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Authors

Sellinger, John J
Gilstad-Hayden, Kathryn
Lazar, Christina
et al.

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Original Research Article

Impact of the COVID-19 pandemic on participants in pragmatic clinical trials for chronic pain: implications for trial outcomes and beyond

John J. Sellinger, PhD[1,2,*], Kathryn Gilstad-Hayden, MS[1,2], Christina Lazar, MPH[1,2], Karen Seal, MD, MPH[3,4], Natalie Purcell, PhD, MPA[3,4], Diana J. Burgess, PhD[5,6], Steve Martino, PhD[1,2], Alicia Heapy, PhD[1,2], Diana Higgins, PhD[7,8], Marc I. Rosen, MD[1,2]

[1]VA Connecticut Healthcare System, West Haven, CT 06516, United States
[2]Yale University School of Medicine, New Haven, CT 06504, United States
[3]San Francisco VA Healthcare System, Integrative Health Service San Francisco, San Francisco, CA 94121, United States
[4]University of California, San Francisco, San Francisco, CA 94158, United States
[5]VA HSR&D Center for Care Delivery and Outcomes Research, Minneapolis VA Healthcare System, Minneapolis, MN 55417, United States
[6]University of Minnesota Medical School, Minneapolis, MN 55455, United States
[7]Durham VA Healthcare System, Durham, NC 27705, United States
[8]Boston University Chobanian & Avedisian School of Medicine, Boston, MA 02118, United States
*Corresponding author: VA Connecticut Healthcare System (116B), 950 Campbell Avenue, West Haven, CT 06516, USA. Email: John.Sellinger1@va.gov

Abstract

Objective: The COVID-19 pandemic had profound effects on society, including those living with chronic pain. This study sought to examine pandemic impacts on individuals enrolled in pragmatic clinical trials focused on nonpharmacological treatments for chronic pain.

Methods: We evaluated responses to a questionnaire on COVID-19 impacts that had been administered to participants ($n=2024$) during study enrollment in 3 pragmatic clinical trials for chronic pain treatment. All trials were part of the National Institutes of Health (NIH)–Department of Veterans Affairs (VA)–Department of Defense (DOD) Pain Management Collaboratory. COVID-19–related impacts on access to health care, mental health, finances, ability to meet basic needs, and social support were assessed.

Results: Pandemic impacts were found in all domains assessed, including access to health care, mental and emotional health, ability to meet basic needs, finances, and social support. Impacts varied by demographic and clinical characteristics. The participants most negatively impacted by the pandemic were younger, Black or Latino, female, more educated, and unemployed and had screened positive for depression. No impact differences were found with regard to alcohol use disorder screenings or a prior history of COVID-19. Higher levels of pain were associated with worse pandemic impacts, and negative impacts declined over time.

Conclusions: Negative impacts of the pandemic on individuals living with chronic pain cut across aspects of life that are also central to effective pain management, including access to health care, social support, and mental and emotional health, with differential impacts found across key demographic and clinical factors. These findings should yield consideration of pandemic impacts in clinical practice and as moderating effects of treatment outcomes in clinical trials conducted during the pandemic.

Keywords: chronic pain; COVID-19; substance use; Veterans.

Introduction

Global impacts of the COVID-19 (SARS-CoV-2) pandemic were profound. Social distancing brought about disruptions in how people worked, socialized, exercised, and accessed health care. People already burdened by significant physical, emotional, and social limitations imposed by chronic pain were likely at even greater risk during this period. The imposition of social isolation, restrictions on daily activities, and other pandemic-related stresses, such as the loss of loved ones to COVID-19, would be especially hard on people living with chronic pain who might be more dependent on social, financial, medical, and emotional support.[1]

In a review of the multifaceted "social threats" imposed by the COVID-19 pandemic, Karos and colleagues[1] detailed several social factors that put individuals at risk of worsening chronic pain. In addition to reduced access to health care and exacerbation of social inequities, they also point to social disconnection and isolation, perceived invalidation and reduced support, sickness-reinforcing behaviors from others, and increased child and family care burdens as threats that could worsen the impact of chronic pain. The authors suggested directions for research to help understand the impacts that these factors have on individuals living with chronic pain. Suggestions included examining impacts of demographic variables, resilience mechanisms, social determinants of health, and biopsychosocial mechanisms on the bidirectional relationship between social factors and pain. These suggestions are consistent with the aims of the present study, which sought to examine similar pandemic-related social threats among individuals enrolled in pain pragmatic clinical trials.

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Some literature on pandemic impacts suggests that individuals with chronic pain are a particularly vulnerable population.[2,3] In the psychological domain, the pandemic brought about widespread increases in depression, anxiety, and insomnia.[4–6] Individuals living with chronic pain are already at higher risk of similar psychological comorbidities, each of which worsens the course of the comorbid condition.[7–10] One effective self-management strategy that can reduce depression, anxiety, and chronic pain is engagement in physical activity.[11,12] However, the pandemic resulted in reduced engagement in physical activity and increases in sedentary behavior.[13,14] Unmitigated stress and anxiety are associated with increased pain perception, also referred to as hyperalgesia.[15] Thus, the increase in pandemic-related psychological symptoms and reduced engagement in strategies to mitigate such symptoms presented increased challenges for individuals living with chronic pain.

Reduced utilization of health care services due to the need for social distancing was another impact of the pandemic that would be expected to especially harm people living with chronic pain. Social restrictions resulted in reductions in routine visits, hospital admissions, diagnostic services, and delivery of therapeutics.[16] The impact of these restrictions on individuals living with chronic pain could be profound, given the emphasis on the biopsychosocial approach to understanding chronic pain and the multimodal treatment perspective that stems from this approach. With lack of direct access to an array of such treatments and rehabilitation services, including physical and occupational therapy, diagnostics and physical examination, and mental health support, the compounding impacts of increased pain, reduced functional status, and worsening social and emotional well-being stood to enhance the disabling effects of chronic pain. The early months of the pandemic saw an 80% decrease in in-person health care visits, and the health care industry quickly pivoted to the use of telehealth platforms to deliver care.[17,18]

However, the advantages of telehealth were not experienced equally by all segments of society. Studies of electronic health records and insurance claim data during the pandemic revealed discrepancies in telehealth utilization across patients by racial identity, gender, age, employment status, and education.[19,20] Collectively, these findings demonstrate pandemic-related impacts on health care access and demographic-related disparities in how telehealth services were used. This lack of a telehealth alternative to in-person care is likely to further compound the previously cited impacts of reduced health care access for individuals living with chronic pain. Therefore, in the present study, we examined the impact of the pandemic on access to health care, with analyses focused on examination of potential differences across demographic variables.

With demonstrated widespread impacts of the pandemic on important clinical domains such as access to health care, social support, and emotional well-being, it became clear that such impacts also needed to be considered in the context of ongoing clinical trials. Authors representing the National Institutes of Health (NIH), Department of Defense (DOD), and Department of Veterans Affairs (VA) Pain Management Collaboratory (PMC) reviewed the importance of considering the impact of the COVID-19 pandemic on clinical trials of chronic pain.[21] They discussed impacts on recruitment, study protocols, overall study design and implementation, and moderation of treatment effects caused by the pandemic. Using implementation science methodology, members of the PMC assessed and described changes made to the 11 pragmatic clinical trials that were being overseen by the PMC, including the 3 trials that were part of the present study.[22] They found that changes were made to trial protocols in an effort to increase treatment feasibility in the setting of the pandemic, reduce exposure to COVID-19, and maintain the core elements of the trials' interventions. The group also developed the PMC Coronavirus Pandemic (COVID-19) Measure[23] to help assess the pandemic's impacts on trial participants in discrete domains, thus providing investigators with data for determining potential moderation of treatment effects based on COVID-19. The domains assessed included ability to access health care, social support, mental and emotional health, ability to meet basic needs, and finances.

This study presents data from 3 of the PMC's multisite pragmatic clinical trials, all based within the VA, that used the PMC COVID-19 Measure. Building on the work of Midboe and colleagues,[22] which sought to illustrate the impact of the pandemic on PMC study trials (ie, protocol changes, recruitment, etc), the present study aims to assess the impacts of the pandemic on the participants in 3 of those trials, including evaluation of differential impacts across demographic and socioeconomic groups.

Methods

This study is an aggregated analysis of baseline data on the pandemic's impact on study participants drawn from 3 separate pragmatic randomized controlled trials: Screening, Brief Intervention, and Referral to Treatment for Pain Management (SBIRT-PM), Learning to Apply Mindfulness to Pain (LAMP), and Whole Health Options and Pain Education (*w*HOPE). Each study is part of the PMC. Details of each study are described elsewhere[24–26] and are described briefly here.

Studies

Trial 1: Screening, Brief Intervention, and Referral to Treatment for Pain Management (SBIRT-PM)

SBIRT-PM is a multisite, pragmatic randomized control trial comparing SBIRT-PM to usual care. Veterans seeking service-connected disability for a painful musculoskeletal condition were recruited, and the SBIRT-PM intervention delivered brief telephone-based, motivational interviewing–informed counseling designed to encourage veteran enrollment in multimodal pain treatment services offered at their local VA medical center. Additionally, veterans presenting with risky alcohol use were counseled on their alcohol use and were offered referral to treatment. Outcomes assessed included pain severity; pain interference; overall pain assessed with the Pain, Enjoyment of Life, and General Activity (PEG) scale; health-related quality of life; substance misuse; and pain and substance use treatment service utilization. Inclusion criteria specified that participants must be post-9/11 veterans who filed service-connected claims for a musculoskeletal-related painful condition in the back, neck, shoulder, or knee, with moderate to severe pain severity as determined by a score of ≥4 on the Brief Pain Inventory, and with access to a telephone. Exclusion criteria were receipt of more than 2 nonpharmacological pain services in the prior 12 weeks, self-reported inability to participate during study enrollment, or enrollment in another pain-related research trial at the time of study enrollment.[25]

Trial 2: Learning to Apply Mindfulness to Pain (LAMP)

LAMP is a pragmatic randomized control trial that tested the effectiveness of 2 mobile-based approaches to delivering mindfulness-based interventions to patients with moderate to severe chronic pain: one using prerecorded modules presented by a mindfulness instructor and viewed in an online group setting with facilitator-led discussion, and the other with the same prerecorded modules without the group component. Outcomes assessed included measures of both pain and mental health comorbidities. Inclusion criteria included medical record documentation of pain diagnoses on at least 2 occasions, at least 90 days apart, within the prior 2 years; pain duration of at least 6 months and pain severity of ≥4 on the numeric rating scale; and access to a smartphone. Exclusion criteria included diagnoses of schizophrenia, bipolar disorder, or other psychosis within the prior 18 months; active psychotic symptoms; suicidality; current severe depression or active manic episode or poorly controlled bipolar disorder; enrollment in another pain research study; or engagement in a mindfulness-based stress reduction intervention.[24]

Trial 3: Whole Health Options and Pain Education (wHOPE)

*w*HOPE is a pragmatic randomized control trial that compared a Whole Health Team approach with Primary Care Group Education and with Usual Primary Care. Featuring a medical provider, a complementary and integrative health provider, and a Whole Health coach, the Whole Health Team collaborated with patients to develop a personalized health plan that incorporated complementary and integrative health approaches to pain management. The Primary Care Group Education group received an adapted group cognitive behavioral therapy intervention. Outcomes assessed included pain interference, pain severity, quality of life, mental health symptoms, and use of pharmacological and nonpharmacological pain treatments. Eligibility criteria included at least one primary care visit in the prior year; pain every day or nearly every day for ≥6 months; and overall pain severity on the PEG scale of ≥5. Exclusion criteria included moderate–severe cognitive impairment; active suicidal ideation; unstable medical or psychiatric condition; enrollment in hospice care; lack of telephone access; non-English speaker; plans to relocate within 12 months; or participation in another pain-related research trial.[26]

Data sources and measurement

The 3 clinical trials from which data were pooled were all conducted at VA medical centers. Therefore, permission was sought from the Department of Veterans Affairs Central Institutional Review Board to pool data across sites. A data-sharing agreement between investigators at each site was developed to establish the parameters for data sharing and use, and data were transmitted securely behind the VA electronic firewall. All data used in the present study were collected at baseline assessments before treatment interventions were delivered. SBIRT-PM data were collected via self-report through telephone interviews conducted by a research assistant between June 5, 2020, and March 2, 2023. LAMP baseline data were collected online via the study website from November 7, 2020, to April 12, 2022. *w*HOPE data were collected from September 18, 2020, through October 31, 2022, through interviewer-administered telephone assessments.

Measures

Each study administered the PMC COVID-19 Measure[23] to assess pandemic impacts. The measure assessed participants' personal experience with COVID-19, including whether they thought they or a housemate had been sick with the coronavirus. Participants who responded that they (or their housemate) thought they were sick with the coronavirus were coded as having COVID-19 (or their housemate having COVID-19). The items from the COVID-19 Measure that were of primary interest in the present study were those assessing pandemic impacts with the question, "Over the past 3 months, how has the coronavirus pandemic affected your …," followed by 5 life domains, including access to health care, mental and emotional health, social support, finances, and ability to meet basic needs. Response options included a 4-point ordinal scale on which participants noted whether these domains were a lot worse, a little worse, not affected, or improved because of the pandemic.

Participants self-reported their age in years, race, gender, education level, and employment status, which were used as covariates in the present study. Age was categorized as 20–44, 45–64, or 65+ years. Race/ethnicity was operationalized as Hispanic, non-Hispanic Black, non-Hispanic White, or non-Hispanic race other than Black or White. Employment status was categorized as working for pay, not working for pay, or student.

Pain intensity and interference were measured with the Pain, Enjoyment of Life, and General Activity scale (PEG),[27] a 3-item scale that asked participants to rate their average pain, how pain has interfered with their enjoyment of life, and how pain has interfered with general activities over the prior week. These ratings assume the influence of both exacerbating and alleviating factors, including the effects of prior or ongoing pain treatments. Ratings range from 0 (no pain) to 10 (pain as bad as you can imagine), with scores calculated by averaging the 3 ratings. The PEG scale has shown high reliability and construct validity comparable to that of the longer Brief Pain Inventory.

Depression was assessed with the PHQ-8, an 8-item version of the Patient Health Questionnaire Depression scale (PHQ-9).[28] The PHQ-9 is a validated screening measure for depression, and the PHQ-8 is comparable for depression screening.[29] Items are assessed on a scale from 0 (not at all) to 3 (nearly every day) and are summed across the 8 items for a score range of 0 to 24, with higher scores indicating more severe depression. This variable was dichotomized, with PHQ-8 score ≥10 indicating significant clinical depression.[30]

Alcohol use disorder was measured with the Alcohol Use Disorders Identification (AUDIT-C), a 3-item screening measure that asks about frequency and amount of drinking and number of heavy drinking days. Scores from each item are summed for a score range of 0 to 12, with scores of 4 or more in men and 3 or more in women considered positive for hazardous drinking or alcohol use disorder.[31] The AUDIT-C has been validated as a screen for alcohol use disorder in veteran populations.[32]

The assessment cohort was divided into 3 categories: June 2020 to May 2021, June 2021 to April 2022, and May 2022 to March 2023. The first cut point reflects the lowest death toll due to COVID-19 after vaccines were first available, and the second is the lowest death toll after vaccines became more widely available.[33] These sequential time points are also associated with progressive loosening of COVID-19–related restrictions, thus allowing for resumption of in-person health care visits, public gatherings, and other social activities.

Study size

At the time of data pooling, 2091 participants across the 3 trials had completed the PMC COVID-19 Measure at baseline: 820 from SBIRT-PM, 811 from LAMP, and 460 from *w*HOPE. After exclusion of 67 participants with missing explanatory variable data, the analytical sample included 2024 participants. All participants completed the PMC COVID-19 Measure, but a small number of participants were missing items on the scale (≤3 participants per item) and were excluded from individual analyses.

Statistical methods

Descriptive statistics were used to characterize the sample and to show the distribution of responses to the COVID-19 questionnaire items overall and by demographic and clinical characteristics of participants.

Multinomial logistic regression models were used to determine the independent associations of participant characteristics and assessment cohort with COVID-19 impact. Five separate models were analyzed—one for each domain of pandemic impact. Given the low numbers of participants reporting that COVID-19 improved any of the domains, the "not affected" and "improved" categories were combined to form the reference category, and separate comparisons were made to the "a lot worse" and "a little worse" categories. Explanatory variables in the model included age (20–44, 45–64, or 65+ years), race/ethnicity (Hispanic, non-Hispanic-Black, non-Hispanic Other, or non-Hispanic White), gender (female vs male), assessment cohort (June 2020 to May 2021, June 2021 to April 2022, or May 2022 to March 2023), PEG score, significant clinical depression (yes vs no), alcohol use disorder (yes vs no), and personal or household COVID-19 infection status (yes vs no). Multinomial logistic regression models also adjusted for parent study.

All analyses were conducted in SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Because this was an exploratory analysis, statistical significance was set at $P < .05$, and no adjustments for multiple comparisons were made. Missing data were addressed with list-wise deletion given that only <3.3% of participants were excluded from analyses.

Results

The analytical sample included 2024 participants with complete covariate data and is described in Table 1. Participants were 50.1 (SD = 15.1) years old on average. The majority were non-Hispanic White (67%) and male (68%). More than one fifth of participants reported that a housemate had been sick with COVID-19 at the time of their assessment. Almost one half (49%) of participants had significant clinical depression, and 27% screened positive for alcohol use disorder. The mean PEG score was 5.9 (SD = 1.9), indicating moderate pain on average.

Figure 1 shows the response distribution of the 5 COVID-19 impact questions. The mental health and social support domains had the highest percentage (24% each) of respondents selecting the "a lot worse" option. For the other domains, access to health care was a lot worse for 19% of participants, and finances and ability to meet basic needs were a lot worse in 17% and 10%, respectively.

Figure 2A and B show the response distribution of the 5 COVID-19 impact questions by demographic and clinical characteristics of participants, respectively. Younger veterans tended to report more negative impacts on their access to health care, finances, ability to meet basic needs, and mental health, but not social support, than did older veterans. Non-Hispanic White participants were generally more likely than other races/ethnicities to report that their social support, finances, ability to meet basic needs, and mental health were not affected or improved and less likely to report that these domains were a lot worse. Females were more likely than males to report worse mental health, social support, and finances because of the pandemic. The percentage of veterans reporting negative impacts on access to health care, social support, and mental health was lower among those with a high school degree or no degree than among those with higher education levels, but the percentage of veterans reporting negative impacts on finances and ability to meet basic needs tended to decrease with more education. Access to health care, social support, and mental health tended to improve with later assessment dates, but finances and ability to meet basic needs did not. Veterans with depression were more likely than those without to be negatively affected across all domains. Note that because of the larger number of comparisons being made, these observed differences are based on raw percentages, not statistical inference testing, so these bivariate differences might not be statistically significant. Mean pain severity and interference (PEG) scores were significantly higher among participants selecting "a lot worse" than among participants selecting other categories for COVID-19 impact (see Figure 3).

Table 2 shows the results from the multinomial regression models. The youngest group of veterans (20–44 years of age) were more likely than the oldest group (65 years of age or more) to report that their access to health care (OR = 1.85, 95% CI = 1.14–3.01), finances (OR = 3.89, 95% CI = 2.27–6.65), ability to meet basic needs (OR = 2.79, 95% CI = 1.50–2.23), and mental health (OR = 3.22, 95% CI = 1.89–5.48) were *a lot worse* versus *not affected or improved*. Finances (OR = 1.79, 95% CI = 1.18 to 2.73) and mental health (OR = 1.50, 95% CI = 1.01 to 2.23) were also more likely to be *a little worse* (vs *not affected or improved*) in the youngest age group than in the oldest. No differences in social support were found among the age groups.

Black veterans were more likely than White veterans to report that their finances were *a little worse* (OR = 1.71, 95% CI = 1.28–2.29), that their ability to meet basic needs was *a little worse* (OR = 1.49, 95% CI = 1.12–1.97) or *a lot worse* (OR = 1.61, 95% CI = 1.05–2.46), and that their mental health was *a lot worse* (OR = 1.57, 95% CI = 1.09–2.26) versus *not affected or improved*. No differences in access to health care or social support were found between Black and White veterans. Hispanic veterans and veterans in the Other race category were more likely than White veterans to report that their social support ($OR_{HISPANIC} = 1.53$, 95% CI = 1.02–2.30; $OR_{OTHER} = 2.04$, 95% CI = 1.25–3.35) and mental health were *a lot worse* ($OR_{HISPANIC} = 2.00$, 95% CI = 1.29–3.12; $OR_{OTHER} = 2.66$, 95% CI = 1.46–4.85) versus *not affected or improved*. Additionally, veterans in the Other race category were more likely than White veterans to report that their ability to meet basic needs was *a little worse* (OR = 1.82, 95% CI = 1.17–2.83) or *a lot worse* (OR = 2.16, 95% CI = 1.13–4.12) versus *not affected or improved*.

Table 1. Participant characteristics.

	Overall (*n* = 2024)		SBIRT-PM (Trial 1) (*n* = 790)		LAMP (Trial 2) (*n* = 794)		*w*HOPE (Trial 3) (*n* = 440)	
Age, mean (SD)	50.1	(15.1)	39.2	(11.1)	54.6	(12.9)	61.5	(12.2)
Race/ethnicity, *n* (%)								
Non-Hispanic White	1349	(66.7%)	561	(71.0%)	501	(63.1%)	287	(65.2%)
Non-Hispanic Black	362	(17.9%)	90	(11.4%)	196	(24.7%)	76	(17.3%)
Hispanic	201	(9.9%)	111	(14.1%)	51	(6.4%)	39	(8.9%)
Non-Hispanic Other Race	112	(5.5%)	28	(3.5%)	46	(5.8%)	38	(8.6%)
Sex, *n* (%)								
Male	1380	(68.2%)	683	(86.5%)	413	(52.0%)	284	(64.6%)
Female	644	(31.8%)	107	(13.5%)	381	(48.0%)	156	(35.5%)
Education, *n* (%)								
High school degree (or less)	283	(14.0%)	161	(20.4%)	52	(6.6%)	70	(15.9%)
Some postsecondary	869	(42.9%)	307	(38.9%)	347	(43.7%)	215	(48.9%)
Bachelor's degree	476	(23.5%)	176	(22.3%)	218	(27.5%)	82	(18.6%)
Advanced degree	396	(19.6%)	146	(18.5%)	177	(22.3%)	73	(16.6%)
Employment, *n* (%)								
Working for pay	1071	(52.9%)	624	(79.0%)	328	(41.3%)	119	(27.1%)
Student	70	(3.5%)	44	(5.6%)	21	(2.6%)	5	(1.1%)
Not working for pay	883	(43.6%)	122	(15.4%)	445	(56.1%)	316	(71.8%)
Study assessment date range, *n* (%)								
June 2020 to May 2021	585	(28.9%)	137	(17.3%)	328	(41.3%)	120	(27.3%)
June 2021 to April 2022	987	(48.8%)	285	(36.1%)	466	(58.7%)	236	(53.6%)
May 2022 to March 2023	452	(22.3%)	368	(46.6%)	0	(0.0%)	84	(19.1%)
PEG Score,[a] mean (SD)	5.9	(1.9)	5.8	(2)	5.8	(1.8)	6.5	(1.6)
PHQ-8 Score,[b] mean (SD)	9.8	(5.8)	10.4	(6)	9.6	(5.7)	9.2	(5.4)
PHQ-8 Category,[b] *n* (%)								
No significant depression	411	(20.3%)	153	(19.4%)	164	(20.7%)	94	(21.4%)
Mild depression	627	(31.0%)	209	(26.5%)	267	(33.6%)	151	(34.3%)
Moderate depression	546	(27.0%)	230	(29.1%)	196	(24.7%)	120	(27.3%)
Moderate–severe depression	310	(15.3%)	125	(15.8%)	127	(16.0%)	58	(13.2%)
Severe depression	130	(6.4%)	73	(9.2%)	40	(5.0%)	17	(3.9%)
AUDIT-C[c] category, *n* (%)								
Negative	1471	(72.7%)	485	(61.4%)	627	(79.0%)	359	(81.6%)
Positive	553	(27.3%)	305	(38.6%)	167	(21.0%)	81	(18.4%)
COVID infection, *n* (%)								
No	1550	(76.6%)	571	(72.3%)	608	(76.6%)	371	(84.3%)
Yes	474	(23.4%)	219	(27.7%)	186	(23.4%)	69	(15.7%)
Housemate had COVID infection, *n* (%)								
No	1586	(78.4%)	568	(71.9%)	633	(79.7%)	385	(87.5%)
Yes	438	(21.6%)	222	(28.1%)	161	(20.3%)	55	(12.5%)

[a] PEG= Pain, Enjoyment of Life, and General Activity scale; scores range from 0 to 10, with higher scores indicating more severe pain.

[b] PHQ-8 is an 8-item version of the Patient Health Questionnaire Depression scale (PHQ-9).[26] Scores range from 0 to 24, with higher scores indicating more severe depression. Scores of 0–4 indicate no or minimal symptoms of depression, while scores of 5–9, 10–14, 15–19, or 20–24 indicate mild, moderate, or severe symptoms, respectively.

[c] AUDIT-C= Alcohol Use Disorders Identification Test; scores range from 0 to 12, with higher scores indicating more hazardous drinking. A score of 4 or higher for men and 3 or higher for women indicates alcohol use disorder.

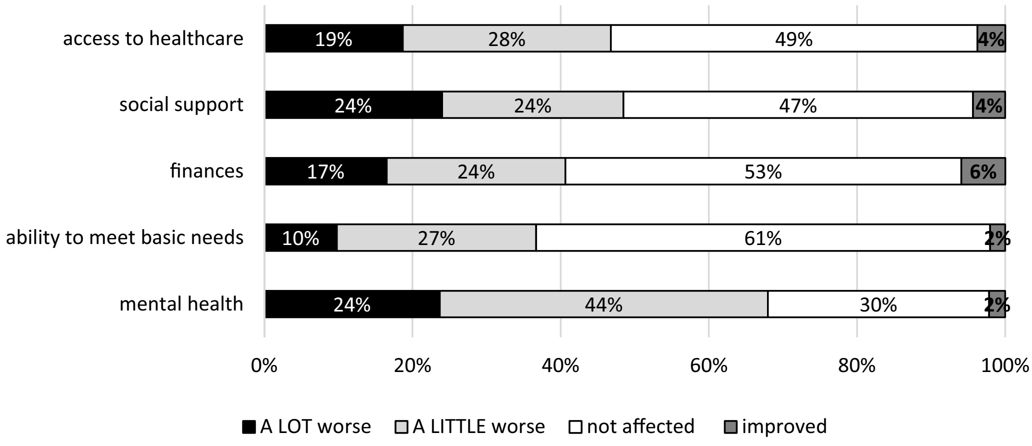

Figure 1. COVID-19 questionnaire response distribution.

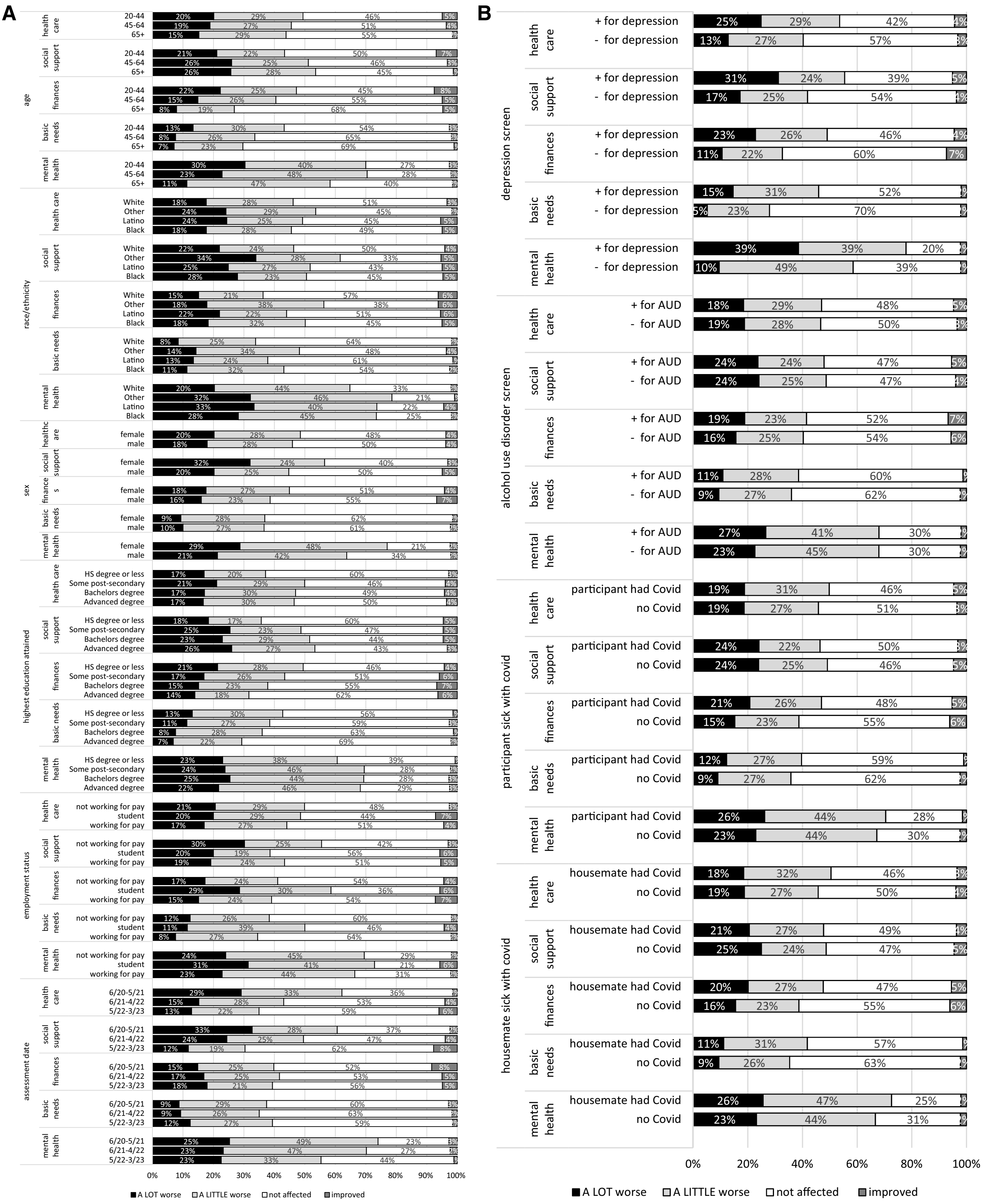

Figure 2. (A) COVID questions response distribution by demographic characteristics. (B) COVID questions response distribution by clinical characteristics. *Abbreviations*: AUD= alcohol use disorder; HS= high school.

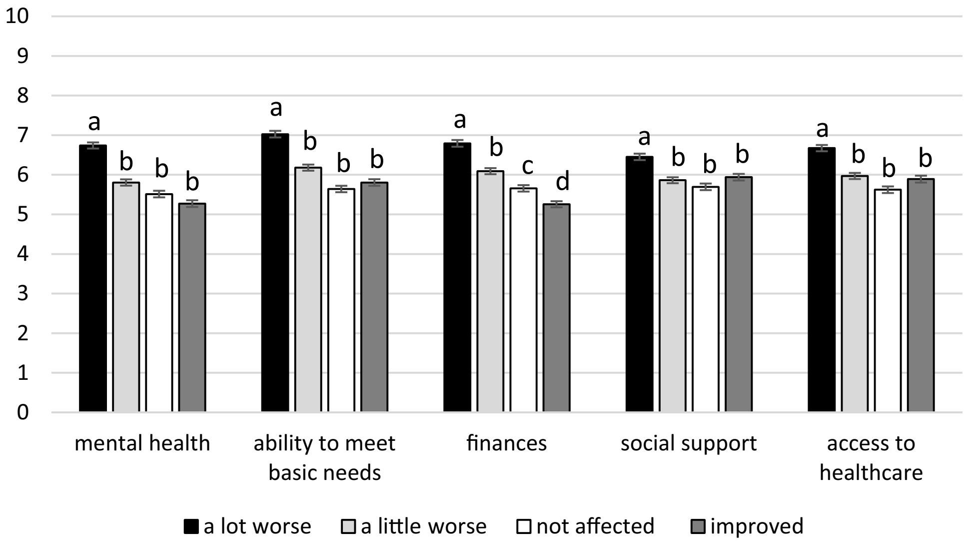

Figure 3. Mean PEG score by response category for COVID questions. PEG = Pain, Enjoyment of Life, and General Activity scale; scores range from 0 to 10, with higher scores indicating more severe pain. Results of post-hoc analysis of variance (ANOVA) Tukey-Kramer tests are shown with letters. Means not statistically different at $P < .05$ share a letter; those that are significantly different do not share a letter. Error bars show 95% confidence interval around mean PEG scores.

Female veterans were more likely than males to report that their social support was *a lot worse* (OR = 1.42, 95% CI = 1.08–1.85) and that their mental health was *a little worse* (OR = 1.41, 95% CI = 1.09–1.83) or *a lot worse* (OR = 2.08, 95% CI = 1.51–2.87).

Veterans with a high school degree or less were less likely than those with an advanced degree to report that their access to health care was *a little worse* (OR = 0.49, 95% CI = 0.33–0.73) and that their social support was *a little worse* (OR = 0.49, 95% CI = 0.32–0.74) or *a lot worse* (OR = 0.58, 95% CI = 0.38–0.89) versus *not affected or improved*. However, they were more likely to report that their finances were *a lot worse* (OR = 1.77, 95% CI = 1.12–2.80) and that their ability to meet basic needs were *a little worse* (OR = 1.51, 95% CI = 1.03–2.19) versus *not affected or improved*.

Odds of negative impacts on access to health care, social support, and mental health declined with later assessment dates, but assessment date was not associated with finances or ability to meet basic needs. Veterans with worse pain and depression were more likely to report that they were a lot worse off in all 5 domains, whereas alcohol use disorder and whether the participant had had COVID-19 were not associated with any domains in the model and therefore were not included in Table 2.

Discussion

Collectively, the findings from the present study demonstrate substantial impacts of the COVID-19 pandemic on participants enrolled across multisite, pain-related pragmatic clinical trials. These impacts were found in all domains, including access to health care, mental and emotional health, finances, ability to meet basic needs, and social support. These results are not unexpected, given the life-altering quarantine mandates, workplace closures, restricted health care access, social distancing requirements, and threats of potential and actual personal losses. Pandemic impacts on pain are highlighted by the finding that participants with higher pain scores were likely to be more adversely affected.

Within the study sample of veterans with pain, the impacts on demographic subsamples were consistent with prior literature. For example, the impact of COVID-19 was more profound for younger participants. Compared with participants 65 years of age and older, those 20–44 years of age were more likely to report that they were *a lot worse* versus *not affected or improved* in all domains except social support. These results are like those reported by Varma and colleagues,[6] who found that younger people were more vulnerable to stress, anxiety, and depression during the pandemic than were older people. This could be related to younger participants' greater engagement in societal activities that would have seen a higher impact from pandemic restrictions, including work, school, and social activities. With regard to social support, it might be that younger people were more accustomed to accessing such support via technology, such as through virtual platforms, text messaging, and cell phone use, thus mitigating effects of the pandemic on social support. However, an alternative explanation might come from the work of Lisitsa and colleagues,[34] who found that young adults were lonelier during the pandemic than were older adults, and though they were higher users of social media, younger adults reported lower social support seeking. Thus, the lack of difference in impact on social support across age groups found in the present study could be explained either by younger adults' putting less effort into seeking social support or by their maintenance of social connectivity via social media platforms, thus resulting in an impact level more comparable to that of other age groups.

Consistent with prior literature, race was another demographic characteristic by which the pandemic yielded variable impacts. Particularly noteworthy was that, compared with White participants, the participants from all other racial groups were more likely to report doing *a lot worse* in the domain of mental and emotional health. This is consistent with other reported findings,[35] and there is speculation that the COVID-19 pandemic, coupled with the racial and social

Table 2. Results from multinomial logistic regression models.

	Access to health care ($n = 2023$)		Social support ($n = 2022$)		Finances ($n = 2021$)		Basic needs ($n = 2022$)		Mental health ($n = 2023$)	
	A little worse OR (95% CI)	A lot worse OR (95% CI)	A little worse OR (95% CI)	A lot worse OR (95% CI)	A little worse OR (95% CI)	A lot worse OR (95% CI)	A little worse OR (95% CI)	A lot worse OR (95% CI)	A little worse OR (95% CI)	A lot worse OR (95% CI)
Age: 20–44 vs 65+ years	1.36 (0.92–2.03)	**1.85** **(1.14–3.01)**	1.01 (0.67–1.54)	1.11 (0.72–1.71)	**1.79** **(1.18–2.73)**	**3.89** **(2.27–6.65)**	1.29 (0.87–1.93)	**2.79** **(1.50–5.20)**	**1.50** **(1.01–2.23)**	**3.22** **(1.89–5.48)**
Age: 45–64 vs 65+ years	1.02 (0.74–1.41)	1.37 (0.92–2.04)	0.93 (0.67–1.31)	0.96 (0.68–1.36)	**1.47** **(1.04–2.07)**	**2.20** **(1.38–3.50)**	1.04 (0.75–1.45)	1.17 (0.69–1.99)	1.35 (0.99–1.84)	**2.32** **(1.48–3.65)**
Race/ethnicity: Black vs white	1.00 (0.75–1.34)	0.90 (0.63–1.28)	0.94 (0.69–1.29)	1.04 (0.76–1.42)	**1.71** **(1.28–2.29)**	1.32 (0.93–1.87)	**1.49** **(1.12–1.97)**	**1.61** **(1.05–2.46)**	1.12 (0.83–1.51)	**1.57** **(1.09–2.26)**
Race/ethnicity: Latino vs white	0.95 (0.65–1.39)	1.44 (0.95–2.17)	1.45 (0.99–2.11)	**1.53** **(1.02–2.30)**	1.05 (0.71–1.56)	1.17 (0.77–1.76)	0.90 (0.63–1.31)	1.23 (0.74–2.03)	1.30 (0.88–1.91)	**2.00** **(1.29–3.12)**
Race/ethnicity: Other vs white	1.27 (0.79–2.03)	1.60 (0.94–2.72)	1.49 (0.91–2.45)	**2.04** **(1.25–3.35)**	2.66 (1.70–4.16)	1.61 (0.90–2.89)	**1.82** **(1.17–2.83)**	**2.16** **(1.13–4.12)**	1.65 (0.98–2.76)	**2.66** **(1.46–4.85)**
Sex: Female vs male	1.08 (0.84–1.39)	1.23 (0.91–1.66)	0.97 (0.74–1.27)	**1.42** **(1.08–1.85)**	1.18 (0.91–1.53)	1.17 (0.86–1.60)	1.07 (0.83–1.37)	1.03 (0.69–1.52)	**1.41** **(1.09–1.83)**	**2.08** **(1.51–2.87)**
Education: HS degree or less vs advanced degree	**0.49** **(0.33–0.73)**	0.68 (0.43–1.09)	**0.49** **(0.32–0.74)**	**0.58** **(0.38–0.89)**	2.43 (1.62–3.65)	**1.77** **(1.12–2.80)**	**1.51** **(1.03–2.19)**	1.54 (0.86–2.76)	0.78 (0.54–1.13)	0.76 (0.47–1.22)
Education: some postsecondary vs advanced degree	0.93 (0.70–1.24)	1.10 (0.77–1.57)	**0.72** **(0.53–0.98)**	0.78 (0.56–1.06)	1.86 (1.35–2.56)	1.26 (0.87–1.82)	1.33 (0.99–1.78)	1.44 (0.89–2.34)	1.02 (0.76–1.36)	0.95 (0.65–1.38)
Employment: student vs not working for pay	0.68 (0.37–1.26)	0.68 (0.33–1.39)	0.61 (0.31–1.22)	**0.49** **(0.24–0.97)**	1.37 (0.73–2.56)	1.10 (0.57–2.13)	1.24 (0.70–2.20)	0.48 (0.20–1.13)	0.87 (0.45–1.67)	0.55 (0.26–1.16)
Employment: working for pay vs not working for pay	**0.76** **(0.58–0.99)**	0.73 (0.54–1.00)	0.99 (0.75–1.31)	**0.67** **(0.51–0.90)**	0.93 (0.70–1.22)	**0.54** **(0.39–0.75)**	0.82 (0.63–1.07)	0.33 (0.22–0.50)	0.94 (0.72–1.24)	0.58 (0.42–0.81)
Assessment date June 2020–May 2021 vs May 2022–March 2023	**3.77** **(2.66–5.35)**	**6.87** **(4.56–10.36)**	**2.27** **(1.58–3.25)**	**3.38** **(2.26–5.05)**	1.16 (0.81–1.65)	1.08 (0.72–1.62)	1.26 (0.91–1.75)	0.90 (0.56–1.47)	**2.45** **(1.74–3.46)**	**3.57** **(2.35–5.42)**
Assessment date June 2021–April 2022 vs May 2022–March 2023	**1.83** **(1.35–2.49)**	**1.85** **(1.26–2.71)**	**1.56** **(1.13–2.15)**	**1.80** **(1.23–2.63)**	1.05 (0.75–1.45)	1.07 (0.75–1.54)	0.98 (0.73–1.32)	0.83 (0.54–1.28)	**1.80** **(1.34–2.44)**	**1.94** **(1.34–2.80)**
PEG score[a]	**1.08** **(1.02–1.15)**	**1.26** **(1.17–1.36)**	1.00 (0.94–1.07)	**1.14** **(1.06–1.22)**	1.10 (1.03–1.17)	**1.32** **(1.22–1.43)**	**1.12** **(1.05–1.19)**	**1.36** **(1.23–1.50)**	1.05 (0.99–1.11)	**1.21** **(1.12–1.31)**
Depression screen[b] Positive vs negative	1.21 (0.97–1.53)	**1.85** **(1.40–2.44)**	**1.45** **(1.14–1.85)**	**2.30** **(1.78–2.97)**	1.28 (1.01–1.62)	**1.63** **(1.23–2.17)**	**1.49** **(1.19–1.86)**	**2.15** **(1.49–3.10)**	**1.44** **(1.14–1.82)**	5.47 (4.04–7.40)
Housemate had COVID Yes vs no	1.32 (0.99–1.77)	1.19 (0.83–1.70)	**1.53** **(1.12–2.08)**	0.91 (0.65–1.28)	1.31 (0.96–1.77)	1.14 (0.80–1.63)	1.34 (1.00–1.79)	0.98 (0.62–1.55)	**1.51** **(1.11–2.04)**	1.33 (0.91–1.95)

The covariates alcohol use disorder, participant having COVID-19, and education (bachelor vs advanced degree) were excluded from the table because of a lack of significant associations.

[a] PEG = Pain, Enjoyment of Life, and General Activity scale; scores range from 0 to 10, with higher scores indicating more severe pain.

[b] Screen based on PHQ-8 (Patient Health Questionnaire Depression scale [PHQ-9]).[26] Scores of 10–24 indicate significant depression.

unrest in the United States related to the killing of George Floyd near the outset of the pandemic, negatively impacted the mental and emotional well-being of African Americans. Combined with structural racism and inequities in mental health treatment access,[36] the pandemic yielded what Shim and colleagues refer to as an "emerging syndemic" (synergistic epidemics) during the COVID-19 pandemic.[37] Adding chronic pain to the conditions that negatively impact the mental and emotional health of individuals, we can see the compounding effects in minoritized populations. This highlights the need for further efforts to improve access to mental health services among minoritized groups, both as a standard of care and to buffer the effects of a future public health emergency. However, as Adepoju and colleagues have demonstrated, the introduction of telehealth services alone is insufficient. Consideration must be given to intersecting systemic issues within and among racial groups, such as socioeconomic status, education level, employment status, and lack of access to technology and internet, all of which can impact the use of telehealth modalities for minoritized groups.[19,20]

The finding that Hispanic participants were more likely than White participants to report that their social support was *a lot worse* because of the pandemic might speak to the culture of "familism" among Hispanics. Social support from the family has been reported to be the most important aspect of familism for Hispanics.[38] Hispanic people, even those who were highly acculturated, were found to be more familistic than non-Hispanic Whites.[39] Familism could help to explain why participants from minoritized groups have been more likely to report that their social support was much worse than it was for White participants. The imposed social restrictions likely disproportionately impacted cultural groups that have a greater sense of family and community and therefore a greater propensity for social support.

Educational status was another demographic variable that showed differential associations across COVID-19 impacts. The finding that those with an advanced degree experienced greater negative impacts on access to health care and social support than did those with a high school degree or less could reflect intersection with associated socioeconomic variables. For example, it might be that those with advanced degrees had greater pre-pandemic access to health care, thus enhancing the experience of loss when such access was restricted. Similarly, it might be assumed that those with advanced degrees were more likely to be employed, which afforded them opportunities for more work-based socialization. The loss of the same because of quarantine restrictions might explain the greater impact in the social support domain for this group. Conversely, those with a high school degree or less reported greater pandemic-related impact in the domains of finances and ability to meet basic needs. This could be related to reduced financial resources and security for this group, thus making the socioeconomic restrictions imposed by the pandemic more impactful.

Another demographic factor associated with differential impacts of the pandemic was participant gender. Compared with males, females reported that their social support and mental health were *a lot worse*. These findings could be related to greater caregiver burden experienced by females, as caregiver demands shifted during the pandemic because of mandated quarantines, working from home, homeschooling, and overall reduction of social opportunities outside of the home. This is supported by the work of Dinella and colleagues,[40] who showed a disproportionate increase in burdens experienced by women compared with men in domains such as household responsibilities, worries about their children's well-being, finances, health care, housing and food security, physical safety, domestic violence, and overall stress during the pandemic.

Associated with caregiver burden and chronic pain is the experience of depression. As would be expected, results showed that participants with depression were more likely than participants who were not depressed to report impacts of the pandemic that were *a lot worse* in all domains assessed. The high degree of comorbidity between chronic pain and depression is well documented,[7,10] and the results of the present study demonstrate the compounding effects of these comorbid conditions on participants' ability to cope with the psychosocial stressors imposed by the pandemic. Unexpectedly, similar effects were not found for participants who screened positive on the AUDIT-C, as this measure was not found to be associated with impact in any of the domains assessed. The pandemic itself, through reduced social and occupational obligations imposed by quarantine restrictions and lockdowns, might have served to mitigate the adverse effects of excessive alcohol use, thus clouding the unique impacts of such use in the domains assessed on the COVID-19 questionnaire.

One promising finding from the present study was that negative impacts in some domains were reduced as the pandemic progressed, with fewer negative impacts found later in the pandemic. This pattern was found in access to health care, social support, and mental and emotional health. These findings are not surprising, as the passage of time during the pandemic coincided with loosening of quarantine measures, the establishment of broader-reaching virtual health care services, the resumption of in-person services, and the introduction of governmental financial support programs that helped to temporarily mitigate financial burdens. These observed trends support the validity of the PMC COVID-19 Measure, as pandemic-related impacts should lessen with the passage of time as society emerged from the pandemic-related restrictions.

There are methodological issues with the present study that limit interpretation and application of the study findings. First, the data used came from a convenience sample of military veterans receiving care through the Department of Veterans Affairs, thus limiting application to non-veteran samples. Additionally, the analyses were conducted on self-report data, and we did not have objective data on which to further assess the outcomes (eg, participant health care utilization data). We also did not have longitudinal data that would help to contextualize participants' self-reports of pandemic impact. Though the methods used to the develop the PMC COVID-19 Measure were comprehensive,[23] the measure is novel, and the items and associated scaling of the measure have not been tested for criterion validity or reliability with patients. The high rate of depression found in the study sample was noteworthy, and depression might have led individuals to disproportionately attribute problems in multiple domains to the pandemic, when it might have been new-onset or worsening depression that was weighing on the other impact ratings.

Implications

Results from the present study demonstrate that the COVID-19 pandemic had a significant impact on key psychosocial domains for veterans living with chronic pain—a population already vulnerable to the negative impacts of psychological and social factors on their physical condition. As suggested by Coleman and colleagues,[21] the assessment of COVID-19 impacts in the setting of pain clinical trials conducted during the pandemic is essential to account for the influence of such effects on study participants and the treatment effects for which they are being assessed. This is particularly true in pragmatic trials, where a controlled research environment, which could help to mitigate some of these impacts, is absent. Through use of the PMC COVID-19 Measure, we have been able to quantify the impacts of the pandemic on 5 key domains representing areas in which individuals living with chronic pain are already vulnerable. As pragmatic clinical trials conducted during the pandemic move to analysis of final outcomes, results from this impact measure will help to contextualize those findings and control for the moderating effect of pandemic impacts on study results.

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