

**Demographic Characteristics Associated with Utilization of Noninvasive Treatments for Chronic Low Back Pain and Related Clinical Outcomes During the COVID-19 Pandemic in the United States**

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## **ABSTRACT**

### **Introduction**

This study was conducted to determine if limited access to health care during the COVID-19 pandemic impacted utilization of recommended non-pharmacological treatments, nonsteroidal anti-inflammatory drugs (NSAIDs), and opioids by persons with chronic low back pain and affected clinical outcomes relating to pain intensity and disability.

### **Methods**

Participants within the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation were eligible if they provided encounter data in the three months immediately before and after the national emergency proclamation date (NEPD).

### **Results**

The mean age of the 528 study participants was 53.9 yr and 74.1% were women. Utilization of exercise therapy, massage therapy, and spinal manipulation decreased during the pandemic. Increasing age was associated with decreased utilization of all non-pharmacological treatments except exercise therapy, and with increased opioid use during the pandemic. African-American participants reported decreased utilization of yoga and spinal manipulation during the pandemic. Overall, mean change scores for pain intensity and disability before and after the NEPD were not significant. However, African-American participants consistently reported worse pain intensity and disability outcomes during the pandemic. Marginally worse outcomes were observed less consistently for pain intensity with increasing age and for disability among women.

## **Discussion**

Social distancing during the pandemic impacted the uptake of recommended non-pharmacological treatments for chronic low back pain that require visiting community-based facilities or interacting closely with providers.

## **Conclusions**

The pandemic threatens to exacerbate the impact of chronic low back pain, particularly among African-American patients and the older population, by impeding access to guideline-informed noninvasive treatments.

## INTRODUCTION

A proclamation of national emergency in the United States was issued on March 13, 2020, pursuant to the declaration by the World Health Organization of the pandemic of coronavirus disease (COVID-19) caused by the novel virus known as SARS-CoV-2.<sup>1</sup> Non-essential commercial activities and discretionary health care services were subsequently “locked down” in many states following this proclamation. It is unclear how such restrictions may have impacted the management of chronic pain, particularly with regard to noninvasive treatments that form the basis for major guideline recommendations developed by the Centers for Disease Control and Prevention (CDC) and the American College of Physicians (ACP). The CDC guideline recommends that non-pharmacological and non-opioid pharmacological treatments are the preferred approaches for patients with chronic pain prior to considering opioids and, that if opioids are used, the former treatments be with combined with opioids when appropriate.<sup>2</sup> The ACP guideline, which is specific to low back pain, recommends that exercise therapy, yoga, spinal manipulation, acupuncture, or cognitive behavioral therapy be selected as initial treatments for patients with chronic low back pain.<sup>3</sup>

Non-pharmacological treatments for low back pain may be difficult to access during a pandemic when health care facilities are closed or their services limited by social distancing recommendations and related mandates. Under such circumstances, chronic pain management may not be in accord with best practices. The Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) routinely collects data on both non-pharmacological and pharmacological treatments for chronic low back pain, as well as on pain and functioning outcomes. Thus, these aspects of the registry facilitate research to determine the demographic characteristics associated with utilization of such noninvasive treatments as exercise therapy, yoga, massage therapy, spinal manipulation, acupuncture, cognitive behavioral therapy, nonsteroidal anti-inflammatory drugs

(NSAIDs), and opioids for chronic low back pain and affected clinical outcomes relating to pain intensity and disability of participants during the COVID-19 pandemic in the United States.

## **METHODS**

The PRECISION Pain Research Registry was established at the University of North Texas Health Science Center in 2016. The registry initially focused on building local research infrastructure relating to low back pain using in-person data collection methods through 2018.<sup>4</sup> However, in response to an identified need for national registries in the Federal Pain Research Strategy,<sup>5</sup> the PRECISION Pain Research Registry implemented a digital research platform that eventually enabled it to extend its geographical reach to conduct research specifically on chronic low back pain in the 48 contiguous states and District of Columbia in 2020. Upon enrolling in the registry, all participants provide responses to a series of validated research instruments, including the Minimum Dataset recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain,<sup>6</sup> Roland-Morris Disability Questionnaire (RMDQ),<sup>7</sup> Patient-Reported Outcomes Measurement Information System with 29 items (PROMIS-29),<sup>8</sup> Pain Catastrophizing Scale,<sup>9</sup> and Pain Self-Efficacy Questionnaire.<sup>10</sup> Participants also provide data on their history of common comorbid medical conditions and on current utilization of non-pharmacological and pharmacological treatments for chronic low back pain.

Participants with chronic low back pain enrolled in the PRECISION Pain Research Registry were included in this study if they provided quarterly encounter data relating to pain management and clinical outcomes during the intervals of three months immediately before (pre-COVID-19) and after (during COVID-19) the national emergency proclamation relating to the pandemic that was issued on March 13, 2020. Each participant was scheduled to provide ongoing registry data collection at intervals of 3 months  $\pm$  2 weeks. Thus, the time difference between pre-COVID-19 and during-COVID-19 responses for

each participant was in the range of 10 to 14 weeks. The diagnosis of chronic low back pain was based on the case definition established by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain, which requires that participants report having low back pain for at least the past 3 to 6 months and with a daily frequency of at least one-half of the days in the past 6 months.<sup>6</sup> The current utilization of exercise therapy (at a facility outside the home), yoga, massage therapy, spinal manipulation, acupuncture, and cognitive behavioral therapy was measured before and after the national emergency proclamation date, as was the current use of NSAIDs and opioids for low back pain. Similarly, a numerical rating scale (NRS) for low back pain intensity and the RMDQ for back-related disability were both administered before and after the national emergency proclamation date. Other clinical outcome measures were not analyzed in this study because they were not routinely collected at all quarterly registry encounters. This study was approved by the North Texas Institutional Review Board and all participants provided written informed consent.

Descriptive statistics were used to summarize participant characteristics using the mean  $\pm$  SD for continuous variables and the number and percentage for categorical variables. The change in utilization of each non-pharmacological and pharmacological treatment before and after the national emergency proclamation date was analyzed using McNemar's test. The latter compared the frequency of discordant utilization patterns pre-COVID-19 and during COVID-19 for each participant (i.e., utilization of a given treatment pre-COVID-19 vs. no utilization of the treatment during COVID-19, or vice-versa). Multiple logistic regression was used to identify demographic factors associated with utilization of each non-pharmacological and pharmacological treatment during the pandemic. The mean change scores for paired measures of the NRS for low back pain intensity and RMDQ for back-related disability for each participant before and after the national emergency proclamation date were analyzed using t-tests. Linear regression was further used to measure the associations among age, sex, race, and ethnicity and

low back pain intensity and back-related disability during the pandemic. A series of regression models were used, including a simple linear regression model with each demographic characteristic as a predictor (model 1), a partially-adjusted model that controlled for each demographic characteristic (model 2), and a fully-adjusted model that adjusted for each demographic characteristic and utilization of each non-pharmacological treatment, NSAIDs, and opioids (model 3). The logistic and linear regression models excluded participants within the racial categories other than African-American or White to avoid unstable estimates for these other categories because of small cell counts; however, there were sufficient numbers of Hispanic participants to include ethnicity in these models. Data management and statistical analyses were primarily performed with the IBM SPSS Statistics software package (Version 25). Two-sided tests and significance thresholds of  $P \leq 0.05$  were used for all statistical analyses.

## RESULTS

A total of 528 registry participants with chronic low back pain, including 469 (88.8%) from Texas, provided paired data pre-COVID-19 and during COVID-19. The mean age of participants pre-COVID-19 was  $53.9 \text{ yr} \pm 13.0 \text{ yr}$  and 391 (74.1%) participants were women (**Table 1**). In the pre-COVID-19 period, about one-half of participants currently reported depression and almost one-fourth reported widespread pain. The pre-COVID-19 mean scores on the NRS for low back pain intensity and RMDQ for back-related disability were  $5.8 \pm 2.2$  and  $13.7 \pm 6.7$ , respectively. Upon enrolling in the registry, participants also reported poor quality-of-life on all PROMIS-29 scales, including substantial deficits ( $>1$  SD worse than the mean of the United States general population) in scores for physical function ( $38.2 \pm 6.8$ ) and pain interference with activities ( $62.8 \pm 7.4$ ).

The utilization of exercise therapy (OR, 0.42; 95% CI, 0.27-0.65), massage therapy (OR, 0.42; 95% CI, 0.25-0.71), and spinal manipulation (OR, 0.30; 95% CI, 0.15-0.57) for chronic low back pain each decreased during the pandemic (**Table 2**). However, there was no significant change in the utilization of NSAIDs or opioids for low back pain during the pandemic. After controlling for sex, race, and ethnicity, increasing age was associated with decreased utilization of all non-pharmacological treatments except exercise therapy during the pandemic (**Table 3**). However, increasing age was associated with increased use of opioids during the pandemic (multivariate OR, 1.23; 95% CI, 1.05-1.44). African-American participants reported decreased utilization of yoga (multivariate OR, 0.40; 95% CI, 0.16-0.97) and spinal manipulation (multivariate OR, 0.37; 95% CI, 0.16-0.85) during the pandemic. Sex and ethnicity were not associated with utilization of any non-pharmacological or pharmacological treatment during the pandemic.

The mean change scores from before to after the national emergency proclamation date were -0.08 (95% CI, -0.21 to 0.06) on the NRS for low back pain intensity and -0.01 (95% CI, -0.29 to 0.27) on the RMDQ for back-related disability. Although significant overall changes in low back pain intensity and back-related disability were not observed during the pandemic, African-American participants consistently reported worse pain and functioning outcomes in each linear regression model (**Table 4**). Marginally worse outcomes were observed less consistently for low back pain intensity with increasing age and for back-related disability among women.

## **DISCUSSION**

The use of the PRECISION Pain Research Registry facilitated this short-term assessment of the impact of the COVID-19 pandemic on the management of chronic low back pain because it routinely collects data from participants at quarterly encounters using digital technology that does not require in-person visits.

Thus, the registry was able to efficiently acquire data on the processes and outcomes of chronic low back pain management that may not have been possible using conventional clinical research methods during a pandemic. The study findings indicate that utilization of first-line non-pharmacological treatments recommended for chronic low back pain (i.e., exercise therapy and spinal manipulation) in the ACP guideline decreased during the first 3 months of the pandemic. Use of massage therapy, which is consistent with the CDC guideline recommendation for use of first-line non-pharmacological treatments for chronic pain, also decreased during the pandemic. Overall, there was no evidence of increased use of NSAIDs or opioids during the pandemic to compensate for decreased utilization of non-pharmacological treatments. However, it is important to note that older participants more often reported using opioids during the pandemic and there was also a trend toward more frequent opioid use among African-American participants.

The findings indicate that social distancing during the early stages of the COVID-19 pandemic significantly impacted the uptake of recommended non-pharmacological treatments for chronic low back pain that require visiting community-based facilities or interacting closely with providers. A variety of remotely supported services for chronic pain management during the pandemic are now being considered for rapid deployment.<sup>11</sup> These include such modalities as telemedicine, electronic health information, mobile health applications, and virtual and augmented reality technology. The degree to which remote interventions may be adopted to help manage chronic low back pain during the ongoing pandemic remains unclear. However, in a recent randomized controlled trial, Internet-delivered cognitive behavioral therapy has shown moderate to large treatment effects for pain intensity over a period of 3 months.<sup>12</sup> The application of technology and smartphone apps for chronic pain management also shows promise in reducing the use of opioids.<sup>13</sup> Examples of such interventions include electronic pain diary smartphone apps, Internet-based patient educational tools emphasizing self-management,

Internet-delivered cognitive behavioral therapy, and combined treatment regimens using technology to provide education, support, documentation, and feedback. Remote technology may also potentially be used to facilitate utilization of such non-pharmacological treatments as exercise therapy and yoga in a home environment. However, patients previously treated with massage therapy, spinal manipulation, or acupuncture may experience difficulty in continuing to access these services during the pandemic and may be candidates for remote delivery of other non-pharmacological treatments for chronic low back pain.

Despite the significant decrease in utilization of several non-pharmacological treatments for chronic low back pain observed during COVID-19, an overall impact on low back pain intensity or back-related disability outcomes was not observed during the short-term follow-up. However, increasing age and being African-American were both important demographic factors that predicted lower utilization of various non-pharmacological treatments. African-American participants also consistently reported worse pain and functioning outcomes during the pandemic. These racial disparities remained after adjusting for other demographic characteristics and use of each of the non-pharmacological and pharmacological treatments studied herein. Beyond age and race, high levels of depression and widespread pain and substantial quality-of-life deficits in physical function and pain interference with activities suggest that many study participants may be at high risk of poor outcomes if the pandemic further limits long-term access to appropriate medical care for chronic low back pain that is in alignment with current clinical practice guidelines.<sup>2,3</sup>

In light of the study findings, cultural adaptations for chronic pain management in African-American patients may be beneficial. Use of African-American facilitators, salient cultural values, self-empowerment, story-telling, culturally-relevant terminology and resources, and community-sanctioned locations have been recommended by focus group participants.<sup>14</sup> Literacy and cultural adaptations for

cognitive behavioral therapy in a chronic pain population in the Black Belt of Alabama have been developed.<sup>15</sup> These include adapting a patient workbook to reduce cognitive demand by eliminating distractors, using repetition, limiting the amount of information, using teach back methods to confirm understanding, and teaching to goal to assure learning mastery. In a subsequent randomized controlled trial involving cognitive behavioral therapy for chronic pain in a predominantly African-American population in western Alabama, patient workbooks were supplemented with CDs that provided instructions for skills practice and a relaxation exercise.<sup>16</sup> The cognitive behavioral therapy group reported improved pain, physical function, and depression outcomes over 6 months compared with usual care. It is possible that such literacy- and culturally-adapted workbooks and CDs for cognitive behavioral therapy may be targeted for African-American patients during the pandemic.

Although there were advantages in using the PRECISION Pain Research Registry to conduct this study, there were also several limitations that should be noted. First, at present, only short-term data over 3 months were available on the use of noninvasive treatments for chronic low back pain and related clinical outcomes during the pandemic. The utilization of such treatments and clinical outcomes may change over time as the pandemic continues. Our registry is well positioned to regularly measure longitudinal changes in pain intensity and disability at quarterly intervals and to also measure changes in health-related quality of life at longer intervals during the pandemic. Second, it was not feasible to analyze other clinical outcomes (e.g., quality-of-life measures) or potential mediating factors (e.g., pain catastrophizing and pain self-efficacy) immediately before and after the national emergency proclamation date because data on such variables are not collected at all consecutive registry encounters. Third, it was not possible to determine if non-pharmacological treatments reportedly used during COVID-19 were acquired via telemedicine or other remotely supported technologies. Finally, the study findings primarily reflected statewide trends in Texas regarding the utilization of noninvasive

treatments for chronic low back pain before and after the national emergency proclamation date. However, study participants may have resided in municipalities with differing mandates on social distancing and varying dates of implementation within Texas or in other states (each potentially occurring before or after the national emergency proclamation date) in response to local rates of SARS-CoV-2 infection, hospitalization, or mortality. It was not feasible to conduct subgroup analyses to identify geographical differences in utilization of noninvasive treatments for chronic low back pain during the pandemic.

Almost a decade ago, the Institute of Medicine report on Relieving Pain in America indicated that chronic pain is a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment.<sup>17</sup> Coordinated approaches to reduce the burden of pain in the United States involved both the National Pain Strategy<sup>18</sup> and the Federal Pain Research Strategy.<sup>5</sup> The CDC and ACP guidelines cited herein further emphasized the paramount role of first-line non-pharmacological treatments and the secondary role of pharmacological treatments for chronic low back pain. Nevertheless, about 50 million adults in the United States continue to suffer from chronic pain, including 20 million with pain that often interferes with work or life.<sup>19</sup> The COVID-19 pandemic now threatens to further exacerbate the impact of chronic low back pain, particularly in African-American patients and the older population, by impeding access to guideline-informed noninvasive treatments.



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**Table 1. Participant characteristics during the pre-COVID-19 pandemic period (N=528).\***

<b>Characteristic</b>	<b>%</b>
<b>Sociodemographic</b>	
Age, yr (mean ± SD)	53.9 ± 13.0
Sex (female)	74.1
Race (non-White)	25.0
Ethnicity (Hispanic)	11.7
Education (college degree or higher)	38.4
Ever had work loss ≥ 1 mo due to LBP	42.6
Ever received disability or workers' compensation benefits due to LBP	23.1
Ever involved in a legal claim for LBP	11.6
<b>Comorbidity history</b>	
Herniated disc	34.7
Sciatica	40.9
Osteoarthritis	39.0
Hypertension	40.5
Diabetes mellitus	19.3
Asthma	27.5
Depression	49.8
<b>Clinical</b>	
Current smoker	14.2
Current widespread pain	24.2
Ever had LBP surgery	18.8
Body mass index, kg/m <sup>2</sup> (mean ± SD)	32.5 ± 8.2
Pain catastrophizing (PCS) (mean ± SD)†	19.0 ± 13.8
Pain self-efficacy (PSEQ) (mean ± SD)†	34.5 ± 15.0
LBP intensity, NRS (mean ± SD)	5.8 ± 2.2
Back-related disability, RMDQ (mean ± SD)	13.7 ± 6.7
<b>Quality of life (PROMIS-29)†‡</b>	
Physical function (mean ± SD)	38.2 ± 6.8
Anxiety (mean ± SD)	54.1 ± 10.5
Depression (mean ± SD)	52.3 ± 9.6
Low energy/fatigue (mean ± SD)	57.9 ± 10.4
Sleep disturbance (mean ± SD)	56.5 ± 8.5
Participation in social roles and activities (mean ± SD)	44.0 ± 8.8
Pain interference with activities (mean ± SD)	62.8 ± 7.4

\*Table entries are percentages unless otherwise indicated. LBP denotes low back pain; NRS, numerical rating scale; PCS, Pain Catastrophizing Scale; PROMIS-29, Patient-Reported Outcomes Measurement Information System with 29 items; PSEQ, Pain Self-Efficacy Questionnaire; RMDQ, Roland-Morris Disability Questionnaire.

†Data were collected at the time of registry enrollment.

‡Scale scores are normed to the United States general population, with mean  $\pm$  SD = 50  $\pm$  10. Higher scores represent worse quality of life on all scales except physical function and participation in social roles and activities.

**Table 2. Utilization of noninvasive treatments for chronic low back pain before and during the COVID-19 pandemic (N=528).\***

<b>Treatment</b>	<b>Pre- COVID-19 Pandemic (%)</b>	<b>During COVID-19 Pandemic (%)</b>	<b>OR (95% CI)</b>	<b>P</b>
<b>Non-pharmacological</b>				
Exercise therapy	18.0	9.8	0.42 (0.27-0.65)	<.001
Yoga	9.7	10.2	1.13 (0.63-2.04)	0.78
Massage therapy	16.3	10.6	0.42 (0.25-0.71)	<.001
Spinal manipulation	18.0	12.3	0.30 (0.15-0.57)	<.001
Acupuncture	2.3	1.9	0.78 (0.25-2.35)	0.80
Cognitive behavioral therapy	5.7	3.6	0.52 (0.24-1.09)	0.09
<b>Pharmacological</b>				
Nonsteroidal anti-inflammatory drugs	61.2	58.0	0.70 (0.46-1.07)	0.10
Opioids	29.9	30.1	1.03 (0.60-1.79)	0.99

\*The utilization of each treatment during the COVID-19 pandemic relative to the pre-COVID-19 pandemic period was measured by the OR, based on McNemar's test.



**Table 4. Demographic predictors of low back pain intensity and back-related disability during the COVID-19 pandemic (N=513)\***

Characteristic	Low Back Pain Intensity (Numerical Rating Scale Score)				Back-Related Disability (Roland-Morris Disability Score)			
	$\beta$	SE	t	P	$\beta$	SE	t	P
<b>Model 1 (unadjusted)</b>								
Age (increasing decades)	0.148	0.416	1.98	0.049	0.201	0.231	0.87	0.39
Sex (women)	-0.322	0.222	-1.45	0.15	0.986	0.686	1.44	0.15
Race (African-American)	1.619	0.220	7.37	<0.001	4.135	0.690	5.99	<0.001
Ethnicity (Hispanic)	0.043	0.304	0.14	0.89	-1.065	0.938	-1.14	0.26
<b>Model 2 (partially adjusted)</b>								
Characteristic	$\beta$	SE	t	P	$\beta$	SE	t	P
Age (increasing decades)	0.161	0.072	2.24	0.03	0.209	0.226	0.92	0.36
Sex (women)	-0.127	0.212	-0.60	0.55	1.440	0.668	2.16	0.03
Race (African-American)	1.636	0.222	7.38	<0.001	4.278	0.697	6.14	<0.001
Ethnicity (Hispanic)	0.350	0.293	1.20	0.23	-0.246	0.923	-0.27	0.79
<b>Model 3 (fully adjusted)</b>								
Characteristic	$\beta$	SE	t	P	$\beta$	SE	t	P
Age (increasing decades)	0.124	0.072	1.73	0.08	0.007	0.217	0.03	0.98
Sex (women)	-0.130	0.205	-0.63	0.53	1.427	0.621	2.30	0.02
Race (African-American)	1.543	0.217	7.12	<0.001	3.665	0.656	5.59	<0.001
Ethnicity (Hispanic)	0.312	0.285	1.09	0.27	-0.415	0.861	-0.48	0.63

\*Table entries are for the demographic characteristics in the parentheses. Positive  $\beta$  coefficients represent greater low back pain intensity or back-related disability. Predictors were analyzed using linear regression. Model 1 involved simple linear regression. Model 2 controlled for each of the other demographic characteristics in the table. Model 3 controlled for each of the other demographic characteristics and current utilization of exercise therapy, yoga, massage therapy, spinal manipulation, acupuncture, cognitive behavioral therapy, nonsteroidal anti-inflammatory drugs, and opioids. Fifteen participants in other racial categories were excluded from the analyses to avoid unstable estimates for these categories because of small cell counts.