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Group and Individual-level Change on Health-related Quality of Life in Chiropractic Patients With Chronic Low Back or Neck Pain

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Study Design. A prospective observational study.

Objective. The aim of this study was to evaluate group-level and individual-level change in health-related quality of life among persons with chronic low back pain or neck pain receiving chiropractic care in the United States.

Summary of Background Data. Chiropractors treat chronic low back and neck pain, but there is limited evidence of the effectiveness of their treatment

Methods. A 3-month longitudinal study of 2024 patients with chronic low back pain or neck pain receiving care from 125 chiropractic clinics at six locations throughout the United States was conducted. Ninety-one percent of the sample completed the baseline and 3-month follow-up survey (n = 1835). Average age was 49, 74% females, and most of the sample had a college degree, were non-Hispanic White, worked full-time, and had an annual income of $60,000 or more. Group-level (within-group *t* tests) and individual-level (coefficient of repeatability) changes on the Patient-Reported Outcomes Measurement Information System (PROMIS-29) v2.0 profile measure was evaluated: six multi-item scales (physical functioning, pain, fatigue, sleep disturbance, social health, emotional distress) and physical and mental health summary scores.

Results. Within-group *t* tests indicated significant group-level change ($P < 0.05$) for all scores except for emotional distress, and these changes represented small improvements in health (absolute value of effect sizes ranged from 0.08 for physical functioning to 0.20 for pain). From 13% (physical functioning) to 30% (PROMIS-29 v2.0 Mental Health Summary Score) got better from baseline to 3 months later according to the coefficient of repeatability.

Conclusion. Chiropractic care was associated with significant group-level improvement in health-related quality of life over time, especially in pain. But only a minority of the individuals in the sample got significantly better (''responders''). This study suggests some benefits of chiropractic on functioning and well-being of patients with low back pain or neck pain.

Key words: chiropractic, health-related quality of life, low back pain, neck pain, observational, PROMIS, responders, within group change.

Level of Evidence: 3

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Musculoskeletal disorders are among the most prevalent health problems and the second leading cause of disability worldwide.[1] Low back pain prevalence for adults in the United States (U.S.) is about 20% and estimated to cost $34 billion in 2010.[2] The authors of one cross-sectional study concluded that prevalent neck pain was weakly associated with the SF-36 physical health summary score and not significantly related to the SF-36 mental health summary score after controlling for comorbidities.[3] Similarly, another study reported no significant association between neck pain and the SF-36 mental health summary score, but found a dose-response association with the SF-36 physical health summary score, even after adjusting for age, education, arthritis, low back pain, and depressive symptoms.[4] These authors reported similar associations in a different study for those with low back pain.[5]

More than 50% of U.S. adults have sought care from a chiropractor and about 30% of those with spinal pain in the U.S. have used chiropractic care.[6] Chiropractors treat chronic low back and neck pain, but there is limited evidence of the effectiveness of their treatment.[7] The UK back pain, exercise, and manipulation study documented

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significant improvements over 3 months attributable to manipulation of 2.5 and 2.9 points on the SF-36 physical and mental health summary scores, respectively.[8]

We conducted a longitudinal observational study of a sample of chronic low back pain (CLBP) and chronic neck pain (CNP) patients receiving chiropractic care to evaluate change in health-related quality of life (HRQOL) using the Patient-Reported Outcomes Measurement Information System (PROMIS) measure recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain[9] and administered along with the Neck Disability Index in a recent study.[10] This study is unique because it provides information on a representative sample of chiropractic patients in care for chronic pain. It provides important information on the effect of chiropractic care for those with long-lasting pain.

MATERIALS AND METHODS

We used multistage systematic stratified sampling with four levels: regions/states, sites (*i.e.*, metropolitan areas), providers/clinics, and patients.[11] We recruited chiropractic practices in six states from major geographical regions of the U.S.: San Diego, CA; Tampa, FL; Minneapolis, MN; Seneca Falls/Upstate, NY; Portland, OR; and Dallas, TX.

We sought to recruit 20 or more chiropractic providers/clinics per site and to reflect the national proportions of provider gender, years of experience, and patient load as shown in the 2015 Practice Analysis Report from the National Board of Chiropractic Examiners. Our aim was to recruit 30% female practitioners; 30% with 5 to 15 years of experience and the rest with more than 15 years of experience; and equal proportions of those treating 25 to 74 patients per week *versus* 75 or more patients per week. We excluded providers who had more than half their patients with open personal injury/workers compensation litigation, and providers who do not use manual manipulation or mobilization (*i.e.*, instrument-assisted only practice).

In addition to posters and fliers notifying patients about the study, the front desk staff at each clinic was asked to offer a prescreening questionnaire available to every patient who visited the clinic during a 4-week period and to keep a daily tally of all patients seen by participating chiropractors. This prescreening questionnaire was self-administered on an iPad and used to determine whether patients met the study inclusion/exclusion criteria: at least 21 years of age; could speak English well enough to complete the remaining questionnaires; not currently involved in ongoing personal injury/workers compensation litigation; and have now or ever had chronic low back or neck pain. Patients who met these criteria were invited to be in the study, and if they agreed, they were asked to provide their email addresses and a phone number. All patients who provided email addresses received an electronically delivered $5 gift card.

Patients invited to the study were emailed a longer screening questionnaire to determine whether they met the study criteria for CLBP and CNP (*i.e.*, reported pain for at least 3 months before seeing the chiropractor and/or stated that their pain was chronic). If they were eligible for the study, patients were then consented and asked additional questions. Those not eligible and those who were eligible and started this screening questionnaire but did not finish it received a $5 gift card. Those eligible who consented and went on to complete the remaining questions on this survey received a $20 gift card and were then invited to complete subsequent surveys, including a baseline and 3-month follow-up questionnaire. Participants received a $25 gift card for completing the baseline questionnaire and $25 for completing the 3-month follow-up questionnaire.

The study was approved by the RAND Corporation Human Subjects Protection Committee. This study was registered as an observational study on ClinicalTrials.gov (ID: NCT03162952).

In this paper, we examine 3-month change on the PROMIS-29 v2.0 profile measure.[12,13] The PROMIS-29 v2.0 measure[14] assesses pain intensity using a single 0 to 10 numeric rating item and seven health domains (physical functioning, fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles and activities, and sleep disturbance) using four items for each domain.

We analyzed six multi-item scales (physical functioning, pain, fatigue, sleep disturbance, social health, emotional distress) and physical and mental health summary scores. Each of these is scored on a *T* score metric with a mean of 50 and a standard deviation of 10 in the U.S. general population.[15] Higher scores represent more of the concept assessed: better physical functioning, more pain, greater fatigue, more sleep problems, better social health, more emotional distress, and better physical and mental health, respectively. Internal consistency reliability coefficients[16] were estimated for four and formula by Mosier[17] for the reliability of a composite was estimated for pain (intensity and interference), emotional distress (depressive symptoms and anxiety), and the physical health and mental health summary scores.

Within-group *t* tests were computed to evaluate change from baseline to end of the study 3 months later. The minimally important difference (MID) is "the average change in the domain of interest on the target measure among the subgroup of people deemed to change a minimal (but important) amount according to an 'anchor'."[18] The MID is used to determine whether statistically significant group change is also large enough to be clinically meaningful. It is an additional consideration when interpreting group differences because very trivial differences can be statistically significant when the sample size is large. On the basis of prior estimates of the MID for PROMIS measures,[19,20] we use an effect size of approximately 0.20 SD as the MID threshold.

It has been suggested that the MID be used to identify "responders" to treatment.[21] For example, the U.S. Food and Drug Administration guidance document recommended identifying responders using empirical evidence from anchor-based methods and suggested that the "difference

in the PRO score for persons who rate their condition the same and better or worse can be used to define responders to treatment."[22] But using group-level change to identify responders would lead to misclassification of patients as responders when they have not actually changed. In comparison to group change, much larger change is needed for statistically significant change in an individual's score because of the much larger standard errors for estimates of individual change.[23] Thus, responders need to be identified on the basis of the significance of individual change using indices such as the reliable change index.[24] We used the coefficient of repeatability[25] to classify individuals as got worse, stayed the same, or got better from baseline to endpoint 3 months later: = 1.96∗SQR(2)∗SEM = 2.77∗SEM, where SEM = standard error of measurement = SD [SQR (1 – reliability)]. The coefficient of repeatability is equivalent to the reliable change index.

RESULTS

Table 1 summarizes the characteristic of the baseline sample (n = 2024) and the subset of 1835 (91%) that completed the 3-month endpoint survey. The characteristics of those who completed the endpoint survey is very similar to that of the overall sample. The average age of the endpoint sample was 49, 74% were female, and the majority had a college degree, were non-Hispanic white, worked full-time, and had an annual income of $60,000 or more.

As summarized in Table 2, the reliabilities of the measures ranged from 0.85 (sleep disturbance) to 0.97 (mental health summary score). Baseline means indicate that the sample reported more pain (6 points) and worse physical functioning (4 points) and physical health summary score (4 points) than the U.S. general population. In addition, the sample reported more fatigue (3 points), sleep disturbance (2 points), and worse mental health (2 points) than the general U.S. population. Emotional distress was the same as that of the general population and social health was better (2 points).

Within-group *t* tests indicated significant group-level improvement ($P < 0.05$) for all scores from baseline to endpoint 3 months later except for emotional distress, which did not change significantly (Table 2). As summarized in Table 3, the range of effect size (absolute value) for the scores that changed significantly was 0.08 (physical functioning) to 0.20 (pain). The proportion of individuals who got significantly better ("responders") ranged from 13% (physical functioning) to 30% (PROMIS-29 Mental Health Summary Score).

DISCUSSION

Chiropractic care was associated with significant improvements on all PROMIS-29 v2.0 measures except emotional distress in this sample of patients with CLBP or CNP. The absence of associations of back and neck pain with emotional distress is consistent with previous research.[3–5] The largest mean improvements were observed for pain, sleep disturbance, the PROMIS-29 v2.0 mental health summary score, social health, and fatigue. These improvements over

TABLE 1. Characteristics of the Sample

	Baseline (n = 2024)	Endpoint (n = 1835)
Age, yrs	Mean = 49 (range: 21–95)	Mean = 49 (range: 21–95)
Age 50+	50%	50%
Female (%)	73%	74%
Education		
Less than High School	0.3%	0.3%
HS degree/GED	7%	7%
Some college	37%	37%
Bachelors degree or higher	56%	56%
Race/Ethnicity		
Hispanic	5%	5%
Non-Hispanic		
White	88%	88%
Asian	3%	3%
African-American	2%	2%
American Indian/Pacific Islander/Other	2%	2%
Working full time	59%	59%
Gross income		
Income < $10K	2%	2%
$10K ≥income <$60K	36%	37%
$60K ≥income <$100K	30%	30%
Income ≥$100K	32%	32%
Oswestry Low Back Disability Index	Mean = 20 (SD = 13)	Mean = 18 (SD = 14)
Neck Disability Index	Mean = 23 (SD = 13)	Mean = 20 (SD = 14)

TABLE 2. Baseline and Endpoint Means (SDs) and Reliability of PROMIS-29 v2.0 Scores

Scale	Baseline	Endpoint	*t*-test of Change	*P*	Reliability
Physical functioning	46 (7)	47 (7)	4.15	0.0000	0.86
Pain	56 (7)	54 (8)	−9.48	0.0000	0.88
Fatigue	53 (8)	52 (9)	−7.11	0.0000	0.93
Sleep disturbance	52 (8)	50 (8)	−8.47	0.0000	0.85
Social health	52 (8)	53 (8)	7.61	0.0000	0.93
Emotional distress	50 (7)	50 (8)	−0.04	0.9662	0.93
PROMIS-29 Physical Health Summary Score	46 (7)	47 (8)	5.80	0.0000	0.90
PROMIS-29 Mental Health Summary Score	48 (7)	50 (7)	9.06	0.0000	0.97

Higher score is better for physical functioning, social health, PROMIS-29 Physical Health Summary Score, and PROMIS-29 Mental Health Summary Score. Higher scores are worse for the other four scales.

PROMIS indicates Patient-Reported Outcomes Measurement Information System.

3 months are consistent with prior estimates of minimally important group-level differences of about 2 to 3 points for PROMIS measures.[19,20] In addition, the magnitude of change is similar to what was reported for the SF-36 physical and mental health summary scores in the UK back pain, exercise, and manipulation study using the SF-36 health survey.[8] Note that the corresponding PROMIS-29 v2.0 and SF-36 summary scores correlated 0.82 with one another.[13]

Although some have suggested that group-level MIDs can be used to identify "responders" to treatment (*e.g.*, Coons and Cook[21]), using these thresholds to identify responders is inappropriate because of the larger standard errors associated with individual change estimates.[23] Responders need to be identified on the basis of the significance of individual change. We used the coefficient of repeatability in this study to show that for the scales that showed statistically significant mean improvement, from 13% (physical functioning) to 30% (PROMIS-29 Mental Health Summary Score) could be classified as responders. These estimates are in the ballpark of what was observed over a decade ago in an observational study of patients receiving care at the UCLA Center for East-West Medicine[23] and more recently in a sample of patients treated for chronic myofascial pain.[26]

This study illustrates the importance of reporting the proportion of responders in addition to the significance of group-level change. Observational studies and clinical trials should routinely report responders based on the significance of individual change. Using group-level estimates to identify individuals who have changed needs to be avoided. "A minimum criterion for a responder is that the individual improved significantly (i.e., individual change is greater than the measurement error associated with the PRO measure). There are a variety of related ways to estimate the significance of individual change and one or more of these should be used to determine if individual change is significant or not" (McLeod *et al*, p. 5[18]).

The results of this study contribute to the literature by providing evidence that chiropractic care is associated with improvements in functioning and well-being among individuals with CLBP or CNP. The study findings provide

TABLE 3. Change in PROMIS-29 v2.0 Scores from Baseline to Endpoint

Scale	Effect Size	Got Worse	Same	Got Better
Physical functioning	0.08	9%	78%	13%
Pain	−0.20	8%	75%	17%
Fatigue	−0.15	13%	64%	23%
Sleep disturbance	−0.17	6%	80%	14%
Social health	0.15	12%	67%	21%
Emotional distress	0.01	16%	68%	16%
PROMIS-29 Physical Health Summary Score	0.10	9%	76%	14%
PROMIS-29 Mental Health Summary Score	0.16	18%	52%	30%

Higher score is better for physical functioning, social health, PROMIS-29 Physical Health Summary Score.

Physical, and PROMIS-29 Mental Health Summary Score. Higher scores are worse for the other four scales.

*Change (Got worse or Got better) was determined by coefficient of repeatability = 2.77 * standard error of measurement. "Responders" are those in the "Got Better" subgroup.*

PROMIS indicates Patient-Reported Outcomes Measurement Information System.

empirical verification of why some chronic pain patients utilize chiropractic care on a regular basis. It supports the use of chiropractic care as one option for improving functioning and well-being of patients with CLBP or CNP. Although we are unable to infer the underlying mechanism for the observed improvements in patients, spinal manipulation is designed to relieve pain and improve physical functioning. Studies of the biomechanics indicate that spinal manipulation produces reflex responses and movements of vertebral bodies in the para-physiologic zone.[27]

➢ Key Points

- ❑ Chiropractic care was associated with group-level improvement in health-related quality of life over time.
- ❑ A minority of the individuals in the sample got significantly better ("responders").
- ❑ In addition to the significance of group-level change, observational studies and clinical trials should routinely report the number of responders using the significance of individual change.

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