0.32	1.96	0.45–8.57	0.37

[a]n=692 for each of the unadjusted results unless otherwise noted; n=680 for the adjusted results.

significant factors in this multivariate analysis, having a history of osteoporosis was associated with functional recovery (OR, 8.68; 95% CI, 1.44–52.35; p=0.02).

Discussion

None of the 737 participants in our study reported a pain recovery, and only 16 of 692 participants reported a functional recovery from CLBP that was maintained over 12 months. The findings cast doubt on the feasibility of utilizing pain intensity as a primary measure of CLBP recovery. The Roland-Morris Disability Questionnaire, which is considered an acceptable alternative to health-related quality-of-life measures by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [10], may also focus too narrowly on physical functioning rather than on other outcomes relating to suffering among patients with CLBP. The lack of pain recovery and the exceedingly low likelihood of functional recovery reported herein support the rationale for osteopathic physicians and their patients to set more pragmatic expectations in CLBP management.

A metric for CLBP recovery should consider a constellation of factors beyond pain intensity and physical functioning, in concert with the biopsychosocial model of pain [14]. Therein, the interrelationships among the sociocultural context, psychological status, and biological changes within a patient with chronic pain need to be considered to fully understand the responses to illness and treatment. The holistic approach to pain management that is often attributed to osteopathic medical care is based on key principles that preceded the now widely accepted biopsychosocial model [15]. Such an approach may consider anxiety, depression, stress, and other psychological factors thought to be important in chronic pain management. Indeed, our study found that lower levels of pain catastrophizing and higher levels of pain self-efficacy were associated with a greater likelihood of functional recovery over 12 months, although only the latter finding remained significant in our multivariate analysis. Additional studies are needed to assess health-related quality of life and other metrics that may better reflect CLBP recovery in primary care settings wherein osteopathic medicine is often provided.

Evidence relating to CLBP recovery with osteopathic medical care in general, and with OMT in particular, is scarce despite results from systematic reviews [16, 17], the OSTEOPATHIC Trial [18], and clinical practice guidelines promulgated by the American Osteopathic Association that describe the benefits of OMT in treating low back pain [19, 20]. The type of provider (i.e., osteopathic or allopathic physician) was not associated with a functional pain recovery in our study. This finding is potentially consistent with a recent study that found that the use of OMT is a better predictor of outcomes in patients with CLBP than simply the type of physician [21]. In that study, patients treated by osteopathic physicians who utilized OMT reported better outcomes than patients treated by

osteopathic physicians who did not utilize OMT or by allopathic physicians. Unfortunately, it was not feasible to test the effect of OMT on pain or functional recovery in the present study because none or relatively few participants, respectively, reported such outcomes. A recent mediation analysis involving participants with CLBP in the PRECISION Pain Research Registry found that OMT was significantly associated with improvement in pain intensity over 12 months, but not with improvement in back-related disability [22]. However, it is unclear if those improvements in pain intensity would have met the more rigid criterion utilized for pain recovery in this study.

Data from the OSTEOPATHIC Trial were reanalyzed in response to recommendations for responder analysis from the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain [10]. Utilizing a more specific and rigorous composite measure requiring both a pain recovery (visual analogue scale score ≤10/100 mm for pain intensity) and a functional recovery (Roland-Morris Disability Questionnaire score ≤2/24 for back-related disability), 19% of participants with CLBP randomized to OMT reported recovery, as compared with 8% of participants in the sham OMT arm at 3 months (RR, 2.36; 95% CI, 1.31–4.24; p=0.003) [23]. Although these findings represent only a short-term recovery that may not be maintained over an entire year, the risks of recovery in both treatment arms of the trial were larger than observed at the first quarterly follow-up encounter in the present study despite the more specific and rigorous recovery criteria utilized in the trial. One possible explanation for these discrepant findings may be that the intensive treatment delivered within the context of a randomized controlled trial, including six sessions over 8 weeks in both the active and sham OMT arms in addition to usual care for low back pain, provided greater therapeutic benefit than only usual care in a real-world setting.

A strength of this study was that it was conducted within a national pain research registry that acquired comprehensive data from participants at the time of enrollment and then routinely collected data on pain and physical functioning outcomes at all quarterly encounters over the course of 12 months. There were missing data in fewer than 7% of study participants during the entire period of observation. Nevertheless, the study also had weaknesses. The lack of reported pain recovery over 12 months precluded further analysis to identify factors associated with recovery. The low likelihood of functional recovery reported by participants also yielded relatively imprecise estimates in the logistic regression models utilized herein. This diminished the statistical power of the study to detect other potentially important factors associated with functional recovery, and may have yielded a spurious association of history of osteoporosis with functional recovery.

Conclusions

Given the pain and functional recovery experience observed in our study, it would be prudent for osteopathic physicians to work with patients in setting expectations for CLBP management that involve other pragmatic measures that may serve as more sensitive indicators of health status over time. Comprehensive approaches that integrate a biopsychosocial component of pain management within osteopathic medical care have been advocated and described [15, 24, 25]. Our findings support the potential importance of patient education and counseling that may be provided by osteopathic physicians to enhance the pain self-efficacy of their patients with CLBP. However, more and larger studies are needed to identify other predictors of CLBP recovery. These should involve emerging outcome measures, including those involving health-related quality of life (e.g., anxiety, depression, fatigue, sleep disturbance, and pain interference with activities), to assess the impact of biopsychosocial approaches to CLBP management in primary care settings wherein osteopathic medical care is often provided.

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Competing interests: None reported.
Ethical approval: This study was approved by the North Texas Institutional Review Board (protocol 2015–169); ClinicalTrials.gov registry number: NCT04853732.
Informed consent: All participants provided informed consent prior to entering the study.

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