Testing a Program to Increase Patient Activation Among Patients Prescribed Opioid Medicine for Chronic Pain

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ABSTRACT

Background: Prescription opioid use can present challenges for patients with chronic pain as well as for health systems. These patients typically have multiple chronic conditions and many points of contact with the health system. They can feel disempowered and report concerns about undertreatment of pain, difficulties in obtaining medication, and stigma. Use of prescription opioids is now a controversial approach to managing pain long term, with the prescribing environment becoming more restrictive. At the same time, patients may lack the skills and knowledge to talk to their physicians about their pain and opioid use, and to navigate the health care system. As patients reduce their opioid use, whether voluntarily or involuntarily, physicians must find innovative and effective ways to support these patients and improve their quality of life and function.

Objectives: This study aimed to develop a patient-centered intervention curriculum and compare the effectiveness of the intervention on patient-centered outcomes among patients receiving long-term opioid therapy. The goal of the intervention was to empower patients and move them toward a greater partnership role in their health care team. Our hypotheses were that patients in the intervention would increase their activation; improve self-management of pain; improve pain, function, and quality of life; decrease prescription opioid use; decrease utilization of acute services; and report improved satisfaction and communication with physicians.

Methods: In partnership with patient, clinical, and health system stakeholders, we conducted a pragmatic, randomized trial to examine the effectiveness of a 4-session, 90-minute group-based patient activation intervention for patients receiving long-term opioid therapy in 2 large primary care clinics in an integrated health care system. We randomized 376 patients to either the intervention arm (n = 189) or usual care–only arm (n = 187). The intervention curriculum covered patient activation and empowerment; risks of prescription opioid use; how to talk to physicians about prescription opioid use; and self-management strategies for pain, including how to navigate the health care system and the online patient portal. We developed the study questions, intervention curriculum, patient-centered outcome measures, and dissemination plan with our patient partners and other stakeholders. We conducted interviews at baseline, 6 moths, and 12 months. The primary outcome was patient activation. We also analyzed many secondary outcomes, including overall health, quality of life, depression, pain severity, function, patient–provider communication, patient satisfaction, prescription opioid use, pain management strategies, and health care utilization. We analyzed questionnaire and electronic health record data using bivariate comparisons and repeated measures, mixed-effects regression models.

Results: Among the 376 enrolled patients, 354 (94%) and 342 (91%) completed the 6-month and 12-month follow-up assessments, respectively. We found no effect of the intervention on patient activation scores (estimate of the interaction of intervention and time in the mixed-effects model = 0.17; 95% CI, –1.54 to 1.88; p = 0.85). For the secondary outcomes, bivariate results indicated that participants in the intervention arm, compared with usual care, reported

significantly higher overall health scores at 6 and 12 months (p = 0.001 and 0.007, respectively), as well as function scores at 12 months (p = 0.02, everyday physical activity; p = 0.01, social activity and roles), and lower prevalence of moderate to severe depression at 12 months (p = 0.02). Participants in the intervention also demonstrated more of a decrease in the prevalence of depression over time compared with the usual care arm (estimate of the interaction of intervention and time in mixed-effects model = –0.56; 95% CI, –1.02 to –0.10; p = 0.02). Participants in the intervention arm were more likely to use pain management strategies such as mindfulness and meditation at 6 and 12 months (< 0.001) and exercise at 12 months (< 0.001). The intervention group demonstrated a greater increase in the use of exercise for pain management compared with the usual care arm over the 3 time points (estimate of the interaction of intervention and time in mixed-effects model = 0.44; 95% CI, 0.07-0.81; p = 0.02). Participants in the intervention arm were more likely to use the online portal's health and wellness resources at 6 and 12 months (p = 0.02 and < 0.001, respectively), and the trend was significantly higher for the intervention arm over time (estimate of the interaction of intervention and time in mixed-effects model = 0.41; 95% CI, 0.02-0.79; p = 0.04). We found no effect of the intervention on quality of life, pain severity, patient–provider communication, patient satisfaction, health care utilization, or prescription opioid use.

Conclusions: The intervention did not have an observable effect on patient activation. However, we found modest effects on select secondary outcomes that reflect increased self-care and greater engagement with the health care system. These findings suggest that a limited intervention focused on patient activation and nonpharmacological pain management set in primary care may be an effective adjunct to treatment for patients with chronic pain.

Limitations: Changes in the prescribing environment necessitated expanding study eligibility criteria from patients starting regular opioids to patients taking long-term opioids. Recruitment overall was lower than anticipated, resulting in a modest sample size and potentially limiting our ability to identify smaller effects. Multiple comparisons also require caution in interpreting findings.

BACKGROUND

Chronic pain affects more than 100 million adults in the United States.[1] Individuals with chronic pain (duration ≥ 3 months) are more likely to have worse health status, to use more health care services, and to suffer from more disability than those with less severe pain. The annual cost of chronic pain is estimated to be $560 billion to $635 billion, due to medical costs, lost productivity, and costs associated with disability.[1] Prescription opioids have been the primary treatment for chronic pain, with very liberal use in the United States. The number of opioid prescriptions increased from approximately 76 million in 1991 to nearly 207 million in 2013.[2]

With the opioid crisis, patients and the medical profession are now aware of the lack of evidence of opioids' long-term effectiveness for noncancer pain, as well as their associated risks, such as opioid-induced hyperalgesia, misuse and dependence, and overdose. In 2016, nearly half of all US opioid overdose deaths involved a prescription opioid.[3] In 2015, approximately 2 million people received a prescription opioid use disorder diagnosis,[4] and more than 15 000 people had a fatal overdose related to prescription opioids,[5] higher than in 2014.[6]

In response to the opioid crisis, federal and state agencies have issued comprehensive guidelines and policies to reduce risky opioid use for patients with noncancer pain.[7] Health systems have also initiated programs to reduce opioid prescribing and dosages.[8] In this more restrictive prescribing environment, physicians are less willing to prescribe opioid medications and are highly concerned about misuse and abuse. This has led to decreases in opioid prescribing nationally since 2012,[9,10] although opioid misuse and overdose continue to increase from the increased use of heroin and synthetic opioids.[3] Patients are facing a dilemma of how to manage their pain and health needs in an environment in which opioid access is becoming restricted and awareness of the risks of opioids is increasing. Non-medication-based strategies that are accessible to patients can play a key role in supporting patients.

New prescribing policies are intended to improve patient safety, but it is not clear how patient-centered these types of initiatives are.[11] Patients with pain face difficulty managing

their pain and fear losing access to medication. Patients can find it intimidating to talk with providers and fear being seen as the "difficult patient" or as an "addict."[12] They often experience stigma from using prescription opioids and can feel unheard by the health system.

In this changing environment, the need for a patient-centered approach to pain management that addresses patients' complex needs is critically important. Patients with pain often have sleep disturbance, anxiety, depression, and functional decline (difficulty with everyday tasks), in addition to the underlying condition causing the pain. Effective treatment often necessitates a range of treatment modalities, including psychological, educational, and exercise/physical therapy; pharmacotherapy; mindfulness; and complementary therapies (eg, acupuncture).[13-15] There is a considerable body of research on nonpharmacological and/or multidisciplinary approaches to pain management, but little research has been conducted on patient-centered approaches set in primary care.

The ACTIVATE study addressed this gap by examining the effectiveness of a behavioral intervention in primary care aimed at activating patients with noncancer pain to become more knowledgeable about opioid use and alternative pain strategies, and empowering them to take charge of their health care and proactively communicate with their providers. This self-management approach is consistent with models for managing other chronic medical conditions in primary care[16] and reflects the sentiment of the 2011 Institute of Medicine (IOM) report calling for "the patient as the source of control."[1] We selected the primary care setting because pain is largely managed by primary care, and it is where most prescription opioids are prescribed.[17] In addition, we wanted to identify patients further "upstream," before problems were more severe, and we wanted to locate the study in a less stigmatized setting. The design, four 90-minute sessions, was well suited to a busy primary care clinic where an extensive multidisciplinary approach (as found in specialty care) is not feasible. The intervention was not intended to be a full chronic pain program but rather to be comprehensive enough for less severe patients to see improvement, or to act as a bridge to a more comprehensive program for more severe patients. Although there are several studies on the treatment of chronic pain in

primary care, limited research has been conducted in this population with an intervention emphasizing patient activation.[18,19]

Our conceptual framework drew heavily on Judith Hibbard's definition of patient activation of "understanding one's role in the care process and having the knowledge, skill and confidence to manage one's health and health care" and the belief that an activated patient is a critical component of shared decision making.[20,21] Hibbard et al broke down the definition of patient activation into these characteristics: ability to self-manage illness, ability to engage in activities that maintain function, ability to be involved in treatment and collaborate with providers, and ability to select providers and navigate the health care system.

We also based our approach on work by Bernabeo and Holmboe[22] (adapted from work by Towle and Godolphin).[23] The Bernabeo framework describes patient, physician, and health system competencies that are necessary to achieve patient-centered care. Patient competencies include defining the preferred patient–physician relationship, accessing information and services, sharing information, and giving feedback. Our patient activation intervention incorporated aspects of motivational interviewing (eg, meeting patients where they are)[24] and cognitive behavioral[25] approaches to introduce, motivate, and facilitate patients' engagement in the health system's patient portal and other health education services, and to encourage patients to partner with their physician. Based on this framework, the ACTIVATE intervention aimed to build patients' competencies by expanding their health literacy; educating them on the risks of long-term opioid use, the neurobiology of pain, and nonpharmacological alternatives to pain management; and teaching them strategies for communicating with providers. The curriculum built on a prior patient activation study at the Kaiser Permanente Northern California (KPNC) Division of Research that was shown to be effective in a substance use population, many of whom had chronic pain.[26] It incorporated health information technology as part of the curriculum, teaching patients to access the online patient portal, track health measures (eg, blood pressure), and access online health education and pain management resources. Although several studies have featured interventions

designed to increase patient activation in different patient populations,[27-31] few interventions have focused on increasing activation in primary care or with patients with chronic pain.

Working with an extensive stakeholder group, researchers at the KPNC Division of Research developed the curriculum for a behavioral intervention in primary care (aim 1). Using an intent-to-treat approach, with data from patient surveys and the electronic health record (EHR), we measured the effect of the intervention on patient-centered outcomes (aim 2) and opioid use (aim 3; see Box 1 for study aims and hypotheses).

Box 1. Study Aims and Hypotheses

Aim 1: To refine and finalize a patient-driven intervention curriculum and patient-centered outcomes, working with the stakeholder group.

Aim 2: To compare the effectiveness of a patient activation intervention on patient-centered outcomes. Patients in the intervention:

H2.1: Will have greater improvement in activation, satisfaction, pain and function scores, quality of life, and provider communication over time.

H2.2: Will be more likely to engage in self-management strategies.

H2.3: Will be more likely to use primary care, and less likely to use acute care services.

Aim 3: To compare the effectiveness of a patient activation intervention on prescription opioid use.

H3.1: Patients in the intervention arm will be more likely to reach their goal for prescription opioid use and/or decrease their use over time.

STAKEHOLDER ENGAGEMENT

We engaged a panel of patient and clinical stakeholders in all aspects of the research—from design and implementation to analysis and dissemination. Stakeholders consisted of 5 patient partners (4 by the end of the study, as 1 died during the study), 9 clinical and operational stakeholders, 1 patient advocate, and 1 academic researcher, all with significant professional and/or personal experience with chronic pain and prescription opioids. Three patient stakeholders were from KPNC. Because we were interested in the potential portability of the intervention to a different type of health system, we also included 2 patients from Contra Costa Medical Center (CCMC), a local federally qualified health center (FQHC). To incorporate multiple disciplines that treat pain, we included 7 KPNC clinical and operational leaders representing primary care, emergency medicine, chronic pain, pharmacy, anesthesiology, psychiatry, and addiction medicine. In addition, we included a pain physician and an addiction medicine physician from the CCMC, for an external perspective. The panel also included the director of a national patient chronic pain advocacy organization, and a pain researcher from academia. Stakeholders represented a range of experience and attitudes regarding chronic pain and opioid use. Two of the patients were receiving long-term opioid therapy, and most of the clinical stakeholders espoused the appropriate use of prescription opioids. Although clinical stakeholders represented divergent views, most tended to be conservative, which is the current trend among providers. We based our approach to stakeholder engagement largely on the PCORI engagement rubric.[32,33] The guiding principles for developing partnerships between researchers and stakeholders were honesty, transparency, and respect.

We recruited the KPNC and CCMC patient partners through specialty pain programs from each health system. We attended the patient meetings to identify patient stakeholders with chronic pain who were currently or previously prescribed opioid therapy, were comfortable expressing themselves, and were interested in participating. We selected individuals based on the following criteria: previous experience in a similar capacity, demonstrated ability to participate in group discussions, and ability to commit to the responsibilities of being a stakeholder for the duration of the study. We selected the KPNC

patient partners early in the process, and they contributed to developing the research questions for the PCORI application. We identified the CCMC patient stakeholders after the study was funded. After inviting patients to participate, researchers discussed expectations, roles, compensation, and study timeline. Investigators used their existing networks to identify clinical and operational leaders. Compensation was equitable among stakeholders. We conducted necessary trainings and provided background on the study's goals and outcomes.

Early in the study, we met separately with patient partners to orient them, provide background information, establish roles and responsibilities, and ensure they felt comfortable meeting with the physicians and other clinical stakeholders.[34] We met more frequently with the patient stakeholders as we developed the study questionnaire and curriculum. We also communicated regularly via email and telephone and by periodic e-newsletters. After the first year, we held group quarterly meetings with patient partners and clinical and operational stakeholders.

We involved stakeholders in participant recruitment and retention, development of data collection instruments, intervention curriculum development, data interpretation, and dissemination strategies. We structured meetings to allow time for informal discussions, and we asked patient partners to lead discussions or present their perspectives. We routinely asked stakeholders for feedback on their experience and made modifications when possible.

During the proposal writing and pre-award phase, we conducted a focus group at the KPNC Pain Program to help us refine the study's aims, design the intervention, and develop patient-centered outcomes. Several themes emerged that guided the development of the intervention curriculum. Patients expressed a desire for direct and clear communication about the potential harms and side effects of using opioids long term, in addition to the benefits of pain control. In particular, they wished they had known about the possibility of developing dependence and hyperalgesia, the phenomenon in which pain actually worsens with long-term opioid use. Patients desired more information on alternative treatment options and how to find them. Patients who had successfully tapered off opioids wanted other patients to know that there is life beyond opioids, and that opioids are not the only way to manage pain. Patients

who were receiving long-term opioid therapy stressed the importance of appropriate opioid use for pain management. This feedback guided curriculum development and highlighted the importance of a balanced educational component to the intervention. In addition, patients consistently wanted validation of their pain, and they wanted to feel heard and respected by their medical providers. As a result, one session focused extensively on improving communication with providers.

Throughout the study, patient stakeholders shared their stories and experiences of living with chronic pain and their journey with opioids. Sharing these experiences helped increase other team members' understanding and empathy. Some contributions were more practical; for example, patient stakeholders advised offering afternoon/evening sessions due to pain being worse in the morning, and they emphasized accessibility for patients with walkers and wheelchairs. They suggested lengthening the sessions to provide more opportunity for informal discussions and to facilitate the formation of peer groups. To address recruitment challenges, patient partners suggested we emphasize to eligible participants that patients were participating in the research itself.

In preparation for data interpretation, patients participated in data training sessions conducted by the project manager (topics included understanding statistical tables, *p* values, and clinical vs statistical significance). As a result, the patient partners became intimately familiar with the data and provided unique insights into the results, such as speculating why depression was not higher in the sample. They supported dissemination efforts by identifying overlooked target audiences, promoting awareness through social media, and presenting results at conferences. One patient stakeholder attended the 2016 PCORI Conference and participated in a panel presentation. Another held weekly Facebook live sessions on fibromyalgia. Our KPNC clinical stakeholders have begun to incorporate elements of the study curriculum at their clinic, and several patients have expressed interest in continuing their involvement with patient-centered research.

Clinical stakeholders provided insights specific to their specialties: For example, clinicians from the KPNC Pain Program offered suggestions for making the intervention more

interactive, incorporating practical topics like pacing; other pain specialists offered insights into the issues of opioid tapering; and the pharmacist provided a unique perspective on policies the health care system was enacting to reduce high-risk prescribing. Primary care physicians provided important perspectives on new prescribing guidelines and the challenges they face in treating patients with pain. Clinicians in leadership positions provided context for the shifts in prescribing policies. A representative from the American Chronic Pain Association, a patient advocacy organization, helped raise awareness of the experience of living with pain, provided a deeper understanding of the ways the health care system can improve the lives of people living with pain, and highlighted how pain policy was changing outside KPNC. She emphasized the importance of using patient-centered language, such as "patients with pain," rather than more labeling terminology, such as "chronic pain patients." All stakeholders helped identify and select study outcomes that were relevant and meaningful to patients, such as function, social roles, depression, and sleep.

METHODS

Study Overview

The first aim of the ACTIVATE study was to work with stakeholders to develop the intervention curriculum for primary care patients receiving long-term opioid therapy. The curriculum covered patient activation and empowerment, how to talk to physicians about prescription opioid use, and self-management of chronic pain. The second aim was to test the effectiveness of the intervention by randomizing participants to receive the intervention plus usual care compared with receiving only usual care. We then compared the 2 study arms using patient-centered outcomes (aim 2) and prescription opioid use (aim 3) at 6 and 12 months following baseline. Adherence to the PCORI Methodology Standards is addressed throughout and described in detail in the appendix.

Study Design

The study design was a 2-arm, pragmatic, randomized trial. We selected a pragmatic design because the goal of the study was not to study efficacy, as the efficacy of the intervention

concepts (eg, motivational interviewing, cognitive behavioral therapy) have already been established.[35-38] Instead, the goal was to study the effectiveness of the intervention for real-world clinical practice and policy, and to ensure generalizability by including a wide range of participants (eg, patients with complex health needs). Usual care was the comparator, as most patients receiving long-term opioid therapy are not offered alternatives to usual care in this and other health systems. Some health systems offer pain clinics, but they can manage only a small percentage of patients who need treatment, and the study's focus was a real-world situation. Thus, we implemented the intervention in typical primary care settings and selected patients with minimal exclusion criteria to maximize applicability of results to the general population.[39]

Study Setting

We conducted the study at 2 large primary care clinics in KPNC, an integrated health care delivery system comprising 21 medical centers and serving approximately 4 million members in northern California. The membership is racially and socioeconomically diverse and highly representative of the region's demographic characteristics.[40] We selected the primary care clinics because of their diversity and their ability to provide the necessary sample size. We selected primary care as the setting because the study aims specifically focused on delivering the intervention in primary care, and for the reasons described previously (eg, identifying a range of patient severity, choosing a less stigmatized setting, selecting the setting where most prescription opioids are prescribed).

Participants

Study Recruitment and Eligibility Criteria

We recruited study participants from the target population: patients receiving long-term opioid therapy who were presumed to have chronic pain (prescription opioid use was a proxy for chronic pain, as chronic pain is difficult to identify with *International Classification of Diseases* [*ICD*] codes in the medical record). We identified adult patients (≥ 18 years of age) from the EHR with a primary care physician at 1 of the 2 study clinics who had a cumulative days' supply of opioid medication of at least 3 days per week dispensed in the previous 3-

month period. We mailed lists of potentially eligible patients to the patients' primary care physicians and asked them to exclude patients who had serious medical or psychological issues, or who were otherwise not appropriate for the study (eg, could not participate in groups). The study clinician then conducted a systematic review of the EHR to further exclude patients who were not eligible due to cancer, very poor health, cognitive impairment, or severe mental illness according to their medical record. Study staff mailed recruitment letters to the remaining eligible patients, describing the study and inviting them to participate. Ten days later, trained recruiters called potential participants; they made up to 7 calls. At contact, recruiters confirmed eligibility (Table 1) and eligible patients were invited to participate. The study also recruited eligible patients through self-referral (through posted study flyers at the medical facility) and physician referral. Eligible patients who were willing to be randomized had an in-person baseline appointment in the primary care clinic, where they provided informed written consent and completed a 1-hour online questionnaire. The KPNC Institutional Review Board (IRB) reviewed and approved all research procedures, and the National Institutes of Health (NIH) granted the study a Certificate of Confidentiality.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria
1. Prescription opioid use for pain in the past 3 months (3+ days' supply per week) 2. Aged 18 or older 3. Able to understand and speak English 4. KPNC member with primary care physician at one of the 2 clinic sites 5. Willingness to be randomized
Exclusion Criteria
1. Diagnosis of dementia, bipolar disorder, schizophrenia, a chronic or terminal illness, or other serious health problem that would limit participation in study 2. Active substance use diagnosis documented in EHR and/or substance use treatment 3. Active participation in a pain program 4. Active plan to taper within 30 days to ensure curriculum was relevant 5. Close friend or relative participating in study 6. Participation in other KPNC study 7. KPNC members on the "do not contact" list 8. Excluded by physician

Randomization

We conducted block randomization with a block size of 4 using an SAS random-number generator (SAS Version 9.3). Study staff placed each assignment in a sealed opaque envelope. After confirming patient consent and administering the baseline survey, the research associate opened an envelope and revealed the identity of the treatment group. The trial was not blinded because patients and researchers needed to know the treatment arm to implement the intervention. However, the research staff was blinded to study status during baseline data collection and follow-up interviews, unless the participant revealed his or her status to the interviewer.

Intervention and Usual Care

The behavioral intervention was aimed at "activating" patient behavior about pain management and prescription opioid use. The intervention consisted of four 90-minute group sessions conducted weekly for 4 weeks by a licensed psychologist with expertise in populations with chronic pain. We designed the intervention to be brief and easily accessible for patients; the goal was not to provide an intensive pain program, but to support patients with fewer needs in a more accessible environment in primary care, or to be a "stepping stone" to further treatment for more severely affected patients. The curriculum addressed the following topics: empowering patients to take an active role in pain management and overall health; pain management lifestyle practices, level of readiness to address these strategies, and practicing new pain management skills; an introduction to KPNC's online patient portal and other health information technology resources for active self-care; and a discussion of communication strategies with their primary care team to develop collaborative communication about treatment goals (see Box 2 for details). The curriculum was not intended to promote tapering or discontinuation of opioids. We used motivational interviewing techniques to elicit and share different points of view and encourage a balanced discussion of opioid use. To increase session attendance and ensure patients received the intervention curriculum, we scheduled groups at convenient times and locations, and provided make-up sessions.

Patients randomized to usual care received the standard of care as determined by their provider(s) in the KPNC system. We chose usual care as the comparator group for this

pragmatic trial because we wanted to learn how this intervention could benefit patients in a real-world primary care setting. The primary alternative for treating chronic pain is specialty clinics, which are not universally available in health systems and are not able to accommodate the large number of patients with chronic pain. Utilizing the EHR (eg, utilization and pharmacy data), we quantified the services that the usual care arm received.

Overall Study Outcomes

Investigators and stakeholders identified patient-centered outcome measures that were based on previous research and study aims and reflected priorities for patients (eg, function, depression) as well as clinicians (eg, opioid use, health care utilization). All measures were discussed in stakeholder meetings and reviewed in detail by patient partners. We used standardized, validated instruments when available to be comparable with other studies. In addition to self-reported data collected at baseline, 6 months, and 12 months, we extracted health care utilization and prescription opioid dispensation data from the EHR for the relevant time frames.

Box 2. Overview of 4 ACTIVATE Intervention Sessions

Session 1	***Empowering patients to take an active role in pain management and overall health***
	• Patients' perceptions of their role in their health care; importance of shifting to an active stance • Patients' difficulty talking with providers about opioids and being a patient with pain • Patients' pros and cons of using opioids • Education about whether opiates are the only way to treat pain • Mind–body framework to pain management • Gate Control Theory of Pain; self-regulation strategies
Session 2	***Pain management lifestyle practices, level of readiness to address these strategies, and practicing new pain management skills***
	• Healthy behaviors/lifestyle (eg, exercise, sleep, caffeine, nutrition, alcohol, tobacco, emotional health) related to pain health • Readiness ruler to communicate priorities to physicians • Education on the relationship of stress and pain—stress management skills • Physiological self-regulation skills: 1-Stone Mindful Distraction, body scan, diaphragmatic breathing, pacing, guided imagery
Session 3	***Patient introduction to KPNC's online patient portal and other resources for active management***
	• Practice logging on to KPNC's patient portal to access EHR via computers and smartphones; increase confidence in self-management • Track/graph test results and labs, change providers, book appointments, etc • Online pain programs, mindfulness, sleep programs, resources for acupuncture, nutrition • Patients' shared non-KPNC technological resources
Session 4	***Discussion of communication strategies with patients' primary care team—how to develop collaborative communication about treatment goals***
	• How to collaborate with primary care provider • Set priorities with readiness ruler • Communicate assertively • Bring "My Care Plan" to appointments • What if it doesn't go well? • Discussion of the importance of planning for upcoming periods of increased stress in terms of prevention/sustainability

Primary Study Outcome

Patient Activation

We measured the primary study outcome, patient activation, using the Patient Activation Measure (PAM-13), a 13-item instrument for measuring patient beliefs, knowledge, and confidence in managing health-related tasks.[20,41] We converted raw scores (range 0-52) to PAM-13 scores (range 1-100) using a conversion table, with higher scores related to positive outcomes such as participation in health care and treatment adherence.[42] The score represents the person's concept of himself or herself as an active manager of his or her health and health care. An increase in 3 to 5 points over time is associated with improved health behaviors and outcomes.[42] Scores are often subdivided into 4 groups, known as levels of activation; however, the 0 to 100 score is the most useful for determining patient progress or assessing the impact of interventions.

Secondary Study Outcomes

Depression

We measured depression using the Patient Health Questionnaire-9 (PHQ-9), a reliable and well-validated instrument used to screen and diagnose depression severity.[43] Scores range from 0 to 27 and indicate severity of depression: mild (5-9), moderate (10-14), moderately severe (15-19), and severe (over 20).[44] Depression was also captured as a domain on the PROMIS-29 (a 29-item short form developed by the Patient-reported Outcomes Measurement Information System that is used to measure 7 health domains of particular concern to patients with chronic pain [function, anxiety, depression, fatigue, sleep, social role, and pain interference]).[45-47]

Quality of Life

The PROMIS Global Health measure assessed general perceptions of health and quality of life.[48] The 10 items can be reported individually or as representing 2 dimensions, Mental Health and Physical Health, each with 4 items. We converted raw scores for the Global Mental

and Physical Health score to standardized *T* scores using published conversion tables. *T*-score distributions are standardized such that a 50 represents the mean for the US general population, and the standard deviation (SD) around that mean is 10 points. A high score represents more of the concept being measured. Thus, for Global Mental Health and Global Physical Health, a person who has a *T* score of 60 is 1 SD better than the general population.

Overall Health

Overall health status was represented by the single item on the PROMIS Global Health ("In general, would you say your health is . . .?"). Answers are reported as a raw score with the range 1 to 5, with 1 = poor to 5 = excellent.[48]

Pain Intensity

We used a single item on the PROMIS Global Health to assess pain intensity ("How would you rate your pain, on average?"). Pain level is reported as a raw score with the range 1 to 10, with 1 = no pain to 10 = worst imaginable pain. The published scale is 0 to 10; however, we inadvertently included a 1 to 10 scale in our survey. The omission of the 0 value is unlikely to impact the interpretation of this measure, however, because we report the mean and standard deviation, and both treatment arms used the altered scale. In addition, very few people reported a score of 1 (1 person at baseline, 3 people at 6 months, and 5 people at 12 months).

Functional Status

We used single items on the PROMIS Global Health to assess self-reported performance on social activities and roles, and performance of everyday physical activities (such as carrying groceries and climbing stairs). We also assessed the following functional domains using the PROMIS-29: physical function, satisfaction with social role, and level of pain interference.

Satisfaction with Care

We assessed satisfaction with overall health care, the patient's primary care physician, and pain management care using a 1 to 10 scale, with 1 being the worst, and 10 the best, possible care. Satisfaction with care is a commonly used measure when conducting research in a health care delivery system, and it was an important factor to assess, considering the sensitive topic and the dynamic prescribing environment.

Opioid Misuse

The Screener and Opioid Assessment for Patients in Pain (SOAPP) is a 5-item instrument used to predict the risk of possible misuse for patients considering long-term opioid use.[49,50] Each item is rated 0 = never to 4 = very often; ratings are added for all 5 items for a range of possible scores from 0 to 20, with a score ≥ 4 indicating risk of misuse. Results reported are the number and percentage of participants who score ≥ 4. The Current Opioid Misuse Measure (COMM) is a clinical screening tool used to monitor patients who take opioids for an extended period of time for overuse and misuse in 6 areas.[51] The COMM contains 17 items, with scores ranging from 0 to 68; a score of ≥ 9 is considered positive. It uses a low cutoff value because it is intended to overidentify misuse. Results reported are the number and percentage of participants who score ≥ 9. We used 2 measures to quantify risk because they captured slightly different time frames: SOAPP predicted future misuse and COMM monitored current misuse.

Pain Coping

The Chronic Pain Coping Inventory (CPCI) assesses behavioral and cognitive coping strategies that are typically targeted during pain management treatment.[52] The inventory includes coping strategies that are wellness focused and encouraged in pain management (eg, relaxation, exercise/stretch, task persistence, coping self-statements), coping strategies that are illness focused and discouraged (eg, guarding, resting, asking for assistance), and one neutral strategy (ie, seeking social support) that is neither encouraged or discouraged.[52] The use of wellness-focused coping strategies was a focus of the intervention curriculum and has been associated with positive effects, increased functioning, and higher activity levels.[52] We used the

abbreviated 42-item CPCI (CPCI-42), which contains 8 subscales: guarding, resting, asking for assistance, relaxation, task persistence, exercising/stretch, coping self-statements, and seeking social support.[53] For each subscale, patients were asked the number of days (0-7 days) they performed each task. Scores, which ranged from 0 to 7, were calculated separately for each of the 8 subscales.

Self-efficacy

The Pain Self-efficacy Questionnaire (PSEQ) is a validated 10-item scale used to measure self-efficacy in patients with chronic pain.[54] It assesses patients' expectations of performing particular tasks and confidence in being able to perform tasks despite the pain. Answers are reported on a scale of 0 to 6, with 6 indicating being extremely confident, with an overall score range of 0 to 60.

Patient–Provider Communication

We used 2 standardized validated scales to assess patient–provider communication: the Communication Assessment Tool (CAT) and the Perceived Efficacy in Patient–Physician Interactions (PEPPI) questionnaire. The CAT measures patients' perceptions of physician performance on communication and interpersonal skills.[55] It has 14 items that ask respondents to rate their primary care physician for the last 2 visits using a 5-point rating scale (5 = excellent). Average scores are reported, as are the percentage who report "excellent." The PEPPI assesses patients' confidence when interacting with their physician.[56] Ten items measure patients' perceived self-efficacy in obtaining information about their chief medical concerns. Items are measured on a scale from 1 (not at all confident) to 5 (very confident), with a possible score range of 10 to 50.

Self-report Health Care Utilization

Patients were asked at baseline if they ever used the online patient portal and, if so, the various ways they used it (eg, emailing physician, checking laboratory results, scheduling appointments, ordering refills, using health and wellness resources). Patients were asked about

use in the previous 6 months at the 6- and 12-month follow-up surveys. Patients were also asked about the use of counseling and advice services and use of KPNC's health education classes (excluding the intervention sessions).

Alcohol and Drug Use

We measured alcohol use by using the National Institute on Alcohol Abuse and Alcoholism's evidence-based questions on the number of days of hazardous/harmful alcohol use (≥ 5 drinks per day for men and ≥ 4 drinks per day for women).[57] The National Institute on Drug Abuse–modified Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) assessed use of 9 substances (cannabis, cocaine, prescription stimulants, methamphetamine, inhalants, sedatives or sleeping pills, hallucinogens, street opioids, prescription opioids) in the previous 3 months.[58] Participants were asked about lifetime and past 30-day use of tobacco and e-cigarettes. In addition, at baseline, 6 months, and 12 months, patients were asked, "Did you use marijuana in the past 30 days for medical purposes, as prescribed by a health care provider?" Patients who used medical marijuana in the past 30 days were further asked to indicate all the health or medical reasons for their use.

Pain Management Strategies

At baseline, 6 months, and 12 months, patients reported all the pain management strategies they were currently using: nonopioid medication prescribed by a physician; over-the-counter medication (eg, Tylenol); complementary/alternative medicine (eg, acupuncture, herbs); meditation, relaxation, or mindfulness practice; pain classes or therapy (group or individual); massage or other bodywork; and exercise, stretching, or physical therapy.

Chronic Pain, Opioid Use, and Goals for Opioid Use

Patients were asked to describe their chronic pain (source, duration) and their prescription opioid use at baseline (type of medication, frequency of use, possible side effects, and if they had discussions with their physicians about tapering). Patients reported their long-

term goals for prescription opioid use in 4 categories: stay the same, increase, decrease, and stop. We assessed progress toward goals at the 6- and 12-month follow-ups.

EHR Measures

EHR Measurement Periods

For utilization outcomes, we excluded the 3 months immediately following baseline to ensure that we were not counting intervention activity (eg, logging into the patient portal during sessions) in the outcome measures. To allow for comparisons between the 3 periods, we excluded the first 3 months in each period for counts of health care utilization: The baseline EHR measures covered the 3 months prior to baseline, the 6-month EHR measures covered months 4 to 6 post-baseline, and the 12-month EHR measures covered months 10 to 12 post-baseline.

EHR Health Care Utilization

We assessed patient portal use as the number of days of portal login and use of the portal for sending messages, seeking advice, and viewing laboratory results during each period. We assessed primary care visits as the total count of visits during each period. We created dichotomous variables for any emergency department (ED) visit or inpatient stay during the periods. We derived data used to identify primary care visits, ED visits, and inpatient stays from the KPNC EHR and claims data submitted to the health plan for reimbursement (for members receiving services outside KPNC).

Prescription Opioid Use

We extracted opioid dispensations from the pharmacy EHR data and converted them into morphine milligram equivalents (MMEs) per day using a standard conversion table.[59,60] Dispensation data are typically used to reflect patient medication use.[61,62] We calculated the MME for a dispensation by multiplying the quantity of each prescription by the strength of the prescription (unit dispensed by milligrams of opioid). We then multiplied the resulting product by the conversion factor. We calculated the average daily MME dispensed for the relevant

period (defined as 183 days for the baseline and 12-month periods and 90 days for the 6-month period) by adding the MMEs for the prescriptions dispensed during the period and dividing by the number of days in the period. We also created 3 dichotomous variables to indicate if any opioids were dispensed to patients during the baseline, 6-month, or 12-month periods.

Time Frames

We conducted participant recruitment, including baseline questionnaire completion, from July 2015 to August 2016. We designed a limited intervention (4 sessions, 1 time per week structure) to be feasible in primary care. We defined the *intervention period* as the 4 to 6 weeks during which the patients completed intervention sessions. We allowed up to 6 weeks because some patients missed sessions, and they were allowed to make them up within that time frame. Follow-up interviews were conducted at 6 and 12 months post-baseline. We selected the periods to assess both short-term and long-term time frames to see whether effects were sustained over time, which has been less well studied in the effectiveness literature.

Data Collection and Sources

Participants completed the baseline survey online using a laptop computer in a private space in the primary care clinic. A research assistant conducted the surveys at 6 and 12 months using a computer-assisted telephone interview. We used rigorous methods to maximize the number of follow-up interviews, including several call attempts and tracing methods to obtain recent contact information. We collected alternate phone numbers and the names and contact information of up to 3 friends or family members who participants designated as collateral contacts. When we had difficulty reaching participants, we pursued all collateral contacts and sent follow-up letters to current addresses. For address and phone number updates, we routinely consulted the EHR. We made efforts to schedule the follow-up phone interviews within a 1-month time window, extending the time by 2 weeks if necessary to secure follow-up. Participants were offered $50 Target gift cards for the baseline interview and each follow-up interview. We collected follow-up data from participants, regardless of whether they attended sessions.

We extracted prescription opioid use, primary and acute health care utilization, and KPNC membership status from the EHR. For EHR-based outcomes, we extracted data for all participants who were active KPNC members, regardless of whether they completed the surveys. For the baseline and 12-month EHR outcomes, KPNC membership was required for ≥ 4 months of the 6-month period; for the 6-month EHR outcomes, membership was required for the entire 3 months prior. All patients met the membership requirement for the baseline period; 97% and 96% of patients met the membership requirement for EHR outcomes at 6 months and 12 months, respectively.

Analytical and Statistical Approach

Power Calculations

Our target sample size was 324, based on power calculations that assumed a type 1 error rate of $\alpha = .05$ and power of ≥ .80. Applying a conservative sample retention rate (80%), we estimated a final sample size of approximately 260 patients at the 12-month follow-up. We considered the difference in PAM-13 scores between the intervention and usual care arms in the longitudinal analyses modeled by linear mixed-effects models. Assuming the worst-case scenario of a correlation between the 3 repeated measures (baseline, 6-month, and 12-month questionnaires) to be 0.3 (analyses of prior studies indicate correlations of < 0.3), the power to detect a 24% difference in SD units was 0.80 with a sample size of 230.

Descriptive Analysis

Using chi-square tests for categorical measures, *t* tests for continuous measures, and Wilcoxon rank sum tests for ordinal measures, we compared baseline differences in patient characteristics and outcome measures between the 2 treatment arms, which we expected to be similar due to randomization.

Missing Data

We used several approaches to maximize completion of the follow-up surveys that minimize the occurrence of missing data (see Recruitment and Retention, Data Collection and

Sources, and Intervention and Usual Care sections).[63,64] As a result, we had only a small amount of missing follow-up data (6% did not complete the 6-month survey and 9% did not complete the 12-month survey). We conducted a comparison of patient characteristics between those who did and did not complete the 6- and 12-month follow-up interviews, using chi-square tests for categorical measures and *t* tests for continuous measures (Appendix A). Responders were more likely to be older, unemployed, and more educated than nonresponders. Although unit missingness was low, to address the rigorous PCORI Methodology Standards, we implemented multiple imputation methods using PROC MI and PROC MIANALYZE in SAS.[65-67] This technique created 30 complete data sets, all with plausible values for each missing value, which we analyzed using the modeling approach described below. We then used PROC MIANALYZE to combine the results from the 30 data sets to generate valid estimates and adjust standard errors for inference.[65-67]

Modeling Approach

The descriptive analysis determined that no significant differences existed between the intervention and usual care arms in patient characteristics at baseline; therefore, we did not control for demographic characteristics in the outcomes models. We did, however, adjust for 2 measures (CPCI-42 Relaxation and Exercise/Stretch) that were statistically different at baseline. We examined the 6- and 12-month outcome data in 2 ways. We first performed cross-sectional bivariate comparisons in outcomes between the 2 intervention arms using chi-square tests and Fisher exact tests for categorical measures, a *t* test for continuous measures, and a Wilcoxon rank sum test for ordinal measures. We then used a repeated measures, mixed-effects framework to examine differences in outcomes by treatment arm over time. Repeated measures models are presented for outcomes that differed significantly in the bivariate analyses or were outcomes of high clinical interest even if not significant. We analyzed continuous dependent variables using linear mixed-effects models with random intercepts. We analyzed dichotomous dependent variables with nonlinear mixed-effects models with logit link and random intercepts. We measured ordinal measures with nonlinear mixed-effects models with cumulative logit link and random intercepts. Each patient had 3 repeated measures (baseline, 6 months, and 12

months). All models included an indicator variable for treatment arm (1 = intervention; 0 = usual care), time as continuous variable, and a term for the interaction of treatment by time. We generated and visually inspected residual plots to determine if the assumptions of the mixed-effects models were adequately met. We used the SAS procedures MIXED, NLMIXED, and GLIMMIX. Due to the limited sample size, we did not specify subgroup analysis in the protocol, nor did we conduct post hoc heterogeneity of treatment effect analyses.

In addition to the intent-to-treat analysis with the full sample, we conducted per protocol analyses, which included only those patients who completed all 4 sessions of the treatment protocol (n = 120). We conducted the same analyses on this sample, comparing 6- and 12-month outcomes for usual care (n = 187) and intervention arm patients.

All tests were 2-sided, and we defined statistical significance as $p < 0.05$. We did not adjust for multiple comparisons because we were interested in specific associations between the intervention and outcomes, and not the global null hypothesis.[68,69] However, findings with *p* values close to 0.05 should be viewed cautiously given the number of secondary outcomes that we included in this study. All our outcomes were specified a priori. We conducted analyses using SAS Version 9.3.

Changes to the Original Study Protocol

Study challenges necessitated changes to the original protocol, all of which PCORI formally reviewed and approved, and we amended contracts accordingly. In August 2015, 1 month after study recruitment began, we expanded the patient eligibility criteria to include all patients using opioids long term (>3 months) and removed the limitation on duration of use. In our original application, we limited enrollment to patients using opioids for less than 12 months with a 6-month clear period (no opioid use in 6 months prior to index prescription), as we were focusing primarily on patients who were in the beginning stages of long-term use. However, the number of new prescription opioid patients was inadequate, largely due to changing, more restrictive prescribing behavior in the KPNC region for opioids. We also requested the use of an

Independent Safety Monitor for the study instead of a Data Safety Monitoring Board, due to the low-risk nature of the study.

In December 2015, due to recruitment delays and the overall short timeline of the study, we revised our target sample size to 324 patients (from 432) and revised power calculations. To increase recruitment, we also added a second site from which to recruit patients.

We made minor adjustments to eligibility criteria as unanticipated events arose. For example, we excluded friends, spouses, and roommates from the study to avoid possible contamination, and we excluded patients who were planning to taper from opioids within 30 days of recruitment because the curriculum was most relevant to patients using opioids. We made both modifications to reduce potential bias and improve internal validity.

Qualitative Interviews

Another modification was the addition of a small number of qualitative physician interviews. We interviewed 13 primary care physicians about their experience caring for patients taking prescription opioids to get a sense of the changing attitudes and behaviors about prescribing opioids. Through a series of open-ended questions, we solicited feedback on the current prescribing environment and how it has affected providers' relationships with patients and the quality of care provided. The study's research clinician conducted the interviews, which were recorded, during lunch hours at the primary care clinic. Audio files were transcribed, and summaries of each interview were drafted. The interviews, which were not part of the original protocol, were not intended to be generalizable to the broader population but rather to provide context for the quantitative findings.

RESULTS

Recruitment and Retention

From June 2015 to August 2016, we identified 2742 patients in the EHR that met the initial eligibility criteria. Primary care physicians and the study research clinician excluded 719 patients who had serious medical or psychological issues, or who were otherwise ineligible for the study (eg, discontinued opioids, language barrier, moved out of study area). We mailed recruitment letters to the remaining 2023 patients, describing the study and inviting them to participate. Of these, we were unable to contact 347 (no current contact information or did not respond to letters or phone calls). A total of 851 patients declined to participate, indicating time constraints due to work, travel, and family obligations (n = 289); severe hardships, such as mobility and transportation issues (n = 93); and unspecified/not interested (n = 383). An additional 449 patients were deemed ineligible during the screening process. Reasons for ineligibility are presented in Table 2. Cancer was the primary health condition deeming patients ineligible. The CONSORT diagram of patient recruitment and retention is presented in Figure 1.

Table 2. Reasons for Ineligibility

Reason, No. (%)	Total (n = 1168)
Health/physical limitations (primarily cancer)	576 (49.3)
No longer taking opioids	134 (11.5)
Language barrier	98 (8.4)
Mental health issues	93 (8.0)
No longer a Kaiser member; moved out of area	87 (7.4)
Physician excluded, unspecified	66 (5.7)
In chronic pain program	51 (4.4)
In substance use treatment	26 (2.2)
Deceased	21 (1.8)
Other	16 (1.4)

A total of 376 patients consented, completed the baseline survey, and were randomized (189 intervention arm, 187 usual care arm). Retention rates for follow-up interviews were 94% at 6 months and 91% at 12 months.

Of the 189 patients in the intervention arm, 76% (n = 143) completed 3 or 4 sessions, 7% (n = 14) completed 1 or 2 sessions, and 17% (n = 32) did not attend any of the 4 sessions. The primary reasons given for not attending sessions were transportation, work, childcare, time conflicts, and health issues. In addition to the intent-to-treat analysis using the full sample, we conducted per protocol analyses that included only those patients who completed the treatment originally allocated. We compared 6- and 12-month outcomes for usual care (n = 187) participants and intervention participants who participated in all 4 sessions (n = 120). The bivariate per protocol results were the same as the intent-to-treat results except for pain intensity (less severe for intervention participants in per protocol) and sedative use (higher for intervention participants in per protocol; data not shown).

Patient Demographics

Table 3 shows participant characteristics. The mean age was 60 years and, on average, patients reported having been in pain for 14.6 years, with almost 30% having lived with pain for 20+ years. Most patients (71%) reported back pain as their primary source of pain; about 18% reported widespread pain, such as fibromyalgia (data not shown). Patients reported having taken prescription opioids for an average of 9 years, and at baseline 89% reported having taken prescription opioids for at least 7 days in the previous 2 weeks (data not shown). The intervention and usual care arms had similar demographic characteristics (Table 3), indicating randomization was successful for the demographic characteristics.

Aim 1 Outcomes

We successfully completed aim 1, which was to refine and finalize the intervention curriculum and patient-centered outcomes in collaboration with the stakeholder group. See the Stakeholder Engagement and Methods sections for more details.

Figure 1. CONSORT diagram of recruitment and retention in the ACTIVATE study

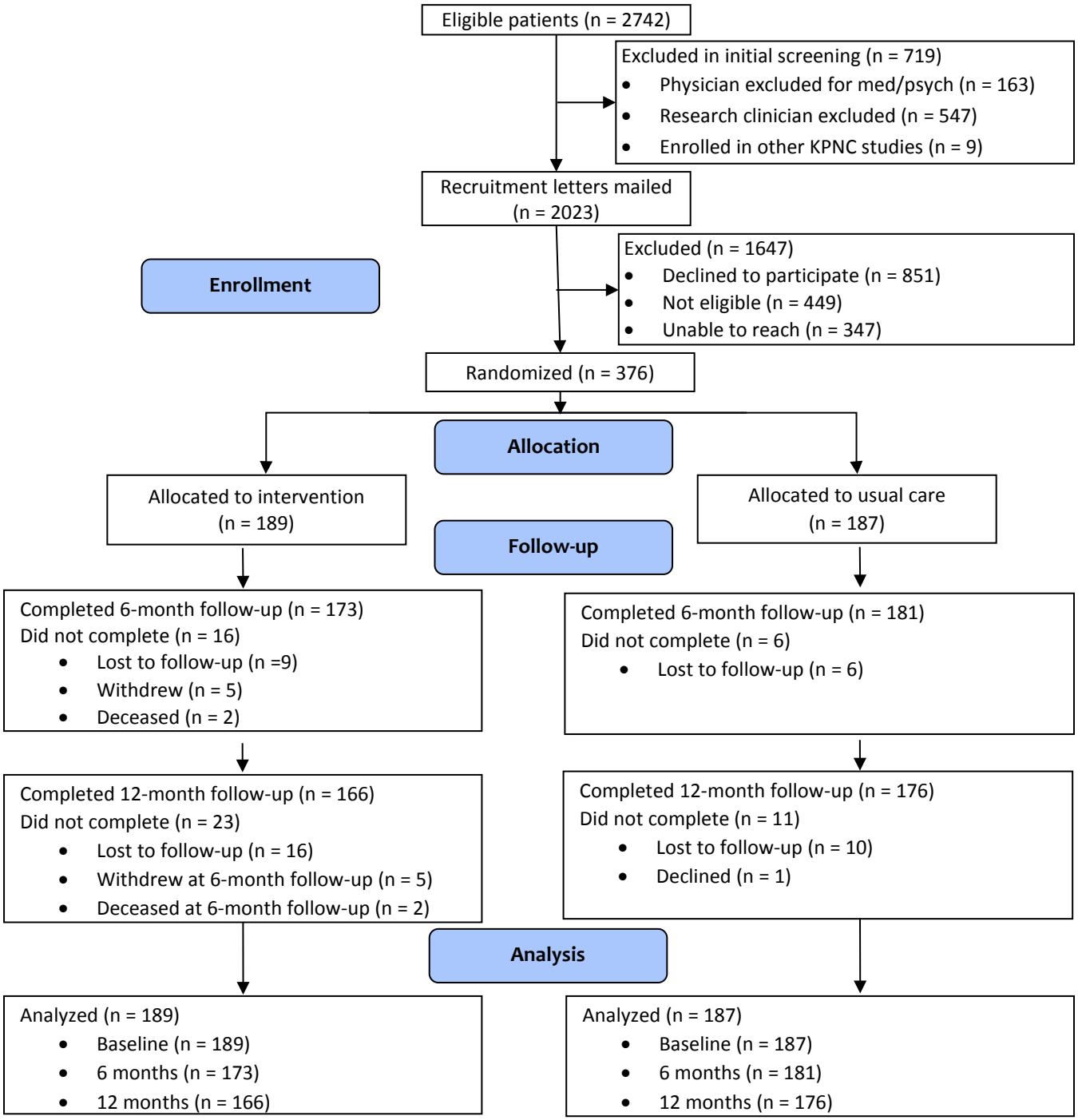

Table 3. Patient Demographic Characteristics

Characteristic, No. (%)	Total (n = 376)	Intervention (n = 189)	Usual Care (n = 187)	*P* Value[a]
Age, y, mean (SD)	59.8 (13.1)	58.8 (13.7)	60.7 (12.4)	0.16
Female sex	219 (58.2)	114 (60.3)	105 (56.1)	0.41
Race/ethnicity[b]				0.56
African American	20 (5.3)	11 (5.8)	9 (4.8)	
Asian	19 (5.1)	7 (3.7)	12 (6.4)	
Hispanic	63 (16.8)	30 (15.9)	33 (17.6)	
Native American	16 (4.3)	11 (5.8)	5 (2.7)	
White	254 (67.6)	128 (67.7)	126 (67.4)	
Annual household income > $50 000	222 (59.0)	112 (59.3)	110 (58.8)	0.69
Education				0.21
≤ High school graduate or GED	132 (35.2)	58 (30.7)	74 (39.6)	
Associate in arts, associate in science, or technical school	115 (30.7)	63 (33.3)	52 (27.8)	
College or higher	128 (34.1)	68 (36.0)	60 (32.1)	
Married	238 (63.3)	116 (61.4)	122 (65.2)	0.44
Employed	165 (43.9)	86 (45.5)	79 (42.2)	0.52

[a] Chi-square or *t* test.
[b] Other categories not reported due to small cell size.

Aim 2 Outcomes

For aim 2, we first compared the intervention arm with the usual care arm using bivariate statistics on several patient-centered outcomes at baseline, 6 months, and 12 months, which are all presented in Tables 4 to 12. Next, we conducted multivariate repeated measures models to examine the effect of the intervention over time (Table 13). Results are presented by measure domain.

For most of the outcome variables, randomization was successful as indicated by no statistical difference between the intervention and usual care arms at baseline (Tables 4-12). We included the 2 variables that were statistically different at baseline (CPCI-42 Relaxation and Exercise/Stretch [see Table 9]) as potential confounders in the repeated measures models (Table 13).

Patient Activation

Mean PAM-13 scores were similar between the 2 study arms at baseline, 6 months, and 12 months (Table 4), as was the proportion of patients who experienced a score increase of ≥ 3 from the previous period.

Table 4. PAM-13

Measure	Time Point[a]	Intervention	Usual Care	*P* Value[b]
PAM-13 score, mean (SD)[c]	Baseline	65.8 (15.0)	65.2 (15.9)	0.69
	6 months	67.3 (13.8)	67.7 (14.5)	0.78
	12 months	67.7 (14.8)	66.6 (14.0)	0.49
Having a PAM-13 score increase ≥ 3 from previous time point, no. (%)	6 months	80 (46.2)	88 (48.6)	0.65
	12 months	75 (45.2)	82 (46.6)	0.79

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.
[b] Chi-square or *t* test.
[c] PAM scale is 1 to 100; a higher score relates to positive outcomes.

Depression

Mean PHQ-9 scores were similar between the 2 arms at all time points, but the percentage of patients with PHQ-9 scores indicating moderate to severe depression (≥ 10) was lower in the intervention arm (15%) than the usual care arm (26%) at 12 months ($p = 0.02$; Table 5). The PROMIS-29 depression *T* scores were also lower for the intervention arm compared with usual care arm at 12 months ($p = 0.05$).

Quality of Life

At 12 months, the PROMIS Global Physical Health score was significantly higher in the intervention arm (mean 40.9; SD 7.6) than in the usual care arm (mean 39.0; SD 6.3; $p = 0.009$; Table 6). Although not statistically significant ($p = 0.06$), the intervention arm had marginally higher average PROMIS Global Mental Health scores compared with usual care at 12 months.

Table 5. Depression, as Measured by the PHQ-9 and PROMIS-29

Measure	Time Point[a]	Intervention	Usual Care	*P* Value[b]
PHQ-9: Score, mean (SD)	Baseline	6.7 (5.3)	7.0 (5.3)	0.64
	6 months	5.6 (5.1)	6.2 (5.6)	0.28
	12 months	5.5 (4.8)	6.2 (4.7)	0.21
PHQ-9: Percentage with moderate to severe depression (score ≥ 10), no. (%)	Baseline	49 (25.9)	46 (24.7)	0.79
	6 months	35 (20.2)	38 (21.0)	0.86
	12 months	25 (15.1)	45 (25.6)	0.02
PROMIS-29 depression, *T* score,[c] mean (SD)	Baseline	51.2 (9.6)	52.1 (9.4)	0.38
	6 months	49.8 (8.6)	49.7 (8.7)	0.89
	12 months	47.4 (7.9)	49.2 (8.4)	0.05

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.

[b] Chi-square or *t* test.

[c] PROMIS-29 raw scores are converted to *T* scores, with a mean of 50 and a standard deviation of 10. A higher score represents more of the concept being measured.

Table 6. Quality of Life, PROMIS Global Health

Measure, Mean (SD)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
PROMIS Global Physical Health, *T* score[c]	Baseline	38.3 (6.3)	38.2 (6.1)	0.91
	6 months	40.2 (6.7)	39.9 (7.0)	0.76
	12 months	40.9 (7.6)	39.0 (6.3)	0.009
PROMIS Global Mental Health, *T* score[c]	Baseline	45.8 (9.4)	45.1 (8.3)	0.46
	6 months	47.4 (8.1)	46.9 (8.3)	0.56
	12 months	47.8 (8.0)	46.2 (7.8)	0.06

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.

[b] *t* test.

[c] PROMIS Global Health raw scores are converted to *T* scores, with a mean of 50 and a standard deviation of 10. A higher score represents more of the concept being measured.

Overall Health, Pain Severity, and Functional Status

We measured pain intensity, overall health, and functional status with single items from the PROMIS Global Health (Table 7). The 2 arms showed no difference in pain intensity at all time points. For overall health, the intervention arm stayed level at 6 and 12 months (mean = 2.8 and 2.7, respectively) relative to baseline, while the usual care arm trended down at 6 to 12 months (mean = 2.5 and 2.4) relative to baseline; patients in the intervention reported significantly higher overall health status at 6 and 12 months compared with usual care (p = 0.001 and 0.007, respectively). Patients in the intervention arm reported a consistent level of satisfaction with social activity and roles (mean = 3.3 for all time points); the usual care arm showed an increase at 6 months (mean = 3.3) before returning to baseline level at 12 months (mean = 3.1). At 12 months, patients in the intervention arm reported higher satisfaction with social activity and roles than patients in the usual care arm (mean = 3.3 vs 3.1; p = 0.01). Patients in the intervention arm also reported a consistent level of satisfaction with everyday physical activity performance at baseline and 6 months (mean = 3.4 for both time points) before increasing at 12 months (mean = 3.6); the usual care arm showed an increase at 6 months (mean = 3.4) before returning to baseline level at 12 months (mean = 3.3). At 12 months, patients in the intervention arm reported higher satisfaction with everyday physical activity performance than patients in the usual care arm (mean = 3.6 vs 3.3; p = 0.02). We noted no significant differences between the 2 treatment arms in PROMIS-29 domains of physical function, satisfaction with social role, and pain interference (Appendix B, Table B1).

Table 7. Pain Intensity, Overall Health Status, and Functional Status (Single Items From PROMIS Global Health)

Measure, Mean (SD)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
Pain intensity scale (raw score with 1-10 scale, 1 = no pain to 10 = worst imaginable pain)	Baseline	6.7 (1.4)	6.7 (1.6)	0.97
	6 months	5.9 (1.8)	5.9 (1.9)	0.75
	12 months	5.8 (2.1)	6.1 (1.7)	0.22
Overall health (raw score with 1-5 scale, 1 = poor to 5 = excellent)	Baseline	2.7 (0.9)	2.6 (0.9)	0.36
	6 months	2.8 (0.9)	2.5 (0.9)	0.001
	12 months	2.7 (0.9)	2.4 (0.9)	0.007
Function: Social activity and roles performance (raw score with 1-5 scale, 1 = poor to 5 = excellent)	Baseline	3.3 (1.1)	3.1 (1.1)	0.17
	6 months	3.3 (0.9)	3.3 (1.0)	0.70
	12 months	3.3 (1.0)	3.1 (0.9)	0.01
Function: Everyday physical activity performance (raw score with 1-5 scale, 1 = not at all to 5 = completely)	Baseline	3.4 (1.0)	3.3 (1.0)	0.83
	6 months	3.4 (1.1)	3.4 (1.1)	0.83
	12 months	3.6 (1.1)	3.3 (1.1)	0.02

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.
[b] Wilcoxon rank-sum test used for 1 to 5 ordinal scales; *t* test used for pain intensity scale.

Satisfaction with Care

Satisfaction with overall health care, pain management care, and the patient's primary care physician was similar for the intervention and usual care arms at all time points (Appendix B, Table B2).

Self-reported Opioid Misuse

Measures of misuse behaviors were similar for the intervention and usual care arms at 6- and 12-month follow-up (Table 8).

Table 8. Opioid Misuse

Measure, No. (%)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
SOAPP ≥ 4	Baseline	48 (25.4)	59 (31.6)	0.19
	6 months	28 (18.2)	28 (17.1)	0.80
	12 months	25 (17.7)	23 (14.6)	0.47
COMM ≥ 9	Baseline	57 (30.2)	68 (36.4)	0.20
	6 months	22 (14.3)	25 (15.2)	0.81
	12 months	14 (9.9)	22 (14.0)	0.28

[a] SOAPP and COMM completed only by current opioid users. Baseline N is 189 for intervention and 187 for usual care; 6-month N is 154 for intervention and 164 for usual care; 12-month N is 141 for intervention and 157 for usual care.
[b] Chi-square.

Pain Coping Strategies

Patients in the intervention arm had higher CPCI-42 scores in the following domains: resting at 6 months (negative coping strategy), relaxation at each time point (positive coping strategy), and exercise/stretch at baseline and 12 months (positive coping strategy; Table 9). The other coping strategies (guarding, asking for assistance, task persistence, seeking social support, and coping self-statements) were not significantly different between the 2 arms at any of the 3 time points (Appendix B, Table B3).

Pain Self-efficacy Questionnaire

The PSEQ scores were similar for the intervention and usual care arms, with intervention participants marginally reporting more confidence at 12 months in performing tasks despite their pain ($p = 0.07$; Appendix B, Table B4).

Table 9. CPCI-42, Select Measures

Measure, Mean (SD)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
CPCI-42 Resting[c,d]	Baseline	3.7 (1.9)	3.6 (2.0)	0.72
	6 months	4.3 (1.8)	3.9 (2.0)	0.04
	12 months	3.8 (1.7)	3.8 (2.0)	0.86
CPCI-42 Relaxation[c,e]	Baseline	2.4 (1.9)	2.0 (1.8)	0.04
	6 months	3.0 (1.8)	2.5 (2.0)	0.02
	12 months	2.9 (2.0)	2.3 (1.9)	0.01
CPCI-42 Exercise/Stretch[c,e]	Baseline	3.0 (2.2)	2.6 (1.9)	0.04
	6 months	3.2 (1.9)	3.1 (2.0)	0.52
	12 months	3.3 (2.1)	2.8 (2.0)	0.03

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.
[b] *t* test.
[c] For each subscale, patients were asked the number of days (0-7 days) they performed each task. Scores were calculated separately for each of the subscales, and the scores ranged from 0 to 7.
[d] Negative coping strategy.
[e] Positive coping strategy.

Patient–Provider Communication

No differences were reported between the 2 arms regarding patient perception of physicians' communication and interpersonal skills or regarding patient confidence in communicating with physicians and patient efficacy getting health care needs addressed (Appendix B, Table B5).

Health Care Utilization

We found no differences in self-reported attendance at KPNC health education classes (Table 10). However, the intervention group reported more use of the online portal to check laboratory results or immunization history at 12 months ($p = 0.006$); the intervention group also had marginally significant more emails with providers at 12 months ($p = 0.06$). Self-report also indicated higher usage of the online portal's health and wellness resource at both the 6- and 12-month follow-ups for the intervention group compared with usual care ($p = 0.02$ and < 0.001, respectively). The EHR data also suggested higher rates of any online portal use at 6 months in the intervention arm compared with usual care (90.6% and 83.5%, respectively; $p =$

0.04) but not significantly higher rates at 12 months (88.8% and 84.6%, respectively; $p = 0.25$).

We did not find differences in primary care visits, ED visits, or inpatient stays (Table 10).

Table 10. Use of Primary, Acute, and Self-care Services

Measure	Time Point[a]	Time Reference	Intervention	Usual Care	*P* Value[b]
Self-report					
Attended KPNC health education class, no. (%)	Baseline	Ever	113 (62.4)	108 (60.3)	0.68
	6 months	Previous 6 mos.	22 (12.8)	20 (11.0)	0.61
	12 months	Previous 6 mos.	22 (13.3)	18 (10.3)	0.39
Checked laboratory results or immunization history, no. (%)	Baseline	Ever	160 (85.1)	157 (84.4)	0.85
	6 months	Previous 6 mos.	119 (68.8)	126 (69.6)	0.87
	12 months	Previous 6 mos.	133 (80.1)	118 (67.0)	0.006
Emailed provider or received email from provider, no. (%)	Baseline	Ever	165 (87.8)	157 (84.4)	0.35
	6 months	Previous 6 mos.	147 (85.0)	146 (80.7)	0.28
	12 months	Previous 6 mos.	144 (86.7)	139 (79.0)	0.06
Used patient portal's health and wellness online resources, no. (%)	Baseline	Ever	47 (25.0)	42 (22.6)	0.58
	6 months	Previous 6 mos.	68 (39.3)	50 (27.6)	0.02
	12 months	Previous 6 mos.	76 (45.8)	50 (28.4)	<0.001
EHR					
Used patient portal, no. (%)	Baseline	Previous 3 mos.	163 (86.2)	154 (82.4)	0.30
	6 months	Previous 3 mos.	164 (90.6)	152 (83.5)	0.04
	12 months	Previous 3 mos.	158 (88.8)	154 (84.6)	0.25
Number of primary care visits, mean (SD)	Baseline	Previous 3 mos.	1.3 (1.7)	1.3 (1.5)	0.91
	6 months	Previous 3 mos.	1.2 (1.6)	1.2 (1.5)	0.89
	12 months	Previous 3 mos.	1.4 (1.7)	1.4 (2.2)	0.97
One or more ED visits, no. (%)	Baseline	Previous 3 mos.	19 (10.1)	29 (15.5)	0.11
	6 months	Previous 3 mos.	18 (9.9)	23 (12.6)	0.42
	12 months	Previous 3 mos.	26 (14.6)	22 (12.1)	0.48
One or more inpatient stays, no. (%)	Baseline	Previous 3 mos.	6 (3.2)	11 (5.9)	0.21
	6 months	Previous 3 mos.	6 (3.3)	6 (3.3)	> 0.99
	12 months	Previous 3 mos.	6 (3.4)	6 (3.3)	0.97

[a] Self-report Ns: Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care. EHR Ns: Baseline N is 189 for intervention and 187 for usual care; 6-month N is 181 for intervention and 182 for usual care; 12-month N is 178 for intervention and 182 for usual care.

[b] Chi-square or *t* test.

Substance Use

We noted no differences between the 2 arms in substance use or hazardous/ harmful alcohol use at any of the time points (Table 11). Medical marijuana was used in the past 30 days for approximately 7% to 10% of patients in both the intervention and usual care arms at all 3 time points; the predominant reason for medical marijuana use was pain (data not shown). Baseline prevalence for smoking cigarettes in the past 30 days was 14% in the intervention and usual care arms and 5% for electronic cigarettes (data not shown); we found no significant differences in tobacco use between study arms at any of the time points.

Self-management Strategies

Participants in the intervention arm reported significantly more meditation, relaxation, or mindfulness practice at 6 and 12 months ($p < 0.001$; Table 12). In addition, participants in the intervention arm reported significantly more exercise, stretching, or physical therapy at 12 months ($p < 0.001$).

Table 11. Substance Use

Measure, No. (%)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
Cannabis in past 3 months	Baseline	23 (12.2)	29 (15.7)	0.34
	6 months	19 (11.0)	20 (11.0)	0.98
	12 months	22 (13.3)	17 (9.7)	0.30
Sedatives/sleeping pills in past 3 months[c]	Baseline	53 (28.3)	51 (28.0)	0.95
	6 months	35 (20.2)	35 (19.4)	0.85
	12 months	51 (30.7)	43 (24.4)	0.19
Hazardous/harmful alcohol use	Baseline	11 (5.8)	10 (5.3)	0.84
	6 months	8 (4.6)	9 (5.0)	0.88
	12 months	8 (4.8)	8 (4.5)	0.90
Smoked cigarette in past 30 days	Baseline	26 (13.8)	27 (14.4)	0.87
	6 months	17 (9.9)	24 (13.3)	0.31
	12 months	15 (9.0)	19 (10.8)	0.59

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.
[b] Chi-square.
[c] Opioids are not presented because they were study inclusion criteria, and other substances were omitted due to small numbers.

Table 12. Self-management Strategies

Measure, No. (%)	Time Point[a]	Intervention	Usual Care	*P* Value[b]
Nonopioid medication prescribed by a physician	Baseline	50 (26.5)	61 (32.6)	0.19
	6 months	34 (19.7)	46 (25.4)	0.20
	12 months	33 (19.9)	50 (28.4)	0.07
Over-the-counter medication (eg, Tylenol)	Baseline	74 (39.2)	73 (39.0)	0.98
	6 months	75 (43.4)	75 (41.4)	0.72
	12 months	75 (45.2)	80 (45.5)	0.96
Complementary/alternative medicine (eg, acupuncture, herbs)	Baseline	31 (16.4)	31 (16.6)	0.96
	6 months	25 (14.5)	32 (17.7)	0.41
	12 months	25 (15.1)	17 (9.7)	0.13
Meditation, relaxation, or mindfulness practice	Baseline	64 (33.9)	50 (26.7)	0.13
	6 months	75 (43.4)	45 (24.9)	<0.001
	12 months	61 (36.7)	34 (19.3)	<0.001
Massage or other bodywork	Baseline	52 (27.5)	52 (27.8)	0.95
	6 months	48 (27.7)	49 (27.1)	0.89
	12 months	39 (23.5)	35 (19.9)	0.42
Exercise, stretching, or physical therapy	Baseline	108 (57.1)	95 (50.8)	0.22
	6 months	120 (69.4)	123 (68.0)	0.78
	12 months	127 (76.5)	100 (56.8)	<0.001

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care.
[b] Chi-square.

Repeated Measures Models

In the repeated measures models, we used an interaction of time and study arm to determine if the 2 study arms had different trends over time for outcomes that were of high clinical interest or found to be significantly different between arms in bivariate comparisons. Because the arms were randomized and demographic characteristics were balanced (Table 3), we did not include demographic covariates in the models. We did, however, adjust for 2 measures (CPCI-42 Relaxation and Exercise/Stretch) that were statistically different at baseline. The intervention arm had an increasing trend in physical health (PROMIS Global Physical Health *T* score; $p = 0.009$) and overall health (PROMIS overall health; $p = 0.02$) over time compared with the usual care arm (Table 13). The intervention arm had a decreasing trend of depression over time compared with the usual care arm (PHQ-9 moderate to severe depression; score ≥

10; $p = 0.02$). The intervention arm had an increasing trend of use of patient portal's health and wellness resources over time compared with the usual care arm ($p = 0.04$) and an increasing trend in the use of exercise, stretching, or physical therapy over time compared with the usual care arm ($p = 0.02$). Findings for the modeling with imputed values for missing data (Table 13) were the same as the complete-case analysis without imputed values (not shown).

Aim 3 Outcomes

Prescription Opioid Use

At baseline, 64.6% of the intervention arm and 59.4% of the usual care arm indicated that their opioid use goal was to decrease or stop use ($p = 0.33$; data not shown). Opioid use goals for all 3 periods are shown in Appendix B, Table B6. We found no statistically significant differences between the study arms in the prevalence of prescription opioid use or average daily dose of opioids at 6 or 12 months (Table 14). At 6 months, 161 (89.0%) and 166 (91.2%) patients in the intervention and usual care arms, respectively, had filled an opioid prescription in the previous 3 months ($p = 0.47$). At 12 months, 157 (88.2%) and 166 (91.2%) patients in the intervention and usual care arms, respectively, had filled an opioid prescription in the previous 6 months ($p = 0.35$). Similarly, the average daily dose of opioids decreased for both study arms by 7 MME/day from baseline to 12 months. The intervention and usual care groups had similar average daily doses of opioids at baseline and at 6 and 12 months. Both the usual care and intervention arms significantly reduced their average daily opioid use over time, but we did not find differences between the arms in repeated measure models for the entire cohort or when stratified by baseline opioid use goals (Table 15).

Qualitative Interviews

The 13 qualitative interviews of primary care physicians asked semistructured questions on physician perspective of the KPNC opioid initiative and associated changes in the prescribing climate. Most of the physicians believed overprescribing was a problem prior to the opioid initiative in late 2014, and many indicated that they have become more cautious prescribers in the past few years, suggesting the impact of national and regional initiatives. Nearly all the

physicians indicated that they were comfortable talking with their patients about expectations and boundaries in their opioid use. When asked about nonpharmacological methods of helping their patients with pain, fewer than expected were familiar with the various pain management options available at KPNC. At the end of the interview, physicians provided additional ideas for improvements, and several important themes emerged: the need for multidisciplinary support in primary care (eg, improved access to pharmacists and pain specialists, such as on-call video consultations or roving specialists), information on nonpharmacological referral options, further standardization of prescribing practices, and operational changes to streamline workflow (eg, electronic repositories for opioid-related documents and patient resources).

Table 13. Repeated Measures Models of Self-reported Survey Outcomes[a]

	Time				Intervention				Time × Intervention			
	Est.	95% CI	SE	*P* Value	Est.	95% CI	SE	*P* Value	Est.	95% CI	SE	*P* Value
Continuous Outcomes												
PAM-13, *T* score	0.76	–0.43 to 1.94	0.61	0.21	–0.43	–3.19 to 2.34	1.41	0.76	0.17	–1.54 to 1.88	0.87	0.85
PROMIS Global Physical Health, *T* score	0.42	–0.04 to 0.89	0.24	0.08	–0.18	–1.49 to 1.12	0.67	0.79	0.90	0.22 to 1.58	0.35	0.009
PROMIS Global Mental Health, *T* score	0.55	0.0001 to 1.09	0.28	0.05	0.42	–1.23 to 2.07	0.84	0.62	0.46	–0.34 to 1.25	0.41	0.26
PROMIS Pain Intensity Scale	–0.30	–0.45 to –0.16	0.07	<0.001	0.04	–0.29 to 0.38	0.17	0.80	–0.16	–0.37 to 0.05	0.11	0.13
Satisfaction with overall health care	–0.01	–0.14 to 0.11	0.06	0.83	–0.20	–0.53 to 0.13	0.17	0.23	0.10	–0.08 to 0.28	0.09	0.29
Satisfaction with primary care physician	–0.05	–0.17 to 0.07	0.06	0.41	–0.11	–0.45 to 0.23	0.17	0.53	0.09	–0.08 to 0.26	0.09	0.30
CPCI-42 Relaxation	0.18	0.05 to 0.30	0.06	0.006	0.26	–0.09 to 0.61	0.18	0.14	0.07	–0.11 to 0.25	0.09	0.44
CPCI-42 Exercise/Stretch	0.13	–0.02 to 0.28	0.08	0.08	0.17	–0.19 to 0.54	0.19	0.36	0.03	–0.18 to 0.24	0.11	0.81
Binary Outcomes												
Moderate to severe depression (PHQ-9 score ≥ 10)	0.03	–0.28 to 0.35	0.16	0.83	0.19	–0.54 to 0.92	0.37	0.61	–0.56	–1.02 to –0.10	0.24	0.02
Use of patient portal's health and wellness resources	0.20	–0.07 to 0.48	0.14	0.15	0.10	–0.46 to 0.66	0.28	0.73	0.41	0.02 to 0.79	0.20	0.04
Use of patient portal for checking laboratory results or immunization history[b]	–0.16	–0.73 to 0.41	0.29	0.57	–1.17	–2.53 to 0.18	0.69	0.09	1.08	0.24 to 1.93	0.43	0.01

Pain management—use of meditation, relaxation, or mindfulness practice	–0.26	–0.54 to 0.02	0.14	0.07	0.35	–0.14 to 0.83	0.25	0.16	0.33	–0.04 to 0.69	0.19	0.08
Pain management—use of exercise, stretching, or physical therapy	0.18	–0.07 to 0.42	0.13	0.16	–0.07	–0.57 to 0.42	0.25	0.78	0.44	0.07 to 0.81	0.19	0.02
Ordinal Outcomes[c]												
PROMIS overall health	–0.30	–0.51 to –0.08	0.11	0.008	0.41	–0.21 to 1.04	0.32	0.20	0.37	0.05 to 0.68	0.16	0.02
Function: PROMIS social activity/roles	–0.02	–0.22 to 0.17	0.10	0.81	–0.23	–0.26 to 0.72	0.25	0.36	0.09	–0.19 to 0.38	0.15	0.53
Function: PROMIS physical activity	–0.01	–0.21 to 0.19	0.10	0.91	–0.10	–0.63 to 0.43	0.27	0.72	0.27	–0.02 to 0.55	0.15	0.07

Abbreviations: est., estimate; SE, standard error.

[a] The independent variables in the models of study outcomes were time, intervention, the interaction of time intervention, baseline CPCI-42 relaxation, and baseline CPCI-42 exercise. The model included 189 patients in the intervention arm and 187 patients in the usual care arm.

[b] For this self-reported measure at baseline, patients were asked if they ever used the service. At the 6- and 12-month follow-up surveys, patients were asked about their use in the previous 6 months. Because the "ever used" proportion was higher than the 6- and 12-month proportions, baseline values were excluded from the model for this measure.

[c] Ordinal outcomes were all assessed on a 1 to 5 scale, with higher values indicating better outcomes.

Table 14. Opioid Use

Measure	Time Point[a]	Intervention	Usual Care	*P* Value[b]
EHR: Any opioid fill, no. (%)	Baseline	188 (99.5)	187 (100.0)	0.32
	6 months	161 (89.0)	166 (91.2)	0.47
	12 months	157 (88.2)	166 (91.2)	0.35
EHR: Average daily dose of opioids, MME/day, mean (SD)	Baseline	35.8 (68.9)	32.1 (43.8)	0.54
	6 months	30.4 (64.3)	28.2 (35.5)	0.68
	12 months	28.0 (70.7)	25.3 (32.9)	0.64
Self-report: Use of opioid medication for pain management, no. (%)	Baseline	185 (97.9)	183 (97.9)	0.99
	6 months	143 (82.7)	156 (86.2)	0.36
	12 months	133 (80.1)	153 (86.9)	0.09

[a] Baseline N is 189 for intervention and 187 for usual care; 6-month N is 173 for intervention and 181 for usual care; 12-month N is 166 for intervention and 176 for usual care. EHR outcomes were measured in the 6 months prior to the baseline and 12-month surveys, but only the 3 months prior to the 6-month survey in order to exclude the intervention period (ie, the 3 months after baseline).
[b] Chi-square or *t* test.

Table 15. Repeated Measures Models of Opioid Use, Stratified by Baseline Opioid Use Goals

	Time			Intervention			Time x Intervention		
Outcome	Est.	SE	*P* Value	Est.	SE	*P* Value	Est.	SE	*P* Value
EHR: Average daily dose of opioids, MME/day[a]	–2.96	1.03	0.004	3.42	5.59	0.54	–0.09	1.47	0.95
Stratified by Baseline Goals									
Goal: To stay the same or increase opioid use: Average daily dose of opioids, MME/day[b]	–3.16	1.96	0.11	–2.62	6.62	0.69	–0.28	2.88	0.92
Goal: To reduce or stop opioid use: Average daily dose of opioids, MME/day[c]	–2.83	1.11	0.01	7.15	8.05	0.37	–0.01	1.57	>0.99

Abbreviations: est., estimate; SE, standard error.
[a] Model included 189 patients in the intervention arm and 187 patients in the usual care arm.
[b] Model included 67 patients in the intervention arm and 76 patients in the usual care arm.
[c] Model included 122 patients in the intervention arm and 111 patients in the usual care arm.

DISCUSSION

Context for Study Results

This patient-centered study examined a patient activation intervention implemented in a primary care setting for patients receiving long-term opioid therapy. Our primary outcome, patient activation, did not show any difference between the 2 study arms at 6- or 12-month follow-up. It is possible that the 4-session program was not intensive enough to observe a change in this measure. Previous studies have found that the impact of patient activation may vary by baseline activation levels, with improvements in activation more likely to be observed for patients with low levels of activation at baseline.[70] Patients in our sample may have already had relatively high levels of activation, so any change would have required more intensive treatment. Some measures suggested that study participants were fairly engaged and satisfied with their health care at baseline (high rates of using online portal, Table 10; high levels of satisfaction with care, Table B2; and high ratings of provider–patient communication, Table B5), and this may be one explanation for not observing increases in patient activation in this population. Finally, patient activation, as conceptualized and measured with the PAM-13, consists of 4 levels: (1) starting to take a role, (2) building confidence and knowledge, (3) taking action, and (4) maintaining behaviors. It is possible that although improvements may have been made in one of these dimensions, the changes were not enough to be captured in the measure.

Despite no increase in patient activation scores, statistically significant differences occurred over time between the 2 arms in several patient-reported outcomes. However, we are cautious about our interpretation because the differences in depression, overall and physical health, and everyday physical activity were not considered to have a minimally clinically important difference.[71] Patients in the intervention arm more frequently utilized the online patient portal, particularly health and wellness resources, and employed more self-care strategies such as mindfulness and meditation, and exercise and stretching. However, many of the differences found between the 2 arms did not occur until the 12-month follow-up period.

Some associations that we anticipated would be significant were not. We did not see an impact of the intervention on EHR measures of health utilization, opioid use, or self-reported pain efficacy (confidence in completing tasks despite pain). The lack of observed change in utilization of primary care services may be because the chronic medical conditions underlying opioid use drove utilization of primary care services equally for patients in the usual care and intervention arms. We did not see a difference in ED use, but the time frame may have been too short to observe a change in this measure, which tends to be a rare event.

We did not observe effects on all measures, but this is not entirely unexpected because behavior change is challenging and often slow, particularly for patients with chronic health conditions. On average, study participants reported having had chronic pain for 14.6 years and having taken prescription opioids for an average of 9 years. In addition, our sample size may not have been large enough to observe differences in some measures. Outcomes with modest statistical significance should be considered preliminary and warrant confirmation in future studies, particularly in light of the multiple comparisons.

Patients reported a slight decrease over time in pain intensity, although we found no significant difference between the 2 arms. While this suggests that the intervention did not impact pain perception, patients reported better overall health and we saw a trend for improved function at 12 months. Pain severity alone does not capture the complexity of the pain experience or reflect fluctuations in pain and given the brevity of the intervention and the long-term nature of chronic pain, this was not a surprising finding. Beyond pain severity, patients emphasize the importance of function and of performing daily activities while having pain, and it is encouraging to see a promising finding for function.

Average daily opioid dose did not differ between study arms, although we did observe a consistent decrease in MMEs and number of opioid fills for both arms over time. Similar to other health systems' initiatives and the Centers for Disease Control and Prevention (CDC) opioid prescribing guidelines,[7,8] this health system implemented a safe opioid prescribing initiative to reduce risky prescribing practices and high dosages during the study time frame. As supported by our qualitative interviews with Kaiser physicians, the decrease in opioid use over

the 12-month study period likely reflects the changing prescribing environment within the health system. These results are consistent with national data showing annual prescribing rates for < 30 days' supply decreased annually by 7.3% from 2012 to 2016, and average daily dose (MME per day) decreased annually by 1.7% from 2013 to 2016.[72]

Our strongest finding in the bivariate analyses was that the intervention arm was more likely to engage in mindfulness practice than the usual care arm at 6 and 12 months; however, the trend in the repeated measures analysis showed only a marginal intervention effect. Although this is a trend, it is consistent with a considerable body of literature, as mindfulness strategies have been shown to be very effective for managing chronic pain and other studies have indicated a correlation between mindfulness and function. Original work by Kabat-Zinn on mindfulness-based stress reduction was conducted with pain populations and has been used widely in multidisciplinary pain programs.[73] Other studies have shown that mindfulness-based interventions can reduce pain intensity[74] and improve mental health.[75] A recent randomized controlled trial showed that a mind–body program for patients with chronic lower back pain improved function and severe pain, although functional improvement was not sustained long term.[76] Findings from a larger trial by Cherkin et al report improved function for both study arms (mindfulness-based stress reduction and cognitive behavior therapy) compared with usual care.[35] The interventions in both of these studies were based on a minimum of 8 weeks of training. Findings from this study suggest that even a brief introduction to mindfulness, which may be more feasible for some patients, could be helpful in encouraging the use of mindfulness practice in daily life. It was also one of the more experiential elements of the curriculum, and one for which patients provided very positive feedback.

The finding for mindfulness may be related to the positive signal for depression. Fewer patients in the intervention arm had moderate to severe depression at 12 months; however, the difference was not large enough to be considered clinically significant.[77] Depression is highly comorbid with chronic pain[78] and high-dose opioid use,[79] and the potential to address depression is a critical element in improving outcomes for patients with chronic pain.

Patients in the intervention arm also reported increased use of the patient portal's health and wellness resources, supporting our expectation for greater engagement with the health system through health information technology and reflecting one of the patient competencies of our conceptual framework. The positive findings for mindfulness and patient portal use suggest patients who use opioids long term are open to nonopioid adjuvants to manage their pain. Outside factors such as stricter prescribing policies, and thus restricted access to opioids, may accentuate receptivity. The shift in KPNC prescribing policies, which we did not anticipate when we submitted the study application, presented a unique opportunity to examine how a patient-centered intervention could support patients during a time of transition and alleviate potential stress regarding their ability to continue using opioid pain medication. Feedback during qualitative interviews with physicians indicated that they appreciated being able to refer patients to the study as an additional resource.

Our findings also suggest increased engagement in strategies to manage pain nonpharmacologically, even at 12-month follow-up. More patients reported increased use of exercise, stretching, and/or physical therapy in the intervention arm, which is consistent with the overall reporting of better physical health. No increases occurred in other self-care strategies such as massage or alternative medicine, perhaps due to higher costs and access to these services. However, the increases in mindfulness and exercise, 2 accessible low-cost strategies, suggests increased engagement in affordable self-care strategies for pain. These increases may also be related to the improvement in depression and function and overall health measures. Because pain scores and opioid dosages did not change, the increase in these strategies could be a mechanism underlying the improvement in function and depression. In the current environment, opioid prescribing will likely continue to become more restrictive. Mindfulness programs are widely available online, not just within this health system, and are often suggested for pain control. It is not necessarily a quick strategy, and acceptability may vary for patients, but offering these techniques within a health system may help address concerns, especially when promoted by one's personal physician.

Coping strategies (purposeful use of cognitive and behavioral techniques to manage stressful demands) are an important skill for patients with chronic pain. Evidence suggests certain types of coping strategies are associated with improved health outcomes and functioning for patients with chronic pain.[52] The intervention focused primarily on wellness-focused or active strategies, such as relaxation, and positive behavior change like exercise. These strategies increased in the intervention arm over time, indicating the adoption of positive coping strategies. However, patients in the intervention arm also reported higher use of "resting" at 6 months. The CPCI considers resting an illness-focused strategy, appropriate for recovering from acute illness or injury rather than for alleviating chronic pain. Its use by patients with chronic pain could be considered a maladaptive coping strategy. Our findings suggest the importance of further research that elucidates the relationship between different pain coping strategies, and the relationship to function and health outcomes (quality of life, depression).

Some strategies did not show any difference between the arms, which could mean that elements of the curriculum that were more experiential and interactive (eg, mindfulness exercise, accessing the online patient portal) were more likely to be sustained than other strategies that were discussed but not practiced in the classes (eg, communication strategies). Although not formally assessed, feedback from group participants suggests the peer support and interactions provided in the group setting helped reinforce concepts and practices.

These findings suggest to health systems, providers, and patients that programs that offer alternatives to opioids may help patients better manage chronic pain, even when relatively brief and limited in scope. Currently, nonpharmacological strategies are typically not covered by insurance, with the exception of some health systems (eg, Kaiser Permanente, the Veterans Health Administration) that offer options such as mindfulness and biofeedback in health education and pain programs. However, even in these systems, access to programs can be limited by capacity and the need for patients to meet severity criteria. Our findings show that patients took advantage of the online portal, which can be an economical way to support and maintain patients managing pain and engaging in self-care. Given the high prevalence of

pain in the population, and the changing prescribing environment for opioids, it is critical to study the impact of these other modalities on patient outcomes, as well as how they might be delivered.

Generalizability of the Findings

Generalizability is limited because we conducted the study in an integrated health care system in northern California. However, KPNC members come from a cross-sectional population and are representative of the general population. The clinical characteristics of patients with chronic pain are similar among settings. We purposely included clinical and patient stakeholders from a local FQHC to help ensure the design and findings could be applicable externally. The patient and physician stakeholders from the FQHC were very active throughout the study. As is true with most research studies, those who participated in the study may be different than those who did not. For example, patients who declined to participate may have more severe pain or disability and less ability to participate in the intervention. However, findings are generalizable to patients similar to those in the study, who in turn exhibit characteristics that are common across populations of patients with pain.

Implementation of Study Results

The intervention is replicable and scalable to a wide range of health care organizations and can be delivered by skilled clinicians with training and/or experience with patients with pain. It does not require membership in an integrated health care system because it does not rely on programs focused on substance use, mental health, or pain that might be contracted out in some health systems. In addition, patients expressed strong interest in alternative strategies to manage pain, as many patients do not want to continue taking prescription opioids.[80] Implementing the intervention in primary care helped to destigmatize receiving treatment for chronic pain and the suspicion of "addiction" that patients report when going to specialty pain programs. The primary challenge of implementing a similar intervention in primary care would be human resources. Our intervention used a doctorate-level clinician, but it could easily be facilitated by a master's degree-level clinician. Primary care physicians were

largely appreciative of the additional support with patients receiving long-term opioids, particularly during a time of changing prescribing policy. Other logistical challenges include space for holding the sessions, because busy medical clinics often have little common space to host sessions. Offering services in primary care can alleviate the need for intensive specialty care and provide a safe place to begin discussions on risks of long-term use.

Subpopulations Considerations

Due to a modest sample size, we were not able to look at patient subgroups by risk factors or comorbidities, and we did not specify hypotheses a priori by subpopulations.

Study Limitations

Study limitations included a low recruitment rate, which impacts the generalizability to patients with pain not represented in the sample. As mentioned earlier, this may mean that patients who were too disabled could not participate, or, on the other end of the spectrum, that patients were not disabled but had commitments such as work schedules that did not permit them to participate. However, study findings would be generalizable to patient populations similar to participants. Given the wide range of disability, and the reasons that an in-person intervention may not be feasible for some patients, research is needed with other modalities (eg, online, app-based) to deliver similar interventions. One approach will not be appropriate for all patients, and identifying which patients benefit from different modalities is an important research topic.

Our sample size was lower than we anticipated, given the difficulty reaching patients and their inability to participate in person. However, this was compounded by the tight study time frame. We could have continued recruitment, but we were limited by the time needed to conduct our follow-up interviews. Recruiting staff and gaining IRB approval for the study took longer than anticipated. If the intervention was located on an ongoing basis in primary care or health education, patients might have more options for scheduling classes/groups.

The intervention was brief (four 90-minute sessions) in order to be feasible in a busy primary care setting, where most patients with pain receive their prescriptions and services for their other health conditions. It was intended to be an introduction to alternative pain management strategies and a stepping stone for patients needing additional support, particularly those who do not identify with the needs and services provided by intensive pain programs. However, it may not have been intense enough to impact some outcomes. Nonetheless, we observed important and promising findings—particularly findings that were of high importance to our patient stakeholders.

While we were conducting the study, the health system implemented a regional initiative to reduce risky opioid-prescribing practices. We had not anticipated the impact of policy changes (increased medication agreements, urine tests, clinic oversight and monitoring) on patient and clinician attitudes and behaviors. However, the initiative should have affected both study arms equally.

Participant adherence to the protocol was another limitation. Of the intervention arm participants, 75% completed 3 or more sessions, despite exhaustive techniques for ensuring compliance. However, this is similar to most randomized interventions as well as real-world programs that have been implemented. We conducted intent-to-treat analyses and per protocol analyses and did not find marked differences. Age, employment, and education were negatively correlated with study completion such that older participants without full-time jobs with more education were more likely to complete the follow-up. This difference is not surprising because older patients without full-time employment have more flexibility and time to participate in research studies.

Finally, the perspectives of the patients and clinical providers may not represent all views. Although we did have a range of experiences, patients and providers with more liberal perspectives on opioid use may be underrepresented. However, the study curriculum did not take a position vis-à-vis opioid use; rather, it tried to elicit from patients in the intervention what they viewed as pros and cons.

Future Research

The primary outcome measure, patient activation, was not significant, nor were some other measures of efficacy or engagement. However, we found promising signals for other measures of self-management, mental health, and overall functioning that suggest further research may be warranted. Future research could examine testing the effectiveness of the ACTIVATE curriculum in other types of medical settings, such as FQHCs, to assess its generalizability to other patient populations. This site may have had patients who were already more activated, which may not be true in other settings.

Exploring how the curriculum may translate into e-health is also worthy of further exploration. Many potential participants declined participation in the intervention, citing barriers that were primarily logistical (eg, time, transportation, work); this suggests patients would benefit from resources in a more accessible format, such as smartphone applications, peer support groups, and online pain/wellness coaching. Our finding that more than 90% of patients used the online portal is consistent with other studies[26] and suggests that online tools could prove useful to this patient population.

Another fruitful area for future research is developing an intervention for clinicians on shared decision making and approaches to communicating with patients about pain, opioids, and alternatives to pain management. Clinicians are, of course, key to the clinical relationship, but many providers are not comfortable discussing these topics. Studies could continue to focus on primary care physicians, who remain the main prescribers of opioids, but also could include the study of other models, such as a multidisciplinary team approach in primary care. In addition, results from qualitative interviews suggest that physicians need training on appropriate nonpharmacological pain management tools and how to talk about changes in prescribing. A future study examining the physician perspective on a shared decision-making model of care with activated patients could prove fruitful. This topic was raised frequently by some stakeholders, who were interested in assessing provider factors and the impact on care.

The implementation of longer follow-ups past 6 months, especially with continued support or booster sessions, deserves further study, as some of the significant findings were not

evident until 12 months. While it might be expected that the intervention's impact on patients could eventually fade, the strategies could alternately become habitual over time and strengthened as a learned behavior. Opioid use is often intermittent, and pain can fluctuate. Patients' needs vary over time, and longer follow-up periods to examine changes over time (or lack thereof) are important, particularly because more health systems are implementing policies concordant to the CDC guidelines, the impacts of which are yet to be fully studied.

Finally, additional examination of other strategies that patients use to manage pain will continue to be critical. While some strategies observed in this study were positive, such as mindfulness, some patients may turn to more negative strategies, like obtaining opioids from illicit sources. Additionally, as more states legalize cannabis, it will be important to study the impact of liberalizing policies on patients' use and perceptions of effectiveness. Providers will likely find themselves fielding more questions about cannabis use for pain from their patients.

CONCLUSION

The patient population with chronic pain is complex and diverse. As opioid-prescribing practices continue to become more restrictive, effective and innovative patient-centered approaches must be developed. Patients with chronic pain are high utilizers of health care services and they are exposed to significant risks from long-term prescription opioid use. Although the intervention did not improve patient activation (the primary study outcome) as measured by the PAM-13, patients in the intervention group showed improvement in some secondary outcomes (self-management of pain and increased function and quality of life). The study demonstrated that, in the absence of a full-service, multidisciplinary program, an intervention of limited scope in primary care is feasible and may improve important patient-centered outcomes. Due to the study limitations, the results—positive and negative—should be interpreted with caution pending confirmation, and further research is warranted. Suggestions for future research include an extended intervention, longer follow-up periods, other settings, and potentially other interventions (eg, e-health). Although not formally measured, feedback from intervention participants suggests there was value in the group format, and peer support was an important component of the group sessions. Finally, we were gratified that many study participants expressed appreciation for the intervention (Box 3).

Box 3. Patient Feedback About Intervention

When you taught us about the neuroplasticity effects in the brain when we take opiates and gave us the opportunity to think through that for ourselves, it really helped me to make up my own mind to taper off.

I think I'm going to ask my doctor to refer me to that Pain Program he has been trying to get me to go to all these years. This class helped me see how helpful this kind of information and support can be. I'm thinking of these 4 weeks as a stepping-stone.

REFERENCES

1. Institute of Medicine. *Relieving Pain in America. A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: The National Academies Press; 2011.
2. Volkow ND. *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*. Washington, DC: United States Senate Caucus on International Narcotics Control; 2014.
3. Rudd RA, Seth P, David F, Scholl L. Increases in drug and opioid-involved overdose deaths—United States, 2010-2015. *MMWR Morb Mortal Wkly Rep*. 2016;65(5051):1445-1452.
4. Center for Behavioral Health Statistics and Quality. *Results From the 2015 National Survey on Drug Use and Health: Detailed Tables*. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2016.
5. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Prescription opioid overdose data. https://www.cdc.gov/drugoverdose/data/overdose.html. Published 2017. Accessed August 5, 2019.
6. Centers for Disease Control and Prevention. Opioid data analysis and resources. https://www.cdc.gov/drugoverdose/data/analysis.html. Published 2017. Updated February 9, 2017. Accessed August 5, 2019.
7. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *MMWR Recomm Rep.* 2016;65(1):1-49.
8. Trescott CE, Beck RM, Seelig MD, Von Korff MR. Group Health's initiative to avert opioid misuse and overdose among patients with chronic noncancer pain. *Health Aff (Millwood).* 2011;30(8):1420-1424.
9. Compton WM, Jones CM, Baldwin GT. Relationship between nonmedical prescription-opioid use and heroin use. *N Engl J Med.* 2016;374(2):154-163.
10. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. US opioid prescribing rate maps. https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html. Published 2017. Updated October 3, 2018. Accessed August 5, 2019.
11. Von Korff MR. Opioids for chronic noncancer pain: as the pendulum swings, who should set prescribing standards for primary care? *Ann Fam Med.* 2012;10(4):302-303.
12. Frosch DL, May SG, Rendle KA, Tietbohl C, Elwyn G. Authoritarian physicians and patients' fear of being labeled 'difficult' among key obstacles to shared decision making. *Health Aff (Millwood).* 2012;31(5):1030-1038.
13. Nahin RL, Boineau R, Khalsa PS, Stussman BJ, Weber WJ. Evidence-based evaluation of complementary health approaches for pain management in the United States. *Mayo Clin Proc.* 2016;91(9):1292-1306.
14. Lamb SE, Mistry D, Lall R, et al. Group cognitive behavioural interventions for low back pain in primary care: extended follow-up of the Back Skills Training Trial (ISRCTN54717854). *Pain.* 2012;153(2):494-501.

15. Chou R, Deyo R, Friedly J, et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians clinical practice guideline. *Ann Intern Med.* 2017;166(7):493-505.
16. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA.* 2002;288(19):2469-2475.
17. Daubresse M, Chang HY, Yu Y, et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000-2010. *Med Care.* 2013;51(10):870-878.
18. Chelminski PR, Ives TJ, Felix KM, et al. A primary care, multi-disciplinary disease management program for opioid-treated patients with chronic non-cancer pain and a high burden of psychiatric comorbidity. *BMC Health Serv Res.* 2005;5(1):3.
19. Kroenke K, Krebs E, Wu J, et al. Stepped Care to Optimize Pain care Effectiveness (SCOPE) trial study design and sample characteristics. *Contemp Clin Trials.* 2013;34(2):270-281.
20. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res.* 2004;39(4, pt 1):1005-1026.
21. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood).* 2013;32(2):207-214.
22. Bernabeo E, Holmboe ES. Patients, providers, and systems need to acquire a specific set of competencies to achieve truly patient-centered care. *Health Aff (Millwood).* 2013;32(2):250-258.
23. Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ.* 1999;319(7212):766-771.
24. Rollnick S, Butler CC, Kinnersley P, Gregory J, Mash B. Motivational interviewing. *BMJ.* 2010;340:c1900. doi: 10.1136/bmj.c1900
25. Driessen E, Hollon S. Motivational interviewing from a cognitive behavioral perspective. *Cogn Behav Pract.* 2011;18:70-73.
26. Weisner CM, Chi FW, Lu Y, et al. Examination of the effects of an intervention aiming to link patients receiving addiction treatment with health care: the Linkage Study clinical trial. *JAMA Psychiatry.* 2016;73(8):804-814.
27. Centers for Disease Control and Prevention, National Center for Health Statistics. *International Classification of Diseases, Ninth Revision* (*ICD-9*). https://www.cdc.gov/nchs/icd/icd9.htm. Published 2009. Last updated September 1, 2009. August 5, 2019.
28. Terry PE, Fowles JB, Xi M, Harvey L. The ACTIVATE study: results from a group-randomized controlled trial comparing a traditional worksite health promotion program with an activated consumer program. *Am J Health Promot.* 2011;26(2):e64-e73. doi: 10.4278/ajhp.091029-QUAN-348
29. Bond GR, Drake RE, McHugo GJ, Peterson AE, Jones AM, Williams J. Long-term sustainability of evidence-based practices in community mental health agencies. *Adm Policy Ment Health.* 2014;41(2):228-236.

30. Druss BG. The Health and Recovery Peer (HARP) program: a peer-led intervention to improve medical self-management for persons with serious mental illness. *Schizophr Res.* 2010;118(1-3):264-270.
31. Peterson AE, Bond GR, Drake RE, McHugo GJ, Jones AM, Williams JR. Predicting the long-term sustainability of evidence-based practices in mental health care: an 8-year longitudinal analysis. *J Behav Health Serv Res.* 2014;41(3):337-346.
32. Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA. The PCORI engagement rubric: promising practices for partnering in research. *Ann Fam Med.* 2017;15(2):165-170.
33. Mahenge B, Stockl H, Mizinduko M, Mazalale J, Jahn A. Adverse childhood experiences and intimate partner violence during pregnancy and their association to postpartum depression. *J Affect Disord.* 2018;229:159-163.
34. Madrid S, Tuzzio L, Stults CD, et al. Sharing experiences and expertise: the Health Care Systems Research Network workshop on patient engagement in research. *J Patient Cent Res Rev.* 2016;3:159-166.
35. Cherkin DC, Sherman KJ, Balderson BH, et al. Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: a randomized clinical trial. *JAMA.* 2016;315(12):1240-1249.
36. Turner JA, Anderson ML, Balderson BH, Cook AJ, Sherman KJ, Cherkin DC. Mindfulness-based stress reduction and cognitive behavioral therapy for chronic low back pain: similar effects on mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial. *Pain.* 2016;157(11):2434-2444.
37. Ehde DM, Dillworth TM, Turner JA. Cognitive-behavioral therapy for individuals with chronic pain: efficacy, innovations, and directions for research. *Am Psychol.* 2014;69(2):153-166.
38. Alperstein D, Sharpe L. The efficacy of motivational interviewing in adults with chronic pain: a meta-analysis and systematic review. *J Pain.* 2016;17(4):393-403.
39. Sox HC, Lewis RJ. Pragmatic trials: practical answers to "real world" questions. *JAMA.* 2016;316(11):1205-1206.
40. Gordon N, Lin T. The Kaiser Permanente Northern California Adult Member Health Survey. *Perm J.* 2016;20(4):34-42.
41. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the Patient Activation Measure. *Health Serv Res.* 2005;40(6, pt 1):1918-1930.
42. Hibbard JH, Greene J, Shi Y, Mittler J, Scanlon D. Taking the long view: how well do patient activation scores predict outcomes four years later? *Med Care Res Rev.* 2015;72(3):324-337.
43. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16(9):606-613.
44. Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatr Ann.* 2002;32(9):509-515.
45. Cella D, Yount S, Rothrock N, et al. The Patient-reported Outcomes Measurement Information System (PROMIS): progress of an NIH roadmap cooperative group during its first two years. *Med Care.* 2007;45(5)(suppl 1):S3-S11.

46. Cella D, Riley W, Stone A, et al. The Patient-reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol.* 2010;63(11):1179-1194.
47. Cook KF, Jensen SE, Schalet BD, et al. PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. *J Clin Epidemiol.* 2016;73:89-102.
48. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res.* 2009;18(7):873-880.
49. Butler SF, Budman SH, Fernandez K, Jamison RN. Validation of a screener and opioid assessment measure for patients with chronic pain. *Pain.* 2004;112(1-2):65-75.
50. Akbik H, Butler SF, Budman SH, Fernandez K, Katz NP, Jamison RN. Validation and clinical application of the Screener and Opioid Assessment for Patients With Pain (SOAPP). *J Pain Symptom Manage.* 2006;32(3):287-293.
51. Butler SF, Budman SH, Fernandez KC, et al. Development and validation of the Current Opioid Misuse Measure. *Pain.* 2007;130(1-2):144-156.
52. Jensen MP, Turner JA, Romano JM, Strom SE. The Chronic Pain Coping Inventory: development and preliminary validation. *Pain.* 1995;60(2):203-216.
53. Romano JM, Jensen MP, Turner JA. The Chronic Pain Coping Inventory-42: reliability and validity. *Pain.* 2003;104:65-73.
54. Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain.* 2007;11(2):153-163.
55. Makoul G, Krupat E, Chang CH. Measuring patient views of physician communication skills: development and testing of the Communication Assessment Tool. *Patient Educ Couns.* 2007;67(3):333-342.
56. Maly RC, Frank JC, Marshall GN, DiMatteo MR, Reuben DB. Perceived efficacy in patient-physician interactions (PEPPI): validation of an instrument in older persons. *J Am Geriatr Soc.* 1998;46(7):889-894.
57. National Institute on Alcohol Abuse and Alcoholism. *Helping Patients Who Drink Too Much: A Clinician's Guide*. Updated 2005 edition. http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm. Published 2005. Updated January 2007. Accessed August 5, 2019.
58. Who Assist Working Group. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility. *Addiction.* 2002;97(9):1183-1194.
59. National Center for Injury Prevention and Control. *CDC Compilation of Benzodiazepines, Muscle Relaxants, Stimulants, Zolpidem, and Opioid Analgesics With Oral Morphine Milligram Equivalent Conversion Factors.* Atlanta, GA: Centers for Disease Control and Prevention; 2016.
60. Von Korff M, Saunders K, Thomas Ray G, et al. De facto long-term opioid therapy for noncancer pain. *Clin J Pain.* 2008;24(6):521-527.
61. Boudreau D, Von Korff M, Rutter CM, et al. Trends in long-term opioid therapy for chronic non-cancer pain. *Pharmacoepidemiol Drug Saf.* 2009;18(12):1166-1175.

62. Weisner CM, Campbell CI, Ray GT, et al. Trends in prescribed opioid therapy for non-cancer pain for individuals with prior substance use disorders. *Pain.* 2009;145(3):287-293.
63. Li T, Hutfless S, Scharfstein DO, et al. Standards should be applied in the prevention and handling of missing data for patient-centered outcomes research: a systematic review and expert consensus. *J Clin Epidemiol.* 2014;67(1):15-32.
64. National Research Council. *The Prevention and Treatment of Missing Data in Clinical Trials.* Washington, DC: National Academies Press; 2010.
65. Smolkowski K, Danaher BG, Seeley JR, Kosty DB, Severson HH. Modeling missing binary outcome data in a successful web-based smokeless tobacco cessation program. *Addiction.* 2010;105(6):1005-1015.
66. Young R, Johnson DR. Imputing the missing Y's: implications for survey producers and survey users. Presented at 64th Annual Conference of the American Association for Public Opinion Research; May 13-16, 2010; Chicago, IL.
67. Yuan Y. Multiple imputation using SAS software. *J Stat Softw.* 2011;45(6):1-25.
68. Rothman KJ. No adjustments are needed for multiple comparisons. *Epidemiology.* 1990;1(1):43-46.
69. Savitz DA, Olshan AF. Multiple comparisons and related issues in the interpretation of epidemiologic data. *Am J Epidemiol.* 1995;142(9):904-908.
70. Hibbard J, Gilburt H. *Supporting People to Manage Their Health: An Introduction to Patient Activation.* London, UK: The King's Fund; 2014.
71. Broderick JE, Schneider S, Junghaenel DU, Schwartz JE, Stone AA. Validity and reliability of patient-reported outcomes measurement information system instruments in osteoarthritis. *Arthritis Care Res (Hoboken).* 2013;65(10):1625-1633.
72. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. *Annual Surveillance Report of Drug-related Risks and Outcomes—United States 2017*. https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf. Published 2017. Accessed August 5, 2019.
73. Kabat-Zinn J. *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness.* New York, NY: Random House; 2005.
74. Reiner K, Tibi L, Lipsitz JD. Do mindfulness-based interventions reduce pain intensity? A critical review of the literature. *Pain Med.* 2013;14(2):230-242.
75. Fjorback LO, Arendt M, Ornbol E, Fink P, Walach H. Mindfulness-based stress reduction and mindfulness-based cognitive therapy: a systematic review of randomized controlled trials. *Acta Psychiatr Scand.* 2011;124(2):102-119.
76. Morone NE, Greco CM, Moore CG, et al. A mind-body program for older adults with chronic low back pain: a randomized clinical trial. *JAMA Intern Med.* 2016;176(3):329-337.
77. Löwe B, Unützer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the Patient Health Questionnaire-9. *Med Care.* 2004;42:1194-1201.
78. Miller LR, Cano A. Comorbid chronic pain and depression: who is at risk? *J Pain.* 2009;10(6):619-627.

79. Smith K, Mattick RP, Bruno R, et al. Factors associated with the development of depression in chronic non-cancer pain patients following the onset of opioid treatment for pain. *J Affect Disord.* 2015;184:72-80.
80. Penney LS, Ritenbaugh C, DeBar LL, Elder C, Deyo RA. Provider and patient perspectives on opioids and alternative treatments for managing chronic pain: a qualitative study. *BMC Family Practice.* 2017;17(1):164.

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