Pain Medicine, 23(9), 2022, 1550–1559
doi: 10.1093/pm/pnac009
Advance Access Publication Date: 21 January 2022
Original Research Article

OXFORD

INTEGRATIVE MEDICINE SECTION

Health-Related Quality of Life Among United States Service Members with Low Back Pain Receiving Usual Care Plus Chiropractic Care vs Usual Care Alone: Secondary Outcomes of a Pragmatic Clinical Trial

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Funding sources: This study was based on work supported by grant W81XWH-11-2-0107 to the RAND Corporation from the Chiropractic Research Program of the Congressionally Directed Medical Research Programs, US Army, US Department of Defense. Hays was supported by the National Center for Complementary and Integrative Health (NCCIH). Grant No. 1R01AT010402-01A1. The funding agencies had no role in the design, data collection, analysis, interpretation, or writing of this manuscript.

Conflict of interest: There are no conflicts of interest to report.

Received on 4 August 2021; revised on 6 December 2021; Accepted on 6 January 2022

Abstract

Objective. This study examines Patient-Reported Outcome Measurement Information System (PROMIS®)-29 v1.0 outcomes of chiropractic care in a multi-site, pragmatic clinical trial and compares the PROMIS measures to: 1) worst pain intensity from a numerical pain rating 0–10 scale, 2) 24-item Roland-Morris Disability Questionnaire (RMDQ); and 3) global improvement (modified visual analog scale). **Design**. A pragmatic, prospective, multisite, parallel-group comparative effectiveness clinical trial comparing usual medical care (UMC) with UMC plus chiropractic care (UMC+CC). **Setting**. Three military treatment facilities **Subjects**. 750 active-duty military personnel with low back pain **Methods**. Linear mixed effects regression models estimated the treatment group differences. Coefficient of repeatability to estimate significant individual change. **Results**. We found statistically significant mean group differences favoring UMC+CC for all PROMIS®-29 scales and the RMDQ score. Area under the curve estimates for global improvement for the PROMIS®-29 scales and the RMDQ, ranged from 0.79 to 0.83. **Conclusions**. Findings from this preplanned secondary analysis demonstrate that chiropractic care impacts health-related quality of life beyond pain and pain-related disability. Further, comparable findings were found between the 24-item RMDQ and the PROMIS®-29 v1.0 briefer scales.

Key Words: Low Back Pain; Health-Related Quality Of Life; PROMIS®; Usual Medical Care; Chiropractic Care; Military; Clinical Trial; Patient Outcome Assessment

Introduction

Low back pain (LBP) is the primary cause of years lived with disability worldwide for the past 3 decades across 126 of 195 countries [1]. The cost of LBP and other musculoskeletal pain conditions is increasing at a greater rate than other highly prevalent conditions [2]. As a result, back and neck pain currently account for the highest healthcare expenditures in the United States (US), estimated at $134.5 billion in 2016 [2]. The public health implications of LBP are exacerbated by our struggle to find safe and effective treatment options. The current literature shows that commonly used therapies, ranging from opioids [3] to spinal fusions, can lead to serious side effects with little impact on the pain experience [4]. In response, LBP guidelines increasingly recommend conservative therapies [5, 6] including spinal manipulation [6–8].

More than half of US adults have received care from a chiropractor [9]. The chiropractic therapeutic approach for LBP includes evaluation, management, and treatment with conservative care options like spinal manipulation, exercise, and lifestyle advice [10]. Meta-analyses have shown that spinal manipulation is effective for acute [11] and chronic LBP [12].

The impact of chiropractic care on health-related quality of life (HRQOL) of patients in military health systems in the United States is unknown [13, 14]. The military population is known to have high rates of LBP [15, 16], a threat to the military's goal of maintaining combat readiness [17]. LBP is associated with poorer mental health and overall quality of life in military service members [15]. There is a need to better understand the relationship of LBP with HRQOL outcomes among military service members [15].

Clinical studies evaluating treatment approaches for LBP have traditionally used measures of pain (89%) and disability (64%) more than other aspects of HRQOL (24%) [18]. This narrow focus potentially misses important aspects of HRQOL for patients with LBP, including those seeking chiropractic care [19].

The Patient-Reported Outcome Measurement Information System (PROMIS®) includes measures of physical, mental, and social health [20]. Observational studies have included PROMIS® outcomes of chiropractic care [21, 22]. However, the validity of these studies is limited by inadequate comparison groups and residual confounding. PROMIS® measures remain unreported in clinical trials assessing chiropractic care. To address this gap, a recent pragmatic, clinical trial of 750 active-duty military personnel designed to compare usual medical care (UMC) to UMC plus chiropractic care (UMC+CC) [13, 14] administered 2 "legacy" measures: the Roland-Morris Disability Questionnaire (RMDQ) [23] and a numeric worse pain intensity item. In addition, the PROMIS®-29 v1.0 profile measure [20] was administered. We report pre-planned secondary PROMIS®-29 v1.0 outcomes of this pragmatic clinical trial and compare these to the legacy measures.

Methods

Sample

This article describes pre-planned secondary outcomes collected in a pragmatic, prospective, multisite, parallel-group comparative effectiveness clinical trial of active-duty US military personnel. The trial was pre-registered in ClinicalTrials.gov (NCT01692275), approved by each participating institution's institutional review board, and oversight was provided by an independent data and safety monitoring committee. Written informed consent was given by all study participants. The study was conducted at three military treatment facilities: Naval Hospital Pensacola, Florida; Walter Reed National Military Medical Center in Bethesda, Maryland; and Naval Medical Center San Diego, California. The detailed protocol and primary results were previously published [13, 14].

Briefly, patients seeking care for LBP at the 3 military treatment facilities were referred to the study by physicians or self-referred. Potential participants were screened with a physical examination by a physician or Independent Duty Corpsmen and deemed eligible if they had LBP of musculoskeletal origin, were able to receive spinal manipulation, and did not have a recent spine fracture, recent spine surgery, or diagnosis of post-traumatic stress disorder. Participants were stratified by military treatment facility and allocated by the data coordinating center equally to UMC or UMC+CC using an adaptive algorithm to balance treatment arms on the baseline variables of age, sex, LBP duration, and worst pain intensity in the past 24 hours.

The active treatment period for the study was 6 weeks which served as the primary end point for outcomes. The clinical trial did not dictate the care to be delivered as part of either usual medical care or chiropractic care; rather the care was determined by the patient and their clinician. Study participants in the usual medical care alone group were asked to refrain from seeking chiropractic care during the 6-week treatment period.

Study Interventions

Medical Care

UMC included treatments and referrals made by military physicians for LBP and was provided to both study arms of the trial; 273/350 in the UMC group and 266/350 in the UMC+CC group had at least one UMC visit [14]. The median (interquartile range) number of UMC visits for those who had at least one visit was 2.0 (1.0–3.0) in the UMC group and 1.0 (1.0–2.0) in the UMC+CC group. Physicians prescribed pain medicine to 72% of participants in the UMC group and 70% in the UMC+CC group. Participants in the UMC group were

referred as follows: 31% to physical therapy; 3% to a pain clinic; and 4% to both physical therapy and a pain clinic. Twenty-three percent of participants in the UMC+CC group were referred by physicians to physical therapy; 3% to a pain clinic; and 6% to both physical therapy and a pain clinic.

Chiropractic Care

Participants in the UMC+CC group received up to 12 visits with a study chiropractor during the 6-week care period in addition to UMC; 350/375 participants had at least 1 chiropractic visit. The median (interquartile range) number of chiropractic visits for those who had at least one visit was 3.5 (2.0–6.0). Study chiropractors delivered spinal manipulation to all 350 participants, strength and flexibility exercises to 49%, electrical muscle stimulation to 47%, hot or cold packs to 47%, functional exercises to 24%, mechanical traction to 23%, and other manual therapies to 23%.

Measures

Study participants were administered the RMDQ, a 0–10 rating of worst pain in the last 24 hours item, and the PROMIS®-29 v1.0 profile survey at baseline, 6 weeks, and 12 weeks. At the 6-week follow-up we included a global improvement item: "Compared to your first visit, your low back pain is *much worse, a little worse, about the same*, *a little better*, *moderately better, much better* or *completely gone*. Participants were more likely to report a positive response to the global improvement item in the UMC+CC group than the UMC group [14]. The RMDQ asks whether each of 24 items about the impact of back pain describe you today (e.g., I walk more slowly than usual because of my back). A simple sum of the number of items endorsed is the overall RMDQ score. The PROMIS®-29 v1.0 measure assesses pain intensity using a single 0 to 10 numeric rating item and 7 health domains (physical function, fatigue, pain interference, depression, anxiety, satisfaction with social role, and sleep disturbance) using four items for each domain. A pain composite that combines the pain intensity item and pain interference scale, an emotional distress composite that combines the anxiety and depression scales, and physical and mental health summary scores were also examined [24].

Analysis Plan

The trial was powered for the co-primary outcomes of RMDQ and average LBP intensity in the prior week. Linear mixed effects regression models were run to estimate the treatment group differences in HRQOL, controlling for site, week, gender, race and ethnicity, age, and duration of LBP. The significance of differences between UMC and UMC+CC was evaluated by the interaction between treatment and time. Participants with missing race and ethnicity data or were non-Hispanic and had missing race were not included in the regression models. Individual change on the HRQOL measures was estimated using the coefficient of repeatability. The coefficient of repeatability is 2.77 times the standard error of measurement and is equivalent to the reliable change index [25]. This index is the one most used and recommended to assess individual change in HRQOL [26]. The significance of differences in the percentage of patients improving between UMC+CC and UMC was assessed using two-sample tests of proportions.

We estimated area under the curve (AUC) in the overall sample using a criterion of significant individual change (improved versus stayed the same or got worse) from baseline to 6 weeks on the 24-item RMDQ score, for the worst pain item, and PROMIS®-29 v1.0 physical function, pain interference, and pain intensity measures. For these analyses, we linear transformed each scale so that a higher score represents better health. The 0–10 worst pain item was recoded as (10 - original worst pain score). Pain interference and pain intensity T-scores were recoded as: 10 - original T-score. We also estimated AUC using the global improvement item ("Compared to your first visit, your low back pain is") administered at the 6-week follow-up by dichotomizing it so that *much worse, a little worse, about the same*, and *a little better* were coded as "0" and *moderately better, much better* and *completely gone* were coded as "1").

Mixed-effects regression analyses were conducted using PROC MIXED in SAS 9.4 (SAS Institute, Cary, NC). Receiver operating characteristic (ROC) analyses were performed using STATA SE 14.2 (StataCorp, 2015 Stata Statistical Software: Release 14. College Station, TX: StataCorp L.P.) using the ROCTAB procedure for nonparametric ROC analysis.

Results

Participant enrollment for the trial began on September 28, 2012, and primary outcome collection was completed November 28, 2016. Figure 1 displays the flow of participants in the trial and the sample characteristics are provided in Table 1. There were 375 participants allocated to each group (mean [SD] age, 31 [9] years, 76% male, 67% white). About half of the participants reported LBP for more than 3 months. Adverse events have previously been described with the primary outcomes [14].

Statistically significant mean group differences favoring UMC+CC over UMC were observed for all PROMIS®-29 v1.0 scale scores and the RMDQ score, with all P values less than .05 (Table 2). The largest differences were observed for pain: PROMIS® pain interference ($F = 15.17$), worse pain intensity in the last 24 hours ($F = 19.26$), the PROMIS® pain composite ($F = 23.64$), and the PROMIS® pain intensity item ($F = 24.22$). Adjusted scores by group for each measure are provided in Table 2 and Supplementary Data shows effect sizes of change over time within groups. Effect sizes for the difference in differences (UMC+CC versus UMC) over time

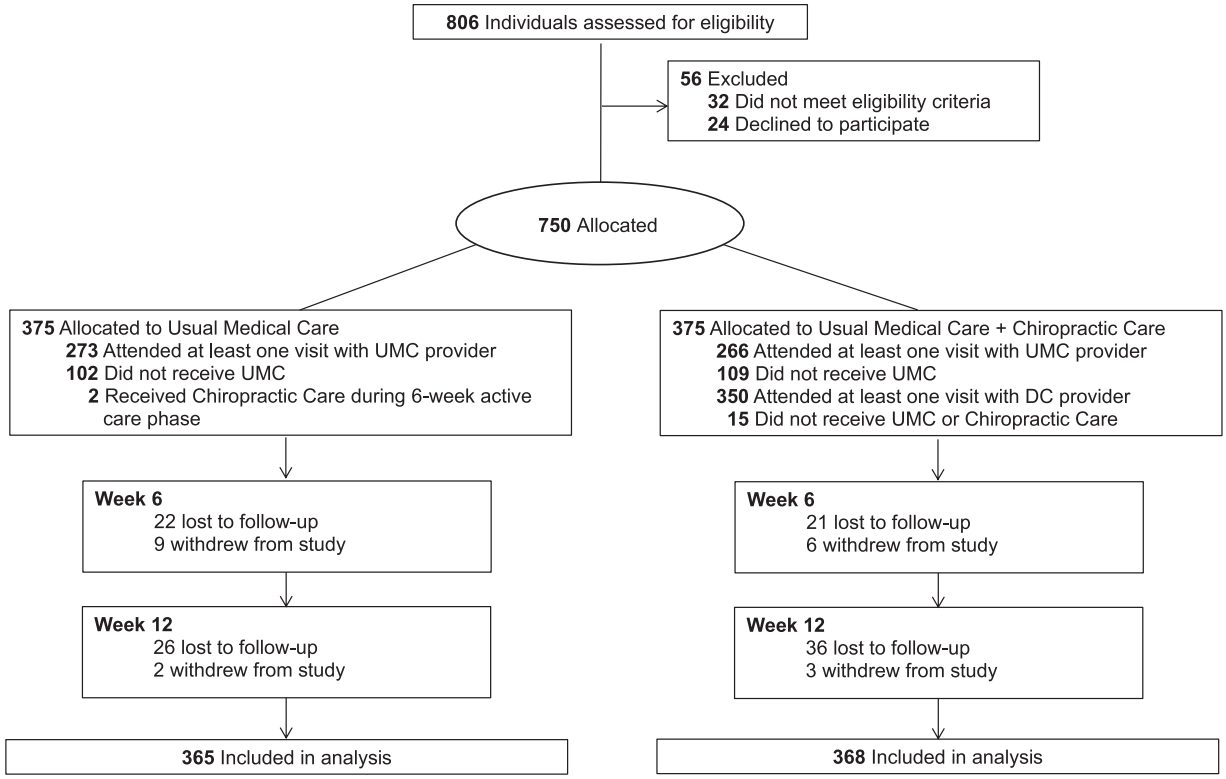

Figure 1. CONSORT flow diagram.

Table 1. Baseline characteristics of the sample

Variable	UMC (n = 375)	UMC+CC (n = 375)
Age, mean (SD), y	31 (9)	31 (9)
Male, n (%)	287 (76)	288 (77)
Ethnicity, n (%)		
Hispanic or Latino	66 (18)	52 (14)
Race, n (%)		
Asian	20 (5)	10 (3)
Black or African American	72 (19)	77 (20)
White	252 (67)	255 (68)
Other or unspecified	31 (8)	33 (7)
Low back pain duration, n (%)		
Acute (<1 month)	144 (38)	143 (38)
Subacute (1–3 months)	40 (11)	39 (10)
Chronic (>3 months)	191 (51)	193 (52)
PROMIS®: Mean (SD)		
Pain interference	58.9 (7)	60.1 (7)
Physical function	43.2 (7)	43.2 (7)
Sleep disturbance	55.5 (8)	55.0 (8)
Fatigue	51.5 (10)	51.8 (10)
Social/role	45.4 (9)	44.9 (9)
Anxiety	48.1 (9)	48.7 (9)
Depression	45.0 (7)	45.8 (7)
Global Average Pain (0–10)	5.0 (2)	5.0 (2)

UMC = usual medical care; UMC+CC = usual medical care plus chiropractic care.

are given in the last two columns of Table 2. The greater magnitude of change for UMC+CC tended to be largest for pain and smallest for depression, anxiety, and the emotional distress composite.

The significance of individual change on the HRQOL measures are given at 6 weeks (Table 3) and 12 weeks (Table 4) after baseline. The percentage of patients who showed improvement in HRQOL measures was greater for UMC+CC than for UMC at 6- and 12-week follow-ups. Differences in the percentage better at 6 weeks were significant at $P < .05$ for every measure except physical function and sleep disturbance. Differences in the percentage better at 12 weeks were significant at $P < .05$ for every measure except the physical health summary score and physical function score. The percentage of patients who showed worsening in HRQOL measures was smaller or equal for each HRQOL measure in the UMC+CC group relative to UMC at 6- and 12-week follow-ups.

A greater proportion of participants with UMC+CC than UMC got significantly better at 6 weeks after baseline (a difference of 2 percentage points for PROMIS® sleep disturbance to 16 percentage points for PROMIS® pain interference) and at 12 weeks after baseline (a difference from 3 percentage points for PROMIS® physical function to 21 percentage points for the PROMIS® pain composite). The percentage of those who improved in the UMC+CC group ranged from 17% (PROMIS® sleep disturbance) to 53% (PROMIS® pain interference) at 6-weeks and 21% (PROMIS® depression) to 59% (PROMIS® mental health summary score) at 12 weeks.

Product-moment correlations of the RMDQ score with the PROMIS® physical function scale was -0.69 (48% shared variance), PROMIS® pain interference scale was 0.65 (42% shared variance), the PROMIS® pain

Table 2. Least square means by treatment and time point

Measure	Treatment	Baseline	6 Weeks	12 Weeks	Treatment by Time F-Ratio	*P*-Value	ES Difference (6 Weeks)	ES Difference (12 Weeks)
Physical function	UMC	43.2	46.3	46.9	6.93	0.0010	0.28	0.32
	UMC+CC	43.2	48.3	49.2				
Pain interference	UMC	59.0	55.4	54.3	15.17	<0.0001	−0.45	−0.52
	UMC+CC	60.1	53.3	51.7				
Pain intensity (0–10)	UMC	5.1	4.4	4.0	24.22	<0.0001	−0.58	−0.63
	UMC+CC	5.1	3.3	2.8				
Pain intensity (T-score)	UMC	62.0	58.9	57.3	24.22	<0.0001	−0.57	−0.63
	UMC+CC	62.1	54.4	52.2				
Pain composite	UMC	60.5	57.2	55.8	23.64	<0.0001	−0.57	−0.65
	UMC+CC	61.1	53.9	52.0				
Fatigue	UMC	51.8	50.1	49.4	8.82	0.0002	−0.29	−0.29
	UMC+CC	52.0	47.4	46.7				
Sleep disturbance	UMC	55.7	54.0	53.7	5.21	0.0057	−0.18	−0.26
	UMC+CC	55.1	52.1	51.2				
Social/role	UMC	45.7	47.4	48.5	7.58	0.0006	−0.33	0.31
	UMC+CC	45.2	49.9	50.8				
Depression	UMC	44.7	44.8	45.0	6.01	0.0026	−0.21	−0.23
	UMC+CC	45.6	44.1	44.2				
Anxiety	UMC	48.0	46.3	46.0	4.29	0.0141	−0.19	−0.19
	UMC+CC	48.6	45.3	44.9				
Emotional distress	UMC	46.3	45.6	45.5	6.16	0.0022	−0.22	−0.23
	UMC+CC	47.1	44.8	44.6				
Physical health summary	UMC	42.6	45.8	46.6	9.47	<0.0001	0.33	0.37
	UMC+CC	42.5	48.1	49.2				
Mental health summary	UMC	46.9	48.7	49.5	15.81	<0.0001	−0.40	0.42
	UMC+CC	46.5	51.2	52.2				
Worst pain (0–10)*	UMC	6.0	4.7	4.2	19.26	<0.0001	−0.55	−0.50
	UMC+CC	5.9	3.5	3.0				
Roland-Morris**	UMC	9.9	7.5	6.5	12.15	<0.0001	−0.38	−0.36
	UMC+CC	9.7	5.2	4.4				

*Not a PROMIS®-29 measure. Worst pain was assessed on a 0–10 scale (0 is no pain and 10 is worst possible pain).

**Not a PROMIS®-29 measure. Note: Linear mixed effects regression models control for site, week, gender, race/ethnicity, age, and duration of low back pain. UMC = usual medical care; UMC+CC = usual medical care plus chiropractic care. Numerator degrees of freedom = 2 and denominator degrees of freedom = 719 for the F-ratios in the table.

intensity item was 0.48 (23% shared variance), and the worst pain item was 0.50 (25% shared variance). AUC values for significant change in RMDQ from baseline to 6-weeks later were 0.85 for the PROMIS® physical function scale, 0.84 for the worst pain intensity item, 0.83 for the PROMIS® pain interference scale, and 0.82 for the PROMIS® pain intensity item (see Figures 2–5). The rank-order from best to worst scale in area under the curve for the global improvement item at 6-weeks was as follows (Figures 6–10): 1) PROMIS® pain intensity item (0.831); 2) RMDQ (0.827); 3) worst pain intensity item (0.813); 4) PROMIS® pain interference scale (0.810); and 5) PROMIS® physical function scale (0.785).

Discussion

Goertz et al. [14] reported chiropractic care imparted beneficial effects on disability, average LBP in the past week, worst LBP in the past 24 hours, and bothersomeness of LBP symptoms. The current study extends this work by showing positive impacts of chiropractic care on all aspects of HRQOL measured in this study (including physical function, pain interference, sleep disturbance, anxiety, depression, and satisfaction with social role). The largest effects were for pain (PROMIS® pain interference, worst pain intensity in the past 24 hours, PROMIS® pain composite, and PROMIS® pain intensity item). While the positive effects of UMC+CC were statistically significant for the mental health measures, the differences between UMC and UMC+CC were small (e.g., at 12 weeks post-baseline depression and anxiety scale scores differed by about 1 T-score point), below the minimally important difference estimated for similar PROMIS measures [27].

Previous studies have also reported beneficial effects of chiropractic care on HRQOL. An observational study of 2024 patients with chronic LBP or neck pain receiving care from 125 chiropractic clinics throughout the United States found significant group-level change over 3 months on all PROMIS®-29 v2.0 scores except for emotional distress, but the average change was small in magnitude, with effect sizes ranging from 0.08 for physical function

Table 3. Significance of individual change from baseline to 6 weeks later

	UMC (n = 316)				UMC+CC (n = 323)				Difference % Better
Measure	% Worse	% Same	% Better	CR	% Worse	% Same	% Better	CR	(*P*-Value)
Physical health summary score	10	59	31	5.60	5	53	42	5.64	11 (.0039)
Physical function	8	62	30	6.31	5	59	36	6.43	6 (.1069)
Mental health summary score	21	42	37	3.47	10	38	51	3.48	14 (.0004)
Fatigue	15	61	24	6.93	7	61	32	7.16	8 (.0244)
Sleep disturbance	6	80	15	8.96	5	78	17	9.09	2 (.4906)
Depression	14	73	13	6.30	10	69	21	6.53	8 (.0072)
Emotional distress composite (anxiety & depression)	14	68	18	5.31	10	63	28	5.34	10 (.0027)
Anxiety	9	74	17	8.62	5	72	24	8.39	7 (.0285)
Pain interference	13	50	37	5.05	6	41	53	5.00	16 (<.0001)
Social/role	24	43	33	4.78	19	36	45	4.70	12 (.0019)
Pain composite (pain interference and intensity)	9	62	29	6.63	2	53	45	6.82	16 (<.0001)
Pain intensity	6	76	19	12.40	1	67	32	12.56	13 (.0002)
Worst pain (0–10)*	3	76	21	3.52	1	66	33	3.15	12 (.0006)
Roland-Morris**	4	78	17	7.44	1	72	27	7.56	10 (.0023)

Note: To estimate significance of change in individuals we use the coefficient of repeatability: 1.96*(SEM*SQRT(2)) = 2.77*SEM (where standard error of measurement [SEM] = SD * SQRT (1-reliability)).

*Not a PROMIS®-29 measure. Worst pain was assessed on a 0–10 scale where 0 is no pain and 10 is worst possible pain. Reliability = 0.70 assumed.

**Not a PROMIS®-29 measure. Reliability of 0.76 estimated from correlations of Roland-Morris measure between adjacent time points.

UMC = usual medical care; UMC+CC = usual medical care plus chiropractic care; CR = coefficient of repeatability.

Table 4. Significance of individual change from baseline to 12 weeks later

	UMC (n = 288)				UMC+CC (n = 287)				Difference % Better
Measure	% Worse	% Same	% Better	CR	% Worse	% Same	% Better	CR	(*P*-Value)
Physical health summary score	11	51	39	5.60	6	50	44	5.64	5 (.2237)
Physical function	9	53	37	6.31	5	55	40	6.43	3 (.4598)
Mental health summary score	20	40	40	3.47	11	30	59	3.48	19 (<.0001)
Fatigue	17	57	26	6.93	10	52	38	7.16	12 (.0020)
Sleep disturbance	5	80	16	8.96	5	71	24	9.09	8 (.0165)
Depression	17	71	12	6.30	11	69	21	6.53	9 (.0036)
Emotional distress composite (anxiety & depression)	11	71	18	5.31	10	61	29	5.34	11 (.0019)
Anxiety	8	75	17	8.62	7	67	26	8.39	9 (.0086)
Pain interference	14	44	42	5.05	5	37	58	5.00	16 (.0001)
Social/role	23	42	35	4.78	15	37	48	4.70	13 (.0016)
Pain composite (pain interference and intensity)	10	55	35	6.63	2	42	56	6.82	21 (<.0001)
Pain intensity	6	68	26	12.40	2	52	46	12.56	20 (<.0001)
Worst pain (0–10)*	4	68	28	3.52	1	57	42	3.15	14 (.0004)
Roland-Morris**	4	73	22	7.44	1	69	30	7.56	8 (.0288)

Note: To estimate significance of change in individuals we use the coefficient of repeatability: 1.96*(SEM*SQRT(2)) = 2.77*SEM (where standard error of measurement [SEM] = SD * SQRT (1-reliability)).

*Not a PROMIS®-29 measure. Worst pain was assessed on a 0–10 scale where 0 is no pain and 10 is worst possible pain. Reliability = 0.70 assumed.

**Not a PROMIS®-29 measure. Reliability of 0.76 estimated from correlations of Roland-Morris measure between adjacent time points..

UMC = usual medical care; UMC+CC = usual medical care plus chiropractic care; CR = coefficient of repeatability.

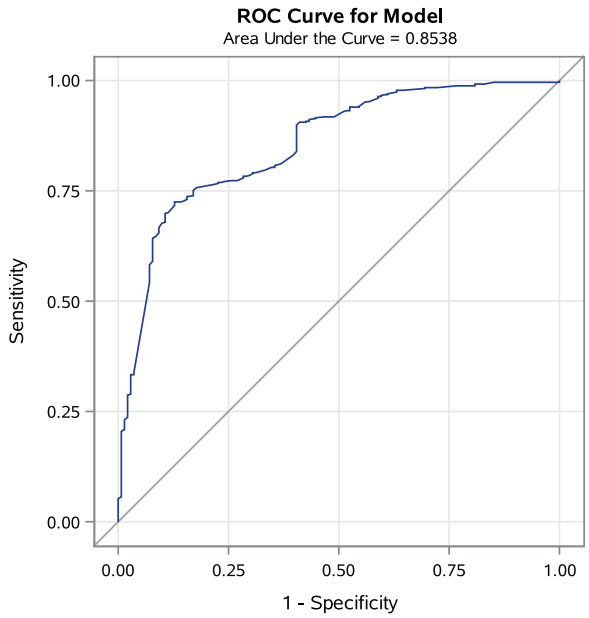

Figure 2. Area under the curve for change in Roland-Morris overall score by change in PROMIS®-29 physical function scale from baseline to 6 weeks later.

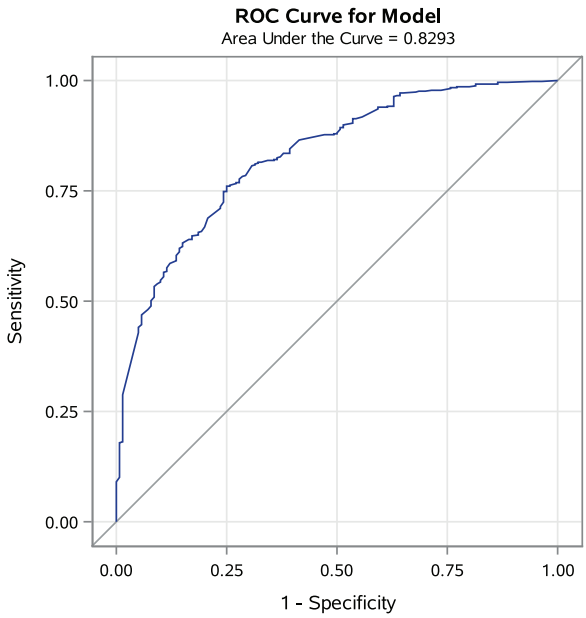

Figure 4. Area under the curve for change in Roland-Morris overall score by change in PROMIS®-29 pain interference scale from Baseline to 6 weeks later.

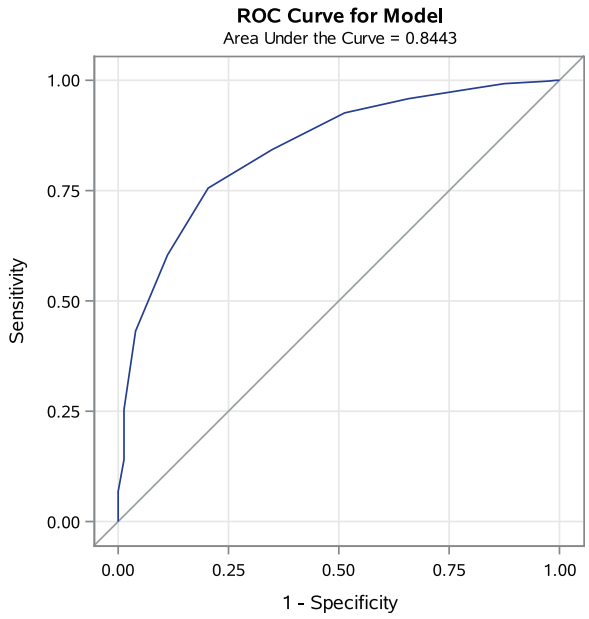

Figure 3. Area under the curve for change in Roland-Morris overall score by change in worst pain intensity (last 24 hours) from baseline to 6 weeks later.

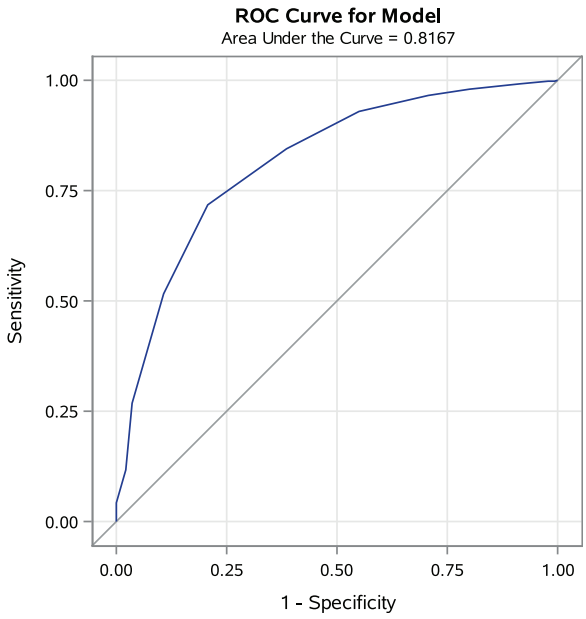

Figure 5. Area under the curve for change in Roland-Morris overall score by change in PROMIS®-29 pain intensity item from Baseline to 6 weeks later.

to 0.20 for pain [21]. The United Kingdom back pain, exercise, and manipulation study documented similar (although slightly larger) improvements over 3 months attributable to manipulation of 2.5 and 2.9 points on the Short-form Health Survey (SF-36) physical and mental health summary scores, respectively [28].

The current study also estimates the percentage of individuals improving on each aspect of HRQOL. The smallest percentage of improvement among those receiving UMC+CC was observed for sleep disturbance (17%) and the largest percentage was on pain interference (53%) at 6 weeks; at 12 weeks the smallest percentage improvement was 21% (depression) and the largest percentage improvement was 58% (pain interference). In comparison, the observational study noted above documented that from 13% (PROMIS®-29 v2.0 physical function) to 30% (PROMIS®-29 v2.0 mental health summary score) of the sample improved from baseline to 3 months

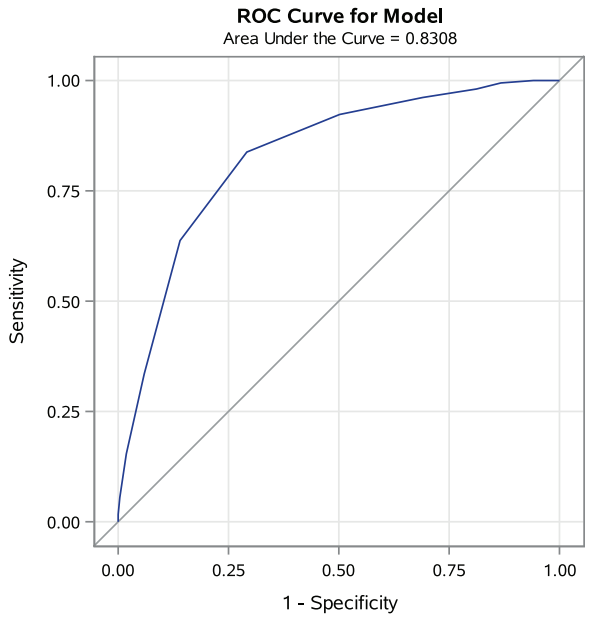

Figure 6. Area under the curve for global improvement by change in PROMIS®-29 pain intensity item from baseline to 6 weeks later.

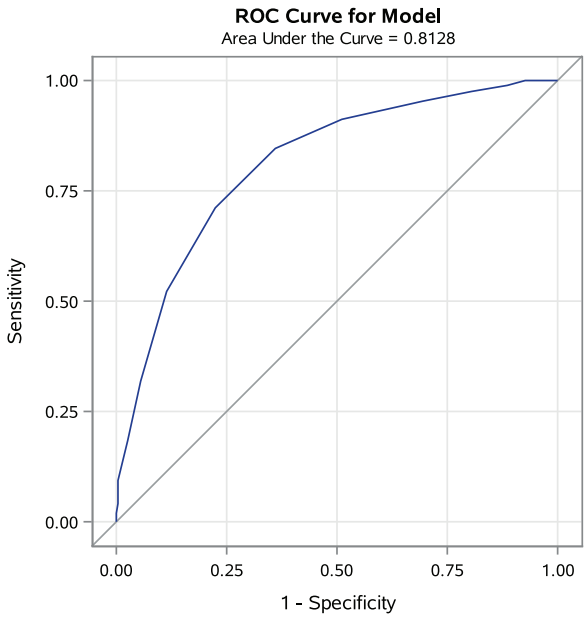

Figure 8. Area under the curve for global improvement by change in worst pain intensity (last 24 hours) from baseline to 6 weeks later.

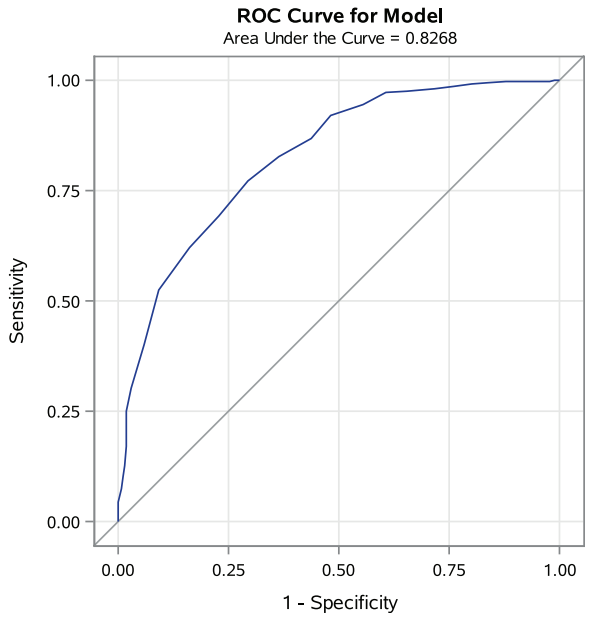

Figure 7. Area under the curve for global improvement by change in Roland-Morris scale from baseline to 6 weeks later.

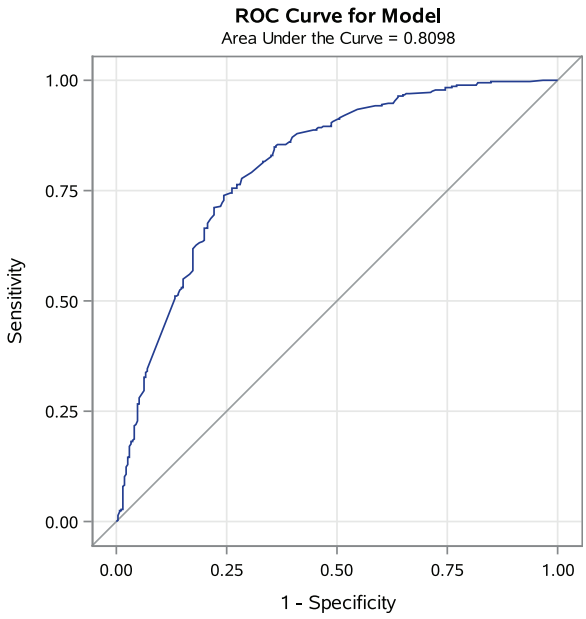

Figure 9. Area Under the Curve for Global Improvement by Change in PROMIS®-29 pain interference scale from Baseline to 6 weeks later.

later [21]. It is possible that chiropractic directly affects physical health and that the smaller changes in mental health measures such as depression and anxiety represent indirect effects. Future research should consider causal mediation analysis to shed light on this possibility.

We found substantial associations between change in the legacy RMDQ measure and change in the PROMIS®-29 physical function, pain interference, and pain intensity scales. AUCs using significant individual change in the RMDQ from baseline to 6-weeks later ranged from 0.82 to 0.85 for the worst pain in the last 24 hours item, and the PROMIS®-29 pain intensity item, pain interference scale, and physical function scale. AUCs with respect to a global improvement in LBP for the RMDQ and PROMIS®-29 v1.0 scales ranged from 0.79 to 0.83. This is important because the RMDQ has 24 items and the longest PROMIS®-29 v1.0 scale is 4 items, while both the global improvement and PROMIS®-29 v1.0 pain intensity measure have only a single item.

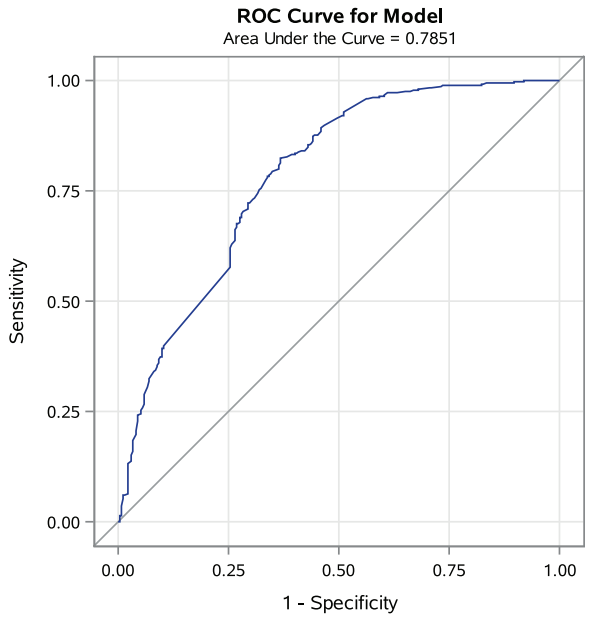

Figure 10. Area under the curve for global improvement by change in PROMIS®-29 physical function scale from baseline to 6 weeks later.

The limitations of the clinical trial have been addressed in detail elsewhere [14]. Limitations include issues of heterogeneity inherent in all LBP research, difficulty in masking participants to group allocation, and a short length of follow-up. In addition, it is uncertain how long the positive effects of chiropractic persist beyond the 12 weeks of follow-up used in this study. Further, the study findings are based on a sample of relatively young and mostly white military personnel treated in multidisciplinary care facilities. The integrated care setting may influence results by improving care coordination between chiropractors and medical providers. These findings should be replicated in non-military samples and with older adults in other settings of care.

Conclusion

Pre-planned secondary outcomes from this rigorous, pragmatic RCT demonstrate that chiropractic care can positively impact HRQOL beyond pain and pain-related disability. This along with prior research suggests positive effects of chiropractic care on patient-reported outcomes up to 3 months. Furthermore, PROMIS® measures of pain and pain-related disability (5 items) performed similarly to the 24-item RMDQ in the evaluation of outcomes for patients under chiropractic care. The use of PROMIS® measures encompassing physical, mental, and social health provided a richer, more holistic picture of response to chiropractic care, with less time commitment for trial participants demonstrating benefit for outcomes assessment in research and clinical practice.

Acknowledgments

We are indebted to the active-duty US military personnel with low back pain who participated in this study.

Supplementary Data

Supplementary data are available at *Pain Medicine* online.

References

1. GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017. Lancet Lond Engl 2018;392(10159):1789–858.
2. Dieleman JL, Cao J, Chapin A, et al. US health care spending by payer and health condition, 1996–2016. JAMA 2020;323(9):863–84.
3. Krebs EE, Gravely A, Nugent S, et al. Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: The SPACE Randomized Clinical Trial. JAMA 2018;319(9):872–82.
4. Chou R, Deyo R, Friedly J, et al. Systemic pharmacologic therapies for low back pain: A systematic review for an American College of Physicians Clinical Practice guideline. Ann Intern Med 2017;166(7):480–92.
5. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: An updated overview. Eur Spine J 2018;27(11):2791–803.
6. Qaseem A, Wilt TJ, McLean RM, et al.; Clinical Guidelines Committee of the American College of Physicians. Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American College of Physicians. Ann Intern Med 2017;166(7):514–30.
7. Beliveau PJH, Wong JJ, Sutton DA, et al. The chiropractic profession: A scoping review of utilization rates, reasons for seeking care, patient profiles, and care provided. Chiropr Man Ther 2017;25:35. doi:10.1186/s12998-017-0165-8.
8. Skelly AC, Chou R, Dettori JR, et al. Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update. Rockville, MD: Agency for Healthcare Research and Quality (US); 2020. (AHRQ Comparative Effectiveness Reviews). Available at: http://www.ncbi.nlm.nih.gov/books/NBK556229/ (accessed February 8, 2020).
9. Gallup, Inc. Americans' Perceptions of Chiropractic. 2015:24. Available at: https://www.palmer.edu/getmedia/8a750f7d-ccc4-4c32-accb-92aef43117ca/gallup-report-palmer-college.pdf (accessed December 2, 2021).
10. Vining RD, Shannon ZK, Salsbury SA, Corber L, Minkalis AL, Goertz CM. Development of a clinical decision aid for chiropractic management of common conditions causing low back pain in veterans: Results of a consensus process. J Manipulative Physiol Ther 2019;42(9):677–93.
11. Paige NM, Miake-Lye IM, Booth MS, et al. Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain: Systematic review and meta-analysis. JAMA 2017;317(14):1451–60.
12. Rubinstein SM, de Zoete A, van Middelkoop M, Assendelft WJJ, de Boer MR, van Tulder MW. Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain:

Systematic review and meta-analysis of randomised controlled trials. BMJ 2019;364:l689.
13. Goertz CM, Long CR, Vining RD, et al. Assessment of chiropractic treatment for active duty, U.S. military personnel with low back pain: Study protocol for a randomized controlled trial. Trials 2016;17(1):70.
14. Goertz CM, Long CR, Vining RD, Pohlman KA, Walter J, Coulter I. Effect of usual medical care plus chiropractic care vs usual medical care alone on pain and disability among US service members with low back pain: A comparative effectiveness clinical trial. JAMA Netw Open 2018;1(1):e180105.
15. Watrous JR, McCabe CT, Jones G, et al. Low back pain, mental health symptoms, and quality of life among injured service members. Health Psychol 2020;39(7):549–57.
16. Kelley AM, MacDonnell J, Grigley D, Campbell J, Gaydos SJ. Reported back pain in army aircrew in relation to airframe, gender, age, and experience. Aerosp Med Hum Perform 2017;88(2):96–103.
17. Koreerat NR, Koreerat CM. Prevalence of musculoskeletal injuries in a security force assistance brigade before, during, and after deployment. Mil Med 2021;186(Suppl 1):704–8.
18. Gianola S, Frigerio P, Agostini M, et al. Completeness of outcomes description reported in low back pain rehabilitation interventions: A survey of 185 randomized trials. Physiother Can 2016;68(3):267–74.
19. Deyo RA, Andersson G, Bombardier C, et al. Outcome measures for studying patients with low back pain. Spine 1994;19(18 Suppl):2032S–6S.
20. Cella D, Choi SW, Condon DM, et al. PROMIS® adult health profiles: Efficient short-form measures of seven health domains. Value Health 2019;22(5):537–44.
21. Hays RD, Spritzer KL, Sherbourne CD, Ryan GW, Coulter ID. Group and individual-level change on health-related quality of life in chiropractic patients with chronic low back or neck pain. Spine 2019;44(9):647–51.
22. Papuga MO, Barnes AL. Correlation of PROMIS CAT instruments with Oswestry Disability Index in chiropractic patients. Complement Ther Clin Pract 2018;31:85–90.
23. Roland M, Morris R. A study of the natural history of back pain. Part I: Development of a reliable and sensitive measure of disability in low-back pain. Spine 1983;8(2):141–4.
24. Hays RD, Spritzer KL, Schalet BD, Cella D. PROMIS®-29 v2.0 profile physical and mental health summary scores. Qual Life Res 2018 Jul;27(7):1885–91.
25. Jacobson NS, Truax P. Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. J Consult Clin Psychol 1991;59(1):12–9.
26. Hays RD, Slaughter ME, Spritzer KL, Herman PM. Estimating responders to treatment using five indices of significant individual change. JMPT submitted for publication.
27. Lee AC, Driban JB, Price LL, Harvey WF, Rodday AM, Wang C. Responsiveness and minimally important differences for 4 patient-reported outcomes measurement information system short forms: Physical function, pain interference, depression, and anxiety in knee osteoarthritis. J Pain 2017;18(9):1096–110. doi:10.1016/j.jpain.2017.05.001.
28. BEAM Trial Team UK. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: Effectiveness of physical treatments for back pain in primary care. BMJ 2004; 329(7479):1377.