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Optimizing chronic pain management through patient engagement with quality of life measures: a randomized controlled trial

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Abstract

Context: Health-related quality of life (HRQOL) represents a new approach for guiding chronic pain management because it is patient-centered and more likely to be understood and accepted by patients.

Objectives: To assess the value and utility of an eHealth intervention for patients with chronic low back pain (CLBP) that was primarily based on HRQOL measures and to measure the clinical outcomes associated with its use.

Methods: A randomized controlled trial was conducted within the Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry) using participants screened from November 2019 through February 2021. A total of 331 registry participants within the 48 contiguous states and the District of Columbia met the eligibility criteria, which included having CLBP and HRQOL deficits. Almost three-fourths of the participants were enrolled after onset of the COVID-19 pandemic. The participants were randomized to an eHealth intervention for HRQOL or wait list control. The primary outcome measures involved HRQOL based on the Patient-Reported Outcomes Measurement Information System (PROMIS), including the SPADE cluster (Sleep disturbance, Pain interference with activities, Anxiety, Depression, and low Energy/fatigue) and each of its five component scales. Secondary outcome measures involved low back pain intensity and back-related functioning. Changes over time for each outcome measure reported by participants in each treatment group were compared utilizing the student's *t*-test for statistical significance and Cohen's *d* statistic for clinical importance. Outcomes were reported as between-group differences in change scores and the *d* statistic, with positive values favoring the experimental treatment group.

Results: There were no significant differences between the experimental and control treatment groups for changes over time in any primary outcome measure. The *d* statistic (95% confidence interval) for the difference between the experimental and control treatment groups on the SPADE cluster was 0.04 (−0.18–0.25). The corresponding *d* statistics for the SPADE scales ranged from −0.06 (−0.27 to 0.16) for anxiety to 0.11 (−0.10 to 0.33) for sleep disturbance. There were also no significant or clinically important differences between the experimental and control treatment groups on the secondary outcome measures. Additionally, in subgroup analyses involving participants treated by osteopathic vs allopathic physicians, no significant interaction effects were observed.

Conclusions: The eHealth intervention studied herein did not achieve statistically significant or clinically important improvements in any of the primary or secondary outcome measures. However, the validity and generalizability of the findings may have been limited by the unforeseen onset and impact of the COVID-19 pandemic shortly after beginning the trial.

Keywords: chronic low back pain; quality of life; randomized controlled trial.

Chronic noncancer pain is an important healthcare issue that transcends the simplistic view that it serves only as a manifestation of more serious medical problems in a

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given patient. Chronic pain management in the United States has been hampered by an overreliance on pain intensity measures and corresponding treatment with pharmacological agents, including opioids [1]. Focusing on health-related quality of life (HRQOL) rather than on pain intensity represents a new approach for guiding chronic pain management because it is patient-centered and consistent with the cultural transformation advocated by the National Pain Strategy [2]. This patient-centeredness also aligns with osteopathic philosophy and its approach to chronic pain management [3]. Patient-reported HRQOL measures have been historically undervalued as medical decision-making tools [4]. However, the Patient-Reported Outcomes Measurement Information System (PROMIS) that was developed with support from the National Institutes of Health (NIH) now includes data elements that are recommended as part of a "minimum dataset" for research on chronic low back pain (CLBP) [5]. The latter include the PROMIS scales for pain interference with activities, physical function, depression, and sleep disturbance. Other commonly utilized PROMIS scales measure anxiety, energy/fatigue level, and participation in social roles.

The main objective of this study was to assess the value and utility of an eHealth intervention for patients with CLBP that was based on PROMIS measures of HRQOL and to assess the clinical outcomes associated with its use. Another objective was to conduct subgroup analyses according to the type of physician (i.e., osteopathic vs allopathic physician) who treated low back pain and to identify and further explore any significant interaction effects.

Methods

Research design

The Optimizing Chronic Pain Management through Patient Engagement with Quality of Life Measures (OPTIQUAL) Trial was conducted by the Osteopathic Research Center utilizing its Pain Registry for Epidemiological, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry). The registry utilizes a digital research platform to collect longitudinal self-reported data from participants with CLBP throughout the 48 contiguous states and the District of Columbia [6]. Methodological features of the registry, which include online screening for eligibility, remote participant consenting, and electronic data capture, represent a new clinical trial paradigm that facilitates the enrollment of large numbers of participants to study real-world effectiveness at a reasonable cost. The protocol for the OPTIQUAL Trial was approved by the North Texas Regional Institutional Review Board (protocol 2015–169) and posted at ClinicalTrials.gov (registry number NCT04168437) [7]. Informed consent was provided by all participants prior to enrolling in the trial, and a Data and Safety Monitoring Board was established to monitor it.

Inclusion and exclusion criteria

Registry participants were screened during the period from November 2019 through February 2021 to identify those who met the following general inclusion criteria: (1) being aged between 21 and 79 years at the time of registry enrollment; (2) having sufficient English language proficiency to complete informed consent and case report forms; and (3) having a physician who treated their low back pain. Registry participants who met all three of the aforementioned criteria were further screened to determine if they met the clinical inclusion criteria. First, they were required to report CLBP based on the case definition recommended by the NIH Task Force on Research Standards for Chronic Low Back Pain, which requires that patients have low back pain for at least the past 3–6 months and with a pain frequency of at least half of the days during the past 6 months [5]. Second, they must also have reported a SPADE (Sleep disturbance, Pain interference with activities, Anxiety, Depression, and low Energy/fatigue) cluster score ≥55 for HRQOL deficits on the PROMIS-29 instrument. Persons who report being pregnant or institutionalized are not enrolled in the PRECISION Pain Research Registry and thus were not eligible for the trial.

Experimental and control treatment arms

A random number generator within the Microsoft Excel software was utilized to allocate participants to treatment. Participants randomized to the experimental treatment group received an eHealth intervention consisting of a two-page HRQOL report and interpretation guide. The report was based exclusively on PROMIS-29 responses for the SPADE cluster and each of its five component scales. The first page included a graphic summary of scores on each of these measures, while the second page provided an interpretation guide that was suitable for both patients and physicians (Appendix 1). The participants were encouraged to utilize the report to identify aspects of their health that needed improvement and then take appropriate action. The latter may have involved such strategies as undertaking self-care or sharing the report with a physician to learn about other approaches or treatments to improve their HRQOL. There was no additional patient education or counseling provided as part of the intervention. The control treatment group was placed on a wait list to receive the eHealth intervention after completing the trial. This occurred 3 months later after reporting clinical outcomes at their exit encounter, and the report was based on HRQOL data provided at that time. Both the experimental and control treatment groups continued to receive their usual care for low back pain during the trial.

Baseline and follow-up measures

Trial baseline data were collected at the index encounter, which may have been at the time of registry enrollment or at any of the three subsequent quarterly encounters that occurred 3, 6, or 9 months following enrollment. Trial exit data were collected at the next quarterly encounter following the index encounter. Thus, participants were followed for only 3 months, regardless of whether they entered the study at the time of registry enrollment or at any quarterly encounter through the ninth month. The study case report forms collected data on basic sociodemographic and clinical variables utilized to describe the trial participants. They also measured the primary and secondary outcome variables. The participants also provided

information on the type of physician (i.e., osteopathic or allopathic physician) who currently treated their low back pain at the index encounter to enable subgroup analyses relating to osteopathic medical care. The participants who were assigned to the experimental treatment group received the eHealth intervention no later than 1 week following the index encounter. They also completed a survey on the value and utility of the eHealth intervention at the end of the trial, 3 months following the index encounter.

Assessment of the eHealth intervention

The eHealth intervention was assessed utilizing a survey that queried participants in the experimental treatment group about the value and utility of their HRQOL report. The value of the report was measured utilizing a visual analogue scale ranging from 0 to 100. The utility of the report was based on such factors as participant actions in response to the report, sharing the report with their physician or others, actions recommended by the physician, and the SPADE scales targeted for improvement based on the report.

Primary outcome measures

Both the primary and secondary outcome measures utilized in the trial were recommended by the NIH Task Force on Research Standards for Chronic Low Back Pain [5]. The primary outcomes involving HRQOL were derived from the SPADE cluster of the PROMIS-29 instrument [8]. The latter includes items derived from the PROMIS pain behavior item bank that measures how low back pain interferes with normal activities, including physical and social functioning, and assesses levels of anxiety, depression, fatigue, and sleep disturbance [9]. Each of the five SPADE scales includes four items, which are rated on an ordinal scale from 1 to 5. Thus, crude scale scores may range from 4 to 20. These scores are then transformed and normed according to the US general population, utilizing "*t* scores" such that the population mean is 50 and the standard deviation is 10. The SPADE cluster score is the mean of its five component scale scores. Higher scores on each of the five SPADE scales, and on the SPADE cluster, represent greater HRQOL deficits (i.e., poorer HRQOL). Prior research on the PROMIS scales indicated that a minimally important change over time ranged from about 3.3 to 6.7; however, this was based on cancer patients and may not be generalizable to other populations [10].

Secondary outcome measures

The two secondary outcome measures involved low back pain intensity and back-related functioning. A numerical rating scale (NRS) was utilized to measure low back pain intensity on average over the past 7 days, utilizing an 11-point scale ranging from 0 ("no pain") to 10 ("worst pain"). The Roland-Morris Disability Questionnaire (RMDQ) was utilized to measure back-related functioning. It consists of 24 items that address how much low back pain adversely affects patient functioning and activities [11]. Each item is scored as either 1 (low back pain has an adverse impact) or 0 (low back pain does not have an adverse impact). The RMDQ is scored as the sum of responses to each item, thereby potentially ranging from 0 to 24. The NRS for pain intensity and the RMDQ are the two patient-reported outcome measures most commonly utilized for low back pain, and research standards for their use and interpretation have been established [5, 12–14].

Statistical analysis

The baseline characteristics of the experimental and control treatment groups were compared utilizing contingency table methods and the Student's *t*-test for categorical and continuous variables, respectively. Survey responses within the experimental treatment group regarding the eHealth intervention were summarized utilizing descriptive statistics. Subgroup differences between participants treated by osteopathic and allopathic physicians were also compared utilizing contingency table methods and the Student's *t*-test for categorical and continuous variables, respectively. Specifically, the student's *t*-test was utilized to compare trial outcomes (i.e., change scores for improvement in the clinical outcome measures over 3 months) in the experimental and control treatment groups. Between-group differences in change scores were utilized to report outcomes, with positive values favoring the experimental treatment group. Cohen's *d* statistic was utilized to further assess the magnitude of the treatment effects attributable to the eHealth intervention. Any d value ≥ 0.20 was considered to reflect a clinically important outcome attributable to the eHealth intervention [15]. All analyses were conducted with the IBM SPSS Statistical Software (Version 28). Hypotheses were assessed at the level of $p \leq 0.05$ utilizing two-sided significance tests. An anticipated total sample size of 320 participants was estimated to provide 99% statistical power to detect significant differences between the experimental and control treatment groups that achieved at least a "medium" treatment effect size ($d \geq 0.5$) for each outcome measure, and to provide 80% statistical power to detect significant differences between the experimental and control treatment groups that were considered to be in the range of a "small-to-medium" treatment effect size ($d \geq 0.32$).

Results

A total of 331 participants were randomized, including 166 in the experimental treatment group and 165 in the control treatment group (Figure 1). The participants in each group were generally comparable (Table 1). Only marginally significant differences between groups were observed for the presence of chronic widespread pain and diabetes mellitus.

The survey for the value and utility of the eHealth intervention was completed by 158 (95.2%) participants randomized to the experimental treatment group. The mean overall value of the report was 63.7 (SD=26.7) (Table 2). A total of 36 (22.8%) participants shared the report with the physician who treated their low back pain. Most participants agreed that the report was easy to understand after reading the interpretation guide (83.5%) and that it provided HRQOL information that they did not know (57.0%). Pain interference with activities was identified as having the most harmful impact on HRQOL, whereas anxiety had the least harmful impact. The latter findings were highly consistent with the participant actions undertaken in response to the report, either individually

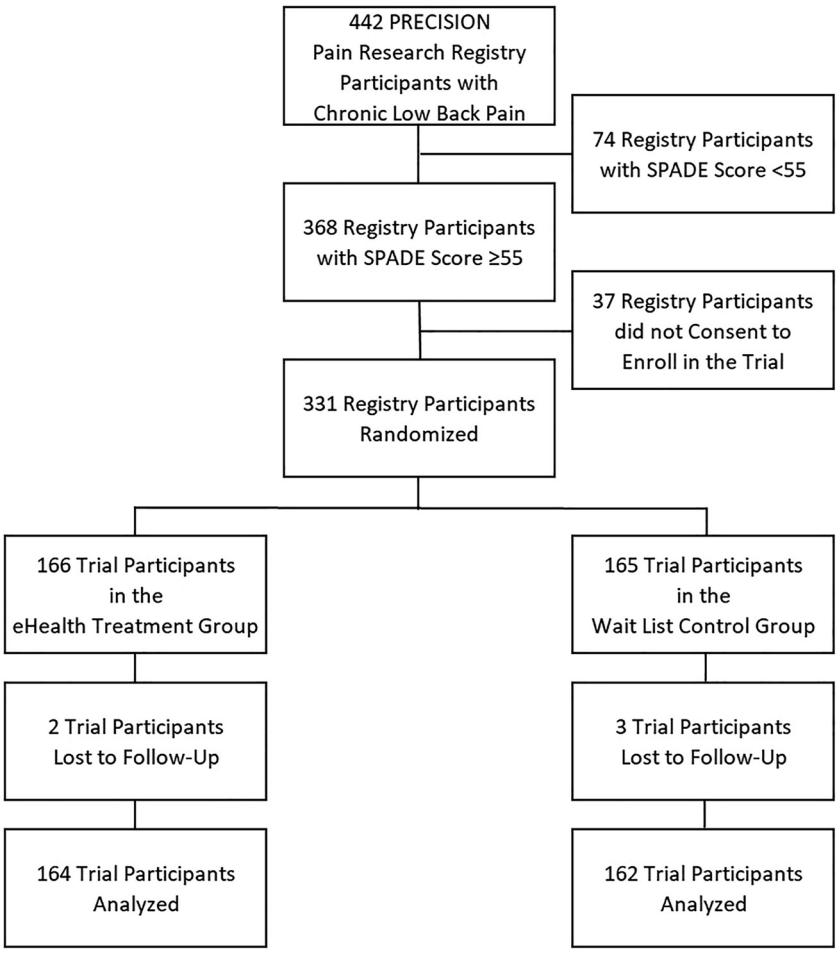

Figure 1: The flow of participants through the trial. SPADE denotes that the cluster score was derived from the Sleep disturbance, Pain interference with activities, Anxiety, Depression, and low Energy/fatigue scales of the Patient-Reported Outcomes Measurement Information System.

through self-care or in consultation with their physician. There were no significant differences in the survey responses between the participants treated by osteopathic or allopathic physicians.

The primary outcome measures for HRQOL reported on the prerandomization and exit case report forms were available for 326 (98.5%) trial completers, including 164 (98.8%) completers in the experimental treatment group and 162 (98.2%) completers in the control treatment group. There were no significant differences between the experimental and control treatment groups on any primary outcome measure (Table 3). Moreover, the *d* statistic for the difference between experimental and control treatment groups on the SPADE cluster was 0.04 (−0.18 to 0.25). The corresponding *d* statistics for the SPADE scales ranged from −0.06 (−0.27 to 0.16) for anxiety to 0.11 (−0.10 to 0.33) for sleep disturbance. Similarly, there were no significant or clinically important differences between the experimental and control treatment groups on the secondary outcome measures. Moreover, in subgroup analyses involving participants treated by osteopathic vs allopathic physicians, no significant interaction effects were observed. There were no serious adverse events reported during the trial. An intention-to-treat analysis was not performed because there were virtually no missing encounter data.

Discussion

The eHealth intervention studied herein did not provide statistically significant or clinically important improvements in any of the primary outcome measures involving HRQOL or secondary outcome measures relating to low back pain intensity or back-related functioning. These findings are similar to those of a previous trial involving 300 participants that included many design features similar to the present study but that provided the HRQOL report to the physician prior to a patient encounter rather than to the patient directly [16]. However, the present findings are partially discrepant with those of the preliminary feasibility trial of the same eHealth intervention involving 102 participants over a 3 month period [17].

Table 1: Participant characteristics according to treatment group.[a]

Characteristic	Experimental treatment (n=166)		Control treatment (n=165)		p-Value
	No.	%	No.	%	
Age, y (mean ± SD; range)	51.9 ± 13.3 21–79		50.2 ± 13.5 21–77		0.26
Sex					0.46
Female	122	73.5	127	77.0	
Male	44	26.5	38	23.0	
Race					0.36
Black	16	9.6	20	12.1	
Other	7	4.2	3	1.8	
White	143	86.1	142	86.1	
Ethnicity					0.47
Hispanic	8	4.8	11	6.7	
Non-Hispanic	158	95.2	154	93.3	
Educational level					0.06
High school or lower	29	17.5	22	13.3	
Some post-high school education	67	40.4	88	53.3	
College degree or higher	70	42.2	55	33.3	
Cigarette smoking status					0.31
Never or former smoker	139	83.7	131	79.4	
Current smoker	27	16.3	34	20.6	
Body mass index (mean ± SD)	32.0 ± 8.2		32.7 ± 8.3		0.42
Duration of low back pain					0.69
≤5 years	43	25.9	46	27.9	
>5 years	123	74.1	119	72.1	
History of low back surgery					0.81
No	130	78.3	131	79.4	
Yes	36	21.7	34	20.6	
Presence of chronic widespread pain					0.03
No	53	31.9	35	21.2	
Yes	113	68.1	130	78.8	
Work loss ≥1 month due to low back pain					0.62
No	88	53.0	83	50.3	
Yes	78	47.0	82	49.7	
Received disability or workers' compensation benefits due to low back pain					0.12
No	132	79.5	119	72.1	
Yes	34	20.5	46	27.9	
Involved in a legal action due to low back pain					0.30
No	149	89.8	142	86.1	
Yes	17	10.2	23	13.9	
Pain catastrophizing (mean ± SD)	22.2 ± 13.2		23.1 ± 12.3		0.51
Pain self-efficacy (mean ± SD)	30.8 ± 13.4		29.1 ± 13.9		0.27
History of medical conditions					
Herniated disc					0.69
No	91	54.8	94	57.0	
Yes	75	45.2	71	43.0	
Sciatica					0.97
No	63	38.0	63	38.2	
Yes	103	62.0	102	61.8	
Osteoarthritis					0.77
No	72	43.4	69	41.8	
Yes	94	56.6	96	58.2	
Osteoporosis					0.54
No	140	84.3	135	81.8	
Yes	26	15.7	30	18.2	

Table 1: (continued)

Characteristic	Experimental treatment (n=166)		Control treatment (n=165)		p-Value
	No.	%	No.	%	
Hypertension					0.35
No	86	51.8	94	57.0	
Yes	80	48.2	71	43.0	
Heart disease					0.71
No	150	90.4	151	91.5	
Yes	16	9.6	14	8.5	
Diabetes mellitus					0.02
No	142	85.5	125	75.8	
Yes	24	14.5	40	24.2	
Asthma					0.26
No	123	74.1	113	68.5	
Yes	43	25.9	52	31.5	
Depression					0.052
No	53	31.9	37	22.4	
Yes	113	68.1	128	77.6	
Type of physician					0.90
Osteopathic	26	15.7	25	15.2	
Allopathic	140	84.3	140	84.8	
Current use of opioids for low back pain					0.97
No	111	66.9	110	66.7	
Yes	55	33.1	55	33.3	
Health-related quality of life					
SPADE cluster (mean ± SD)	61.2 ± 5.5		61.1 ± 5.4		0.87
Sleep disturbance (mean ± SD)	60.3 ± 7.2		60.2 ± 7.6		0.95
Pain interference with activities (mean ± SD)	65.5 ± 6.1		64.8 ± 6.2		0.32
Anxiety (mean ± SD)	59.5 ± 8.4		59.6 ± 7.9		0.91
Depression (mean ± SD)	57.9 ± 8.2		58.3 ± 7.7		0.66
Low energy/fatigue (mean ± SD)	63.1 ± 8.4		62.8 ± 8.5		0.76
Low back pain intensity (mean ± SD)	6.3 ± 1.7		6.1 ± 1.8		0.28
Back-related functioning (mean ± SD)	16.0 ± 5.3		15.8 ± 5.0		0.70

[a]Table entries are No., and % unless otherwise indicated. Chronic widespread pain was present if participants were bothered "a little" or "a lot" by it. Continuous clinical measures included the Pain Catastrophizing Scale for pain catastrophizing, the Pain Self-Efficacy Questionnaire for pain self-efficacy, the Patient-Reported Outcomes Measurement Information System (PROMIS) with 29 items for health-related quality of life, the numerical rating scale from 0 to 10 for low back pain intensity, and the Roland-Morris Disability Questionnaire for back-related functioning. Higher scores represent worse clinical status on each of these measures. SD, standard deviation; SPADE, Sleep disturbance, Pain interference with activities, Anxiety, Depression, and low Energy/fatigue.

Therein, clinically important improvements in the realm of HRQOL involving depression (d=0.37) and anxiety (d=0.24) were observed, as well as improvements in back-related functioning (d=0.36). Because the feasibility trial was meant to inform the research design, experimental treatment, and other aspects of the OPTIQUAL Trial, it is unclear why none of the differences observed herein between the experimental and control treatment groups achieved either statistical significance or clinical importance.

There are at least two possible explanations for the negative findings of the present study. The feasibility trial recruited participants during the period from August 2019 through January 2020. All registry participants during this period resided in Texas, whereas the OPTIQUAL Trial participants were recruited from registry participants throughout the 48 contiguous states and the District of Columbia. Nevertheless, it is unlikely that treatments for and clinical outcomes of CLBP would have varied substantially by extending the research design from a statewide to a national level. More likely, the discrepant findings may have been attributable to the onset of the COVID-19 pandemic on March 13, 2020 [18]. Because almost three-fourths of participants in the OPTIQUAL Trial were enrolled during the pandemic, they may have had limited

Table 2: Survey responses on the value and utility of the eHealth intervention (n=158).[a]

Survey item	%
Overall value (mean ± SD)	63.7 ± 26.7
"The report was easy for me to understand after reading the interpretation guide"	
Strongly agree	38
Agree	46
Neither agree nor disagree	11
Disagree	5
Strongly disagree	0
"The report provided information about my quality of life that I did not know"	
Strongly agree	19
Agree	38
Neither agree nor disagree	34
Disagree	8
Strongly disagree	2
Most harmful impact on health-related quality of life	
Sleep disturbance	23
Pain interference with activities	45
Anxiety	5
Depression	13
Low energy or fatigue	13
Least harmful impact on health-related quality of life	
Sleep disturbance	15
Pain interference with activities	9
Anxiety	29
Depression	26
Low energy or fatigue	21
Persons with whom the report was shared	
Spouse or significant other	40
Other family member	22
Friend	15
Employer	3
Health care provider other than physician	20
Participant actions based on the report	
Reading or learning more about improving health-related quality of life	76
Beginning a new program to improve health-related quality of life	32
Speaking to a healthcare provider other than physician about improving health-related quality of life	32
Speaking to physician who treats their low back pain about improving health-related quality of life	51
Target of the participant actions based on the report (n=133)	
Sleep disturbance	73
Pain interference with activities	83
Anxiety	56
Depression	53
Low energy or fatigue	72
Report shared with physician who treats their low back pain	
Yes	23
No	77
Results of sharing report with physician who treats their low back pain (n=36)	
Physician did not look at report	17
Physician looked at it but did not address it	33
Physician talked about it but did not recommend anything	6
Physician made recommendations to improve health-related quality of life	44
Actions pertaining to health-related quality of life based on report sharing with physician (n=16)	
Participant self-care	100
Specific instructions from physician to participant	75
Prescription for new medication from physician	44

Table 2: (continued)

Survey item	%
Target of participant actions based on instructions or new medication from physician (n=15)	
Sleep disturbance	53
Pain interference with activities	93
Anxiety	40
Depression	53
Low energy or fatigue	60

[a]Survey results are displayed as percentages, except for overall value (based on a visual analogue scale from 0 to 100). Percentages are based on 158 participants unless otherwise noted. Percentages may exceed 100% on items which allowed multiple responses.

Table 3: Changes in primary and secondary outcome measures according to treatment group (n=326).[a]

Outcome measure	Experimental treatment group (n=164)	Control treatment group (n=162)	Difference between treatment groups		Effect size		
	Mean improvement	Mean improvement	Mean	(95% CI)	*d*	(95% CI)	p-Value
Primary outcomes							
SPADE cluster score	0.99	0.84	0.15	−0.73 to 1.03	0.04	−0.18 to 0.25	0.73
SPADE scale score							
Sleep disturbance	1.32	0.62	0.70	−0.65 to 2.05	0.11	−0.10 to 0.33	0.31
Pain interference with activities	0.99	1.06	−0.07	−1.15 to 1.01	−0.01	−0.23 to 0.20	0.90
Anxiety	0.66	1.03	−0.37	−1.84 to 1.10	−0.06	−0.27 to 0.16	0.62
Depression	0.76	0.80	−0.04	−1.50 to 1.42	−0.01	−0.22 to 0.21	0.96
Low energy/fatigue	1.25	0.70	0.55	−0.85 to 1.94	0.09	−0.13 to 0.30	0.44
Secondary outcomes							
Low back pain intensity	0.30	0.14	0.16	−0.20 to 0.51	0.10	−0.12 to 0.31	0.38
Back-related functioning	0.57	0.44	0.12	−0.57 to 0.82	0.04	−0.18 to 0.26	0.73

[a]Positive and negative differences between treatment groups and for effect size favor the experimental and control treatment groups, respectively, the reported p values are for the differences between treatment groups, SPADE, sleep disturbance, pain interference with activities, anxiety, depression, and low energy/fatigue.

access to treatments for low back pain or to other facilities and the services needed to act in response to the HRQOL report. Our findings confirmed that less than one-fourth of the participants shared the report with the physician who treated their low back pain. In other studies, our registry found decreased utilization of several nonpharmacological treatments for low back pain among 528 participants within 3 months [19], and among 476 participants within 6 months [20] of the pandemic onset in the United States. Thus, limited sharing of the report with physicians and decreased access to and utilization of other related facilities and services may have attenuated the differences in outcomes between the experimental and control treatment groups that otherwise would have been observed if the pandemic had not occurred.

There were no significant subgroup differences observed in the reported value and utility of the eHealth intervention, or in the primary or secondary outcome measures, based on the type of physician who treated low back pain. A registry study of 313 participants demonstrated that patients treated for low back pain report better physician interpersonal manner and empathy with osteopathic physicians, as compared with allopathic physicians [21]. A subsequent registry study of 404 participants found better patient-centered care provided by osteopathic physicians in areas that may be germane to follow-up counseling for HRQOL as studied herein, such as being interested in the patient as a whole person [22]. Such osteopathic physician attributes, if present in this study, did not facilitate better outcomes among their patients with CLBP. Again, it is possible that decreased access to healthcare (including osteopathic manipulative treatment) during the COVID-19 pandemic [19, 20] may have attenuated osteopathic vs allopathic physician interaction effects relating to the association between treatment group assignment and outcomes for HRQOL, low back pain intensity, and back-related functioning.

This study had several strengths that should be noted. Randomized registry trials represent a new paradigm that facilitates the enrollment of sizable numbers of research participants quickly and at low cost, often utilizing a representative

sample of persons with the target condition within a real-world setting [23]. The PRECISION Pain Research Registry facilitated the collection of data utilizing a battery of validated research instruments, with minimal attrition and missing data, by utilizing a digital research platform to interact with trial participants. Similarly, the registry enabled the delivery of the eHealth intervention to a national audience rapidly and inexpensively. The limitations of the trial were largely attributable to its performance during the COVID-19 pandemic, as described above, and to the eHealth intervention itself. The 3 month follow-up period prior to collecting exit data may not have been sufficiently lengthy to observe important improvements in the primary and secondary outcome measures. It is possible that many participants did not visit their physician for low back pain within the 3 month follow-up period, particularly during the pandemic In general, and especially because of decreased access to healthcare for low back pain during the pandemic, it may have been necessary to provide a more intensive eHealth intervention to the experimental treatment group. For example, additional self-care modules pertaining to each of the five SPADE scales could have been developed and delivered to participants utilizing the digital research platform. These modules could have been provided comprehensively as a package to all participants to address the overall SPADE cluster, or individually to selected participants according to the priority established by their reported HRQOL scale scores. Finally, the study findings may not be generalizable to patients without computers or cell phones or to those who are not comfortable utilizing such devices.

Conclusions

The eHealth intervention studied herein did not provide statistically significant or clinically important improvements in any of the primary outcome measures involving HRQOL or any of the secondary outcome measures relating to low back pain intensity or back-related functioning. Moreover, in subgroup analyses involving participants treated by osteopathic vs. allopathic physicians, no significant interaction effects were observed. Despite several strengths attributable to utilizing the PRECISION Pain Research Registry to conduct this randomized controlled trial, the validity and generalizability of its findings may have been limited by the unforeseen onset and impact of the COVID-19 pandemic shortly after beginning the trial.

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Competing interests: None reported.

Ethical approval: This study was approved by the North Texas Institutional Review Board (protocol 2015–169); ClinicalTrials registry number: NCT04168437.

Informed consent: All participants in this study provided written informed consent prior to participation.

References

1. Sullivan MD, Ballantyne JC. Must we reduce pain intensity to treat chronic pain? Pain 2016;157:65–9.
2. Ballantyne JC, Sullivan MD. Intensity of chronic pain-the wrong metric? N Engl J Med 2015;373:2098–9.
3. Licciardone JC, Schultz MJ, Amen B. Osteopathic manipulation in the management of chronic pain: current perspectives. J Pain Res 2020;13:1839–47.
4. Baumhauer JF. Patient-reported outcomes – are they living up to their potential? N Engl J Med 2017;377:6–9.
5. Deyo RA, Dworkin SF, Amtmann D, Andersson G, Borenstein D, Carragee E, et al. Report of the NIH task force on research standards for chronic low back pain. J Pain 2014;15:569–85.
6. Clinical Trials.gov. PRECISION pain research registry (PRECISION); 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04853732 [Accessed 11 Jul 2022].
7. Clinical Trials.gov. Optimizing chronic pain management through patient engagement with quality of life measures (OPTIQUAL); 2021. Available from: https://clinicaltrials.gov/ct2/show/NCT04168437. [Accessed 11 Jul 2022].
8. PROMIS.PROMIS adult profile instruments. Evanston, IL: Northwestern University; 2015.
9. Revicki DA, Chen WH, Harnam N, Cook KF, Amtmann D, Callahan LF, et al. Development and psychometric analysis of the PROMIS pain behavior item bank. Pain 2009;146:158–69.
10. Yost KJ, Eton DT, Garcia SF, Cella D. Minimally important differences were estimated for six patient-reported outcomes measurement information system-cancer scales in advanced-stage cancer patients. J Clin Epidemiol 2011;64:507–16.
11. 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;8:141–4.
12. Assendelft WJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low back pain. A meta-analysis of effectiveness relative to other therapies. Ann Intern Med 2003;138:871–81.

13. Ostelo RW, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine 2008;33:90–4.
14. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008;9:105–21.
15. Faraone SV. Interpreting estimates of treatment effects: implications for managed care. P T 2008;33:700–11.
16. Kroenke K, Talib TL, Stump TE, Kean J, Haggstrom DA, DeChant P, et al. Incorporating PROMIS symptom measures into primary care practice-a randomized clinical trial. J Gen Intern Med 2018;33: 1245–52.
17. Licciardone JC, Pandya V. Feasibility trial of an eHealth intervention for health-related quality of life: implications for managing patients with chronic pain during the COVID-19 pandemic. Health Care 2020;8:381.
18. The White House. Proclamation on declaring a national emergency concerning the novel coronavirus disease (COVID-19) outbreak; 2020. Available from: https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/#:~:text=Proclamation%20on%20Declaring%20a%20National%20Emergency%20Concerning%20the,Disease%20(COVID%2D19)%20Outb [Accessed 11 Jul 2022].
19. Licciardone JC. 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. J Am Board Fam Med 2021;34:S77–84.
20. Licciardone JC. Impact of COVID-19 on utilization of nonpharmacological and pharmacological treatments for chronic low back pain and clinical outcomes. J Osteopath Med 2021;121: 625–33.
21. Licciardone JC, Schmitt ME, Aryal S. Osteopathic and allopathic physician interpersonal manner, empathy, and communication style and clinical status of their patients: a pain registry-based study. J Am Osteopath Assoc 2019;119:499–510.
22. Licciardone JC, Aryal S. Patient-centered care or osteopathic manipulative treatment as mediators of clinical outcomes in patients with chronic low back pain. J Osteopath Med 2021;121: 795–804.
23. Lauer MS, D'AgostinoSr RB. The randomized registry trial-the next disruptive technology in clinical research? N Engl J Med 2013;369:1579–81.

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