# JACM

# The Quality of Life of Children Under Chiropractic Care Using PROMIS-25: Results from a Practice-Based Research Network

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## Abstract

*Objectives:* To characterize pediatric chiropractic and assess pediatric quality of life (QoL). *Design:* A prospective cohort.

*Setting/Locations:* Individual offices within a practice-based research network located throughout the United States.

Subjects: A convenience sample of children (8-17 years) under chiropractic care and their parents.

Exposure: Chiropractic spinal adjustments and adjunctive therapies.

**Outcome measures:** Survey instrument measuring sociodemographic information and correlates from the clinical encounter along with the Patient Reported Outcomes Measurement Information System (PROMIS)-25 to measure QoL (i.e., depression, anxiety, and pain interference). Sociodemographic and clinical correlates were analyzed using descriptive statistics (i.e., frequencies/percentages, means, and standard deviations). The PROMIS-25 data were analyzed using scoring manuals, converting raw scores to *T* score metric (mean = 50; SD = 10). A generalized linear mixed model was utilized to examine covariates (i.e., sex, number of visits, and motivation for care) that may have played an important role on the PROMIS outcome.

**Results:** The original data set consisted of 915 parent–child dyads. After data cleaning, a total of 881 parents (747 females, 134 males; mean age=42.03 years) and 881 children (467 females and 414 males; mean age=12.49 years) comprised this study population. The parents were highly educated and presented their child for mainly wellness care. The mean number of days and patient visits from baseline to comparative QoL measures was 38.12 days and 2.74 (SD=2.61), respectively. After controlling for the effects of motivation for care, patient visits, duration of complaint, sex, and pain rating, significant differences were observed in the probability of experiencing problems (vs. no reported problems) across all QoL domains (Wald=82.897, df=4, p < 0.05). *Post hoc* comparisons demonstrated the children were less likely to report any symptoms of depression (Wald=6.1474, df=1, p < 0.05), anxiety (Wald=20.603, df=1, p < 0.05), fatigue (Wald=22.191, df=1, p < 0.05), and pain interference (Wald=47.422, df=1, p < 0.05) after a trial of chiropractic care.

Conclusions: The QoL of children improved with chiropractic care as measured by PROMIS.

Keywords: pediatrics, chiropractic, prospective study

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#### Introduction

▼OMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) ✓ use in the pediatric population continues to remain popular, particularly for children living with chronic and recurrent conditions.<sup>1</sup> In 2000, Lee et al.<sup>2</sup> published the first characterization of the chiropractic care of children based on a survey of Boston chiropractors. The investigators extrapolated that  $\sim 30$  million pediatric visits were made to chiropractors annually in the United States. They estimated the total cost for care at \$1 billion with costs split approximately in half between third-party payers and families paying directly out-of-pocket. In 2010, Alcantara et al.<sup>3</sup> published a more comprehensive characterization of pediatric chiropractic using a practice-based research network (PBRN). Using calculations similar to Lee et al.,<sup>2</sup> these investigators approximated 86 million pediatric visits were made annually to chiropractors in 2007, leading Alcantara et al.<sup>3</sup> to conclude that the chiropractic care of children represents a significant aspect of not only the practice of chiropractic but also pediatric healthcare in general. Indeed, of the various practitioner-based CAM therapies, chiropractic has been found to be popular.<sup>4-6</sup> The treatment of musculoskeletal disorders such as neck pain and low back pain<sup>7</sup> as well as the promotion of health and wellbeing<sup>8,9</sup> has been reported to be common motivations for seeking chiropractic care of children. However, studies that evaluated the frequency of, reasons for, and factors influencing CAM use and specialty pediatrics within the same geographic locale have also found evidence of the utilization of chiropractic care for children with chronic disease, including cancer,<sup>10,11</sup> gastrointestinal disorders,<sup>12</sup> cardiac problems,<sup>13</sup> and neurological<sup>14</sup> problems.

In this era of evidence-informed practice, there is a need by all healthcare providers to document and demonstrate safety and effectiveness. No more is this true than in the care of infants and children. Despite the popularity and high utilization of chiropractic by the pediatric population, to the best of the authors knowledge, no study has examined the quality of life (QoL) of children under this paradigm of care. To address this deficit, the QoL of children under chiropractic care in a PBRN was examined, regardless of coexisting medical impairment or concurrent medical care. This study has two purposes: (1) to understand the utilization of patterns of pediatric populations who receive chiropractic care and (2) to understand how QoL changed in a population of children who self-select into chiropractic care.

### Methods

This study was approved by the Ethics Review Board of Life University (Marietta, GA) and uses a convenience sample of practicing chiropractic physicians and a normative sample of children naturally receiving care from these doctors. Doctors of chiropractic (DCs) (N=280) enrolled in a postgraduate course in pediatric chiropractic were invited to participate in a QoL study of children under chiropractic care (i.e., spinal adjustments and adjunctive therapies). In addition to direct involvement in the care of children, inclusion criteria for DC participation in this PBRN have previously been described.<sup>3,8,15</sup> The participating DCs were encouraged to invite parents and their children under chiropractic care as respondents for this study. Parent and child

inclusion criteria for participation were (1) the parents provided consent and children (i.e., age 8–17 years) provided assent, (2) the children were currently under chiropractic care, and (3) both parent and child have the ability to speak and read English. Exclusion criteria included (1) lack of consent or assent and (2) the child has a coexisting medical, psychiatric, or cognitive impairment(s) that presented a contraindication to chiropractic care or their ability to comprehend the survey instruments.

#### Parent survey

Parent responders in this study provided sociodemographic information for themselves (i.e., age, gender, level of education, and experience with chiropractic care) and their child (i.e., age and gender). In addition, clinical correlates/covariates of the history and physical examination were examined (i.e., motivation for care or presenting complaints, medical care, visits to the Emergency Room, and effectiveness of medical care).

### Pediatric survey

For the pediatric responders, the Patient Reported Outcomes Measurement Information System or PROMIS was utilized for this purpose. PROMIS was a National Institutes of Health initiative to create patient reported outcomes (PROs) to assess domains of physical, psychological, and social health, and QoL.<sup>16</sup> The PROMIS instruments were developed using rigorous qualitative and quantitative methods<sup>17</sup> and standardized to a reference population.<sup>18</sup> To date, the pediatric PROMIS instruments have been implemented in various pediatric populations, including those with cleft lip palate, <sup>19</sup> systemic lupus erythematosus,<sup>20</sup> cancer,<sup>21</sup> obesity,<sup>22</sup> asthma,<sup>23</sup> Crohn's disease,<sup>24</sup> and nephrotic syndrome.<sup>25</sup>

The instrument is a 25-item survey consisting of a fixed collection of short forms for physical functioning mobility, anxiety, depressive symptoms, fatigue, peer relationships, pain interference, and pain based on a numeric rating scale (NRS) (0=no pain; 10=worst pain you can think of). The survey instrument was pilot tested with 10 pediatric respondents without difficulty. The PROMIS pediatric short forms have been found to correlate well with the Pediatric Quality of Life Inventory and demonstrates similar accuracy but with better readability and efficiency.<sup>19</sup> In addition, the PROMIS measures for children have been found to have demonstrated feasibility, internal consistency, construct validity, and responsiveness to change in a clinical setting.<sup>21,26</sup>

Upon consent and assent, study participants (i.e., parents and their children) were asked to complete a baseline survey consisting of the parent survey (i.e., parent and child sociodemographics, motivation for care, or presenting complaints) and pediatric survey (i.e., PROMIS-25 survey) as already described. After a trial of care, the children were then asked to complete a comparative survey consisting of the PROMIS-25 instrument. Study participants involved children at various stages of care (i.e., new patients and existing patients/long-term patients). It was left to the judgment of the participating chiropractor the duration or number of visits from baseline to comparative measures. The only stipulation was that a minimum of 7 days must have elapsed from baseline to comparative measurement as the PROMIS instrument had a 7-day recall.

#### Statistical analysis

Responses were entered into an online data processing center created specifically for the purpose of this study and exported to an Excel spreadsheet (Microsoft Corp., Portland, OR) for analysis. The sociodemographic and clinical correlates were analyzed using descriptive statistics. These were provided as frequencies and percentages, means, and standard deviations. The PROMIS-25 data were analyzed using scoring manuals provided by the PROMIS Assessment Center<sup>SM,27</sup> For each PROMIS short form (i.e., physical functioning mobility, anxiety, depressive symptoms, fatigue, peer relationships, pain interference, and pain intensity), a scoring table was developed to associate the raw scores to a *T* score metric with a mean of 50 and standard deviation of 10. The greater the *T* score, the greater the measured QoL domain.

Since the study will involve chiropractors across the United States, this clustering of individual patients from various chiropractic practices can create residual correlations due to systematic differences across the practitioners (i.e., differences in chiropractic technique, skill or clinical experience, or other capacities). To take this variation into account, a generalized linear mixed model with random intercept and logit link was estimated. Each model additionally included a set of covariates that authors theorized might play an important role on the PROMIS outcome. Specifically, the effects of the reason for the visit (i.e., musculoskeletal condition, wellness, or another reason), number of visits, time lapse between baseline and comparative data collection, chronicity of condition, biological sex, and pain ratings were controlled for. All covariates were centered before analyses and entered into the regression model. Within this statistical framework, significant change was assessed through a Wald test of the difference in the thresholds between each baseline and comparative mean T scores for each QoL domain. The parameter of interest was whether the probability of endorsing a problem in each QoL domain changed from baseline to comparison (i.e., at follow-up) in a repeated measures design.

In the event that the distribution of the mean T scores for the various domains (i.e., anxiety, depression, and physical functioning) is highly skewed and leads to non-normality of residuals and violations of typical parametric (i.e., ordinary least squares) model assumptions, the mean T scores for each QoL domain will be dichotomized to reflect whether the children reported having any problems in the domain (e.g., any symptoms of depression or anxiety) versus no symptoms.

To protect against erroneous error due to multiple comparisons, the omnibus test that all thresholds were equal was first tested, then held the false discovery rate at p=0.05 using the Benjamini–Hochberg procedure for all protected *post hoc* comparisons. All analyses were conducted in Mplus version  $7.^{28}$ 

## Results

Of the 88 PBRN chiropractors, sociodemographic and practice characteristics were available for 63 DCs (44 female, 19 males). Their average age was 32.27 years (SD=6.03) with an average practice experience of 5.36 years (SD=4.59). Their primary chiropractic techniques were indicated as diversified technique (N=43), Thompson technique (N=17), activator methods (N=14), sacro-occipital technique (N=2), and "other" (N=10). In these data, it was found that between 5% (i.e., for pain NRS) and 8.8% (i.e., for fatigue) of the variability in the outcome was attributable to differences across DCs, which was interpreted to be small to moderate in size.

The original data set consisted of a total of 915 parentchild dyads. After data cleaning, a total of 881 parents (747 females; 134 males; mean age = 42.03 years) and 881 children (467 females and 414 males; mean age = 12.49 years) comprised the study population. The parents had an average age of 42.03 years (range = 25–71 years; SD = 6.58) and were highly educated. Eighty-five percent (N=755) had some college or higher level of education (i.e., 2% PhDs, 15% Masters, 36% Bachelors, 32% some college education), whereas 13% (N=113) were high school graduates with 1% (N=13) having some high school education. Eighty percent (N=702) of the parents were concurrently under chiropractic care along with their child.

The pediatric responders (N=881; 467 females and 414 males) had a mean age of 12.49 years (range: 8–17 years; SD=2.82). Baseline measurement took place at the first chiropractic appointment for 45% of the youth, during early stages of care (visits 2–9) for 27% of them and during an established patient visit ( $\geq$ 10th visit) for 28%. The mean number of days and patient visits from baseline to comparative QoL measures was 38.12 days and 2.74 (SD=2.61), respectively.

# What are the utilization patterns of children in the PBRN?

The first aim in this study was to understand the utilization patterns and constellation of healthcare services with this sample of children. All children in the sample were under chiropractic care with a chiropractor participating in this PBRN as an inclusionary criterion. This population of

TABLE 1. MEAN BASELINE AND COMPARATIVE T Scores of Children Under Chiropractic Care

Domain	N	Chiropractic baseline	N	Chiropractic comparative	N	Crohn's disease <sup>24</sup>	N	Nephrology <sup>25</sup> (overall scores)
Physical functioning mobility	881	51.3 (7.26)	881	52.57 (6.53)	276	_	150	52 (8.1)
Anxiety	881	46.91 (9.69)	881	44.82 (9.11)	276	47 (11)	151	46 (11.5)
Depressive symptoms	881	45.32 (8.72)	881	44.22 (7.89)	276	43 (8)	148	46 (10.8)
Fatigue	881	45.51 (9.21)	881	43.83 (8.79)	276	48 (12)	68	44 (11.8)
Peer relationships	881	51.75 (9.11)	881	52.66 (9.34)	276	49 (9)	151	50 (10.4)
Pain interference	872	47.38 (8.93)	872	44.84 (8.34)	276	48 (11)	82	47 (11.1)

TABLE 2. FREQUENCIES OF INDICATED NUMERIC RATING SCALE FOR PAIN INTENSITY

Pain NRS	0	1	2	3	4	5	6	7	8	9	10
N	195	115	100	120	99	98	68	58	20	5	3
NPS numer	ic rating scal	۵									

NRS, numeric rating scale.

interest were children under chiropractic care. When inquired about their motivation for this chiropractic care for their child, almost half (49%) of the parents were motivated with wellness care for their child, followed by a clinical presentation involving the musculoskeletal system (27%) and "another reason" (23%). When asked to indicate a duration of suffering that their child may be experiencing (if any), those parents responding indicated the following durations: days (21%; N=187), weeks (12%; N=105), months (17%; N=152), or years (49%; N=430).

Fifty-eight percent of the parents reported that their family medical physician (MD) was not aware of the chiropractic care their child received, whereas 40% reported that their MD was aware of their child's chiropractic care with 2% (of total respondents) indicating their MD referred their child for chiropractic care (2% did not respond to this item or had errors in data entry).

In terms of medical care received, the majority of parents (75%) indicated that their child did not receive prior medical care as it relates to their chiropractic presentation, whereas 15% of children received medical attention prior but no longer, and 10% of the children had on-going medical care in conjunction with chiropractic. Medical care received involved prescription medication (N=66), prescribed over-the-counter medication (N=48), or care that was described as "other" (N=29). Of the 25% (N=218) of parents indicating previous or ongoing medical care for their child, 55% provided an effectiveness rating (i.e., very ineffective, ineffective, neutral, effective, very effective) of their child's medical care. Note that the word "effectiveness" was not defined nor was a validated tool to rate effectiveness used. This question was merely asked simply to determine the degree or extent that medical care produced the desired results (i.e, improvement of symptoms) the parents were seeking. Of 120 parents, 24% rated their child's medical care as ineffective/very ineffective, 30% provided a neutral rating, and 46% rated their child's medical care as effective/very effective.

In terms of the need for emergency care services for their child in the previous 3 months, the majority of parent responders (84%) indicated that their child did not require visit(s) to the ER, whereas  $\sim 3\%$  of the parents indicated taking their child to the ER. The remainder of the parents (13%) indicated that their child's chiropractic care was not related to any medical condition requiring visits to the ER.

Parents were asked about previous or concurrent use of other CAM therapies for their child. Forty-seven percent of the parents indicated the ongoing use of vitamins and other nutritional supplements, 31% indicated previous use of herbal remedies, and 3% indicated ongoing use of herbal remedies. Nine percent of parents indicated previous use of and 5% with ongoing use of homeopathic remedies. Eleven percent of the parents indicated previous use of acupuncture, whereas only 2% had ongoing use of acupuncture. One percent of parents indicated previous chiropractic care elsewhere for their child, whereas 15% had no previous experience or use with CAM therapies for their child.

# How did chiropractic care change for pediatric chiropractic patients?

The baseline and comparative mean T score values for the QoL domains of this study are provided in Table 1. The frequencies for the indicated numeric pain ratings (NRS) are provided in Table 2. Distribution of the T scores for the various QoL domains was very highly skewed. There was a preponderance of children who indicated very low T scores for anxiety, depression, pain interference, fatigue, and high T scores for peer relationship and mobility. Transformations were unsuccessful at improving this non-normality. Descriptive statistics and correlations for all observed variables are given in Table 3.

At comparative measures, the frequencies of children with the following number of visits were determined as follows: 1 visit (N=436; 49.48%), 2 visits (N=134; 15.21%), 3 visits (N=75; 8.51%), 4 visits (N=64; 7.26%), 5 visits (N=39; 4.43%), 6 visits (N=18; 2.04%), 7 visits (N=17; 1.93%), 8 visits (N=14; 1.59%), 9 visits (N=10; 1.13%), and 10 or more visits (N=55; 6.24%). Children attending visits ranging from 2

Covariate	Mean	SD	Time lapse	Visit no.	Chronicity	Motivation for care	Pain NRS	Sex		
Time lapse	2.74	2.61	1	_	_	—	_	_		
Visit No.	1.83	0.84	0.13	1				—		
Duration of complaint	2.94	1.21	0.03	-0.01	1	_				
Motivation for care	0.271 (wellness) 0.494 (MSK) 0.235 (other)		0.01	-0.12	0.40	1	—			
Pain NRS	2.96	2.42	0.06	0.03	0.00	0.02	1			
Sex	0.549 (female) 0.486 (male)		-0.03	-0.02	-0.06	-0.02	-0.04	1		

TABLE 3. MEAN, STANDARD DEVIATIONS, AND CORRELATIONS AMONG OBSERVED COVARIATES

MSK, musculoskeletal; NRS, numeric rating scale.

to 9 comprised less than half of this study population (N=371; 44.11%). Data from 19 children (2.15%) were deleted from analyses due to inconsistent or impossible values on number of visits (e.g., comparative dates preceding baseline dates). The mechanism of missingness was assumed to be missing completely at random, and, therefore, not biased from listwise deletion. There was no other missingness in the data set.

After controlling for the effects of motivation for care, the number of visits at baseline (i.e., visit 1, visits 2-9, visits  $\geq 10$ ), the number of visits between measurement occasions, duration of complaint (i.e., days, weeks, months, and years), patient sex, and pain NRS, this analysis demonstrated significant differences in the probability of experiencing problems (vs. no reported problems) across all QoL domains (Wald=82.897, df=4, p < 0.05). Model-implied probabilities of indicating at least one symptom of each QoL domain values would indicate the predicted probability of youth reporting any of the problems on the PROMIS-25 questionnaire. Post hoc comparisons demonstrated that patients were less likely to report any symptoms of depression (Wald=6.1474, df=1, p < 0.05), anxiety (Wald = 20.603, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1, p < 0.05), fatigue (Wald = 22.191, df = 1,p < 0.05), and pain interference (Wald = 47.422, df = 1, p < 0.05) at comparison than at baseline. Peer relationship and mobility were not analyzed due to the preponderance of children with very high T scores.

# Discussion

In addition to determining the QoL of children under chiropractic care, this study also provided some interesting insights into the patterns and utilization of chiropractic services by this patient population. In the interest of brevity, discussions on the study findings are focused as they pertain to QoL changes concomitant with chiropractic care. The sociodemographic findings with parent responders in terms of age, sex, and educational level are consistent with the literature characterizing adult chiropractic patients<sup>29–32</sup> and previous studies characterizing the chiropractic care of children.<sup>3,8</sup>

To date, this is the largest characterization of children receiving chiropractic care. When the focus of healthcare shifts to value-based care rather than fee-for-service, PROs take on new meaning and importance in documenting patient outcomes. The strength of PROs lies in their ability to provide outcomes with personal and social context that are meaningful on a day-to-day basis for patients. To the authors knowledge, this is the first use of the PROMIS instrument in the pediatric chiropractic population. These findings are such that after a trial of chiropractic care, the overall QoL of the pediatric subjects improved. Mean T scores in physical functioning and peer relationships increased, whereas mean T scores in anxiety, depressive symptoms, fatigue, and pain interference decreased. These changes in mean T scores were statistically significant, regardless of the covariates of time lapse, the number of visits, chronicity, motivation for care, patient sex, and pain NRS.

A major concern with generic health-related QoL measures such as the PROMIS-25 has been that such measures may not be as responsive to changes in symptoms in disease-specific patients, measure specific disease symptoms, and treatment side-effects germane to a particular population of patients. Disease-specific QoL measures may ALCANTARA ET AL.

be more sensitive to specific clinical changes in diseasespecific patients (i.e., asthma) than a generic measure and as such may have greater use in individualized care such as chiropractic. However, as it applies to a chiropractic PBRN, disease-specific instruments are unable to provide comparisons among patients with the plethora of clinical presentations addressed by DCs in everyday practice, including noncondition-based care (i.e., wellness care). A major challenge to performing QoL research in a chiropractic PBRN has been the dependence of a number of QoL measures that are disease dependent (i.e., Bournemouth questionnaire<sup>33</sup> and Oswestry questionnaire<sup>34</sup>). In addition, the plethora, heterogeneity, and inconsistency of use of these disease-dependent outcome measures in chiropractic care make cause and effect inferences with respect to effectiveness of care very challenging.<sup>35</sup> As was found in this PBRN study, children have a plethora of clinical presentations motivating chiropractic care.<sup>9</sup> The application of the PROMIS-25 instrument was found to be promising in chiropractic practice and research. The use of the PROMIS instrument confirmed its comparability (i.e., outcome comparisons were possible despite heterogeneity in clinical presentation and/or motivation), flexibility (i.e., PROMIS was administered online and paper and pencil), and inclusiveness (i.e., PROMIS was administered in a chiropractic PBRN). Furthermore, the PROMIS-25 questionnaire demonstrated its utility for screening of children with or without clinical presentations/motivations, facilitated benchmarking with asymptomatic populations, and provided a means to measure health promotion types care.<sup>36-38</sup> Ongoing efforts to use both generic and disease-specific QoL measures in pediatric healthcare were supported for a more comprehensive evaluation.

Similar to this study, the studies by Arvanitis et al.<sup>24</sup> and Gipson et al.<sup>25</sup> utilized the short forms for the indicated QoL domain. When comparing the mean baseline T scores of chiropractic patients with children with Crohn's disease (Table 1), the following was observed. Comparable anxiety and pain interference scores were found, whereas depressive symptoms and peer relationships are higher and fatigue mean T scores as lower in this pediatric population. Overall, the children presenting for chiropractic care have comparable if not worst QoL measures than those children with Crohn's disease. After a trial of chiropractic care, the QoL scores of the chiropractic patients were found as improving relative to baseline measures as well as compared with children with Crohn's disease. Anxiety and pain interference decreased in mean T scores, whereas peer relationships mean T score increased. When comparing the mean baseline T scores of the chiropractic children with the overall mean T scores of children with nephrotic syndrome, very similar OoL measures in all domains were observed. After a trial of chiropractic care, mean T scores in anxiety, depression, fatigue, and pain interference relatively decreased in the chiropractic population whereas peer relationships relatively increased when compared with the children with nephrotic syndrome. Crohn's disease and nephrotic syndrome are debilitating illnesses. With comparable QoL measures to this pediatric population, the need for chiropractic care of children should not be underestimated.

This study has a number of strengths including high external validity. This study utilized convenience sampling to obtain a naturalistic sample of children under chiropractic care by many different chiropractors with varying clinical experience applying a variety of chiropractic techniques. This sample presented with varying conditions and histories of treatment, reflective of the type of children who seek chiropractic care in a nonresearch setting.

As there are strengths to this study, the authors also wish to acknowledge a number of limitations. As with all surveys, there is the element of subjectivity. As such, responders' emotional states may influence the data at a specific point in time and may not objectively measure their overall healthcare experience. Interpretation of the results from surveys presents challenges since patients have different expectations to their healthcare experience, resulting in responses that may vary widely despite similar care approaches or as in this PBRN setting, different healthcare (i.e., chiropractic technique) approaches. Likewise, as a result of baseline assessment, parents may have been more aware of QoL domains and reported differently at follow-up. The extent to responder biases playing a role will surface through replication. Furthermore, despite improvements/changes in QoL as measured by mean T scores beyond statistical significance, the authors do not have the minimally important difference<sup>39</sup> for the PROMIS-25 instrument for pediatric chiropractic patients. Future research should examine this aspect in the chiropractic pediatric population. Despite the large sample size in this study, generalizability of these study findings to the general pediatric chiropractic population remains uncertain. DC participants of this study were previously or currently trained in pediatric chiropractic through the International Chiropractic Pediatric Association<sup>40</sup> and volunteered to be part of a research study. There may be fundamental differences in the way that these pediatric-trained chiropractors practice than the general chiropractic physician. Similarly, parents and children consented to be part of the study and were not a random sample of all children under chiropractic care. Thus, the generalizability limitations of a convenience sample are applicable here, despite the added strength of the sample coming from a diverse network of doctors in practice. Despite these limitations, surveys provide an important "voice to patients and provide information to improving patient care and establishing healthcare service standards."<sup>41</sup> Last, an important limitation of this repeated measures study is that there was not a control group to mitigate against internal threats to validity, such as maturation or time, or variation between baseline and follow-up measurement. The latter was handled statistically through regression-based controls; however, additional studies employing randomization are warranted to better mitigate against threats related to maturation and time effects and understand the causal role of chiropractic in the reduction of problems related to QoL indicators. This study was the first study of a program of research that shows an association between chiropractic and improved QoL. Results are promising for future studies designed to establish a more rigorous causal link.

## Conclusion

The PROMIS pediatric short forms instrument (PROMIS-25) had demonstrable utility for chiropractic practice and research within a chiropractic PBRN. With a course of chiropractic care, the QoL measures of children improved beyond statistical significance.

#### **Author Disclosure Statement**

The authors of this article received funding from the International Chiropractic Pediatric Association. Dr. Joel Alcantara received additional funding from Life West College of Chiropractic.

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