



RESEARCH ARTICLE

Pre-implementation formative evaluation of cooperative pain education and self-management expanding treatment for real-world access: A pragmatic pain trial

Kristin M. Mattocks PhD^{1,2}  | Kathryn M. LaChappelle MPH³ | Sarah L. Krein PhD^{4,5} | Lynn L. DeBar PhD⁶ | Steve Martino PhD^{3,7} | Sara Edmond PhD^{3,7} | Brett Ankawi PhD^{3,7} | R. Ross MacLean PhD^{3,7} | Diana M. Higgins PhD^{8,9}  | Jennifer L. Murphy PhD¹⁰ | Emily Cooper MPH^{1,2} | Alicia A. Heapy PhD^{3,7}

¹VA Central Western Massachusetts Healthcare System, Leeds, Massachusetts, USA

²University of Massachusetts Medical School, Worcester, Massachusetts, USA

³VA Connecticut Healthcare System Pain Research, Informatics, Multimorbidities, and Education (PRIME) Health Services Research and Development Center of Innovation, West Haven, Connecticut, USA

⁴VA Ann Arbor Center for Clinical Management Research, Health Services Research and Development Center of Innovation, Ann Arbor, Michigan, USA

⁵University of Michigan Medical School, Ann Arbor, Michigan, USA

⁶Kaiser Permanente Washington Health Research Institute, Washington, USA

⁷Yale University School of Medicine, New Haven, Connecticut, USA

⁸VA Boston Healthcare System, Boston, Massachusetts, USA

⁹Boston University School of Medicine, Boston, Massachusetts, USA

¹⁰US Department of Veterans Affairs Central Office, Washington, DC, USA

Correspondence

Kristin M. Mattocks, VA Central Western Massachusetts Healthcare System, Building 12, Room 113, 421 North Main Street, Leeds, MA 01053, USA.
Email: kristin.mattocks@va.gov

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Abstract

Objective: Cognitive behavioral therapy for chronic pain (CBT-CP) is an evidence-based treatment for improving functioning and pain intensity for people with chronic pain with extensive evidence of effectiveness. However, there has been relatively little investigation of the factors associated with successful implementation and uptake of CBT-CP, particularly clinician and system level factors. This formative evaluation examined barriers and facilitators to the successful implementation and uptake of CBT-CP from the perspective of CBT-CP clinicians and referring primary care clinicians.

Methods: Qualitative interviews guided by the Consolidated Framework for Implementation Research were conducted at nine geographically diverse Veterans Affairs sites as part of a pragmatic clinical trial comparing synchronous, clinician-delivered CBT-CP and remotely delivered, technology-assisted CBT-CP. Analysis was informed by a grounded theory approach.

Results: Twenty-six clinicians (CBT-CP clinicians = 17, primary care clinicians = 9) from nine VA medical centers participated in individual qualitative interviews conducted by telephone from April 2019 to August 2020. Four themes emerged in the qualitative interviews: (1) the complexity and variability of referral pathways across sites, (2) referring clinician's lack of knowledge about CBT-CP, (3) referring clinician's difficulty identifying suitable candidates for CBT-CP, and (4) preference for interventions that can be completed from home.

Conclusions: This formative evaluation identified clinician and system barriers to widespread implementation of CBT-CP and allowed for refinement of the subsequent implementation of two forms of CBT-CP in an ongoing pragmatic trial. Identification of relative difference in barriers and facilitators in the two forms of CBT-CP may emerge more clearly in a pragmatic trial that evaluates how treatments perform in real-world settings and may provide important information to guide future system-wide implementation efforts.

KEY WORDS

access, education, pain management, veterans

BACKGROUND

Chronic pain treatment in the United States has undergone considerable change in response to the opioid epidemic and harms associated with opioid use.¹ Current treatment guidelines^{2,3} emphasize restraint in opioid use and a multi-modal strategy that includes nonpharmacological approaches to pain management. One widely studied nonpharmacological approach, cognitive behavioral therapy for chronic pain (CBT-CP), is a psychological intervention that emphasizes the use of cognitive and behavioral pain coping skills to manage pain and promote improved functioning. CBT-CP has significant, small to moderate long-term improvements in pain intensity, disability, and mood compared to usual care for nonheadache pain.^{4,5} To ensure access to CBT-CP for its patients, the Department of Veterans Affairs (VA) undertook a national training and dissemination program in CBT-CP, training over 1000 VA mental health clinicians to deliver CBT-CP to date.⁶ An evaluation of CBT-CP provided by clinicians trained by this program to 1331 VA patients found moderate to large effects on catastrophizing, pain interference, physical quality of life, depression and pain intensity, supporting the effectiveness of the training program.⁷

Though the effectiveness of CBT-CP has been studied extensively, there is relatively little information about factors associated with implementation and uptake of CBT-CP. A few studies have focused on patient-level barriers and facilitators to engaging in CBT-CP.⁸ A consistent reported barrier is that patients often conceptualize pain as having only biomedical causes and doubt that a psychological intervention could address physical pain.^{9,10} Patients also have perceived that the psychologically oriented CBT-CP could delegitimize their physical pain. Further, people with widespread chronic pain have expressed a strong preference for exercise or exercise plus CBT-CP and rather than CBT-CP alone.⁹ Nonetheless, participants who have received CBT-CP have reported that CBT-CP promoted their understanding of pain triggers and proactive use of pain management skills. Post-treatment they have reported more favorable attitudes toward CBT-CP, which suggests patients' negative perceptions may be related to lack of knowledge about CBT-CP and biopsychosocial explanations for chronic pain. Efforts to address negative attitudes toward CBT-CP are needed to promote its uptake.⁸

Additionally, travel to appointments, shortages of trained clinicians, and stigma have been found to be common barriers to nonpharmacological treatments including CBT-CP.^{1,10} Technology-based options, particularly through internet and telephone, are increasingly being used to address travel and clinician shortage barriers by delivering treatments such as CBT-CP to people in their homes.^{11,12} A recent noninferiority trial conducted by our group in VA found that CBT-CP can be delivered via interactive voice response (IVR) with remote,

asynchronous therapist support, and that treatment outcomes for IVR-CBT-CP are comparable to in-person CBT-CP.¹³

Little is known, however, about the *relative* effectiveness or clinician-reported barriers to patient engagement and adherence for asynchronous IVR-CBT-CP and synchronous, real-time forms of CBT-CP (in-person, videoconferencing, or telephone), when implemented on a large-scale basis in real-world care settings. To that end, we conducted a formative evaluation as a prelude to a large-scale pragmatic multi-site trial examining the relative effectiveness of these two treatments to (1) understand pain care practices and referral pathways at the clinical sites where IVR-CBT-CP and synchronous CBT-CP (in-person, videoconferencing, telephone) will be delivered, and (2) identify clinician-reported barriers and facilitators to implementation of both IVR and synchronous CBT-CP. This allowed us to (1) adapt study procedures to local practices and resources levels, (2) identify and monitor factors associated with referral and widespread uptake of each version of CBT-CP, and (3) address implementation barriers that might hinder use of either version in the trial or clinical practice broadly.

METHODS

Study design

This is a qualitative descriptive study that used data collected through semi-structured qualitative interviews to examine clinicians' initial views of contextual factors that could influence the implementation of IVR-CBT-CP and synchronous CBT-CP within the Cooperative Pain Education and Self-management: Expanding Treatment for Real-World Access (COPEs ExTRA) trial. The COPEs ExTRA trial is a randomized pragmatic trial designed to directly evaluate the relative effectiveness of asynchronous IVR-CBT-CP compared to synchronous CBT-CP delivered in person or by videoconferencing platform or telephone as COVID-19 conditions allowed by trained clinicians providing CBT-CP as part of their regular VA clinical duties. A detailed protocol is published elsewhere.¹⁴ These interviews served as the basis for identifying factors before the trial began (i.e., preimplementation phase) that could facilitate or hinder use of either form of CBT-CP in participating medical centers during the trial (i.e., implementation phase). We used the Consolidated Framework for Implementation Research¹⁵ to guide the development of our interviews, which contains constructs organized into five major domains affecting implementation: (1) *intervention characteristics* (e.g., complexity and adaptability), (2) *outer setting* (e.g., broader organization system and policies), (3) *inner setting* (e.g., climate and organizational structures that could affect the intervention), (4) *characteristics of the*

individuals involved (e.g., knowledge and beliefs), and (5) *implementation process* (e.g., strategies and tools employed for adoption). Because interviews focused on the factors present in the study sites prior to the start of the trial, strategies for implementing CBT-CP (item 5, the implementation process) were not examined.

Study setting, sample and recruitment procedures

Participants were recruited from nine VA medical centers across four US Census regions covering the Northeast, Midwest, South, and West. Local site investigators identified staff engaged in referral to or provision of CBT-CP as potential study participants. Sixty-eight VA clinicians from primary care, pain management, and mental health were sent an e-mail describing the study and requesting their participation in a telephone or videoconference interview. Of these clinicians, 26 agreed to an interview. Before the interview, an informed consent document and a brief reiteration of the study purpose was provided, and the interviewer confirmed consent to electronically record the interview for transcription and analysis purposes. Each interview lasted approximately 30 minutes. All interviews were conducted between April 2019 and August 2020. Participants at six of nine sites completed interviews prior to the beginning of the COVID-19 pandemic; three sites participated during the pandemic (July–August 2020). An Institutional Review Board approved the study.

Qualitative interviews

The primary author, a health services researcher, conducted all interviews. The interviews were conducted using a semi-structured interview guide (included in Appendix A) developed by the study team. Guide development was informed by the Consolidated Framework for Implementation Research and information gleaned during site selection about how CBT-CP was delivered at each of the nine sites. After an initial orientation to COPEs EXTRA, interviews assessed the process for pain care referrals (specifically CBT-CP referrals), areas for improvement in the process, and facilitators and barriers to adoption of the intervention. Audio-recordings of all interviews were transcribed. Atlas.Ti software was used to facilitate the analysis. Qualitative analyses were informed by grounded theory methodology, a systematic approach to deriving qualitative themes from textual data.¹⁶ We first conducted open coding in which two investigators (KM and EC) identified key concepts emerging from the language used by participants and assigned codes (descriptive phrases) to segments of text. These codes were used to create a top-level codebook that was applied to all qualitative data. At all stages, coding was

performed and discussed by two investigators, and the codebook was refined until agreement was reached. Themes that emerged in the interviews were examined for similarities and differences in perspectives in a process known as constant comparative method. Subsequently, prominent themes and quotes exemplifying each were presented to the research team and refined.

RESULTS

Participants characteristics

Our sample included 26 CBT-CP or primary care clinicians from nine VA medical centers. Seventeen (65%) of the clinicians were female, and 17 (65%) were psychologists (i.e., CBT-CP clinicians). See Table 1 for site characteristics.

Four major themes emerged from the interviews: (1) Pain care referral pathways were complex and vary substantially across VA medical centers; (2) Limited clinician knowledge of biopsychosocial interventions may limit referrals to CBT-CP; (3) Clinicians find it challenging to identify appropriate candidates for CBT-CP; and (4) Growing preference for telehealth pain care options during the COVID-19 pandemic.

Pain care referral pathways are often complex and vary substantially across VA medical centers

Across the nine VA facilities, there was substantial variability in how veterans were referred to CBT-CP. Most facilities had a multidisciplinary pain clinic that acted as a gatekeeper to a wide variety of pain care options, including CBT-CP. Pain clinics typically consist of medical and behavioral health clinicians jointly assessing patients and making referrals and recommendations for pain care often highlighting nonpharmacological and nonsurgical options. In some facilities, veterans were first required to attend a series of educational sessions that would be used to explain the fundamentals of chronic pain and describe available pain care options, which may include CBT-CP. As one CBT-CP clinician from the West explained:

They are scheduled into a four session education group series where we talk about chronic pain, different treatments, different ways to think about pain. Then they're scheduled into an hour-long intake, (with) a psychologist and a medical provider seeing them together. That's typically the core of their treatment where we will prescribe, refer to different treatments with mostly a non-medication emphasis or non-surgical emphasis.

TABLE 1 Demographic and descriptive information for the COPEX ExTRA trial sites ($N = 9$)

US census region/division	Unique patients (n) ^a	Age under 55 (%)	Race/ethnicity (%)	Female patients (%)	Clinicians participating in interview
Northeast/New England	25,816	25	Black = 5 Hispanic = 5 Asian = 0 Native Am = 0	7.2	4 (primary care = 2, CBT-CP = 2)
Midwest/East North Central	64,363	26	Black = 10 Hispanic = 2 Asian = 0 Native Am = 0	9.9	2 (primary care = 1, CBT-CP = 1)
Midwest/East North Central	54,521	26	Black = 19 Hispanic = 6 Asian = 1 Native Am = 0	10.8	3 (primary care = 1, CBT-CP = 2)
South/South Atlantic	75,395	37	Black = 34 Hispanic = 3 Asian = 1 Native Am = 0	14.8	2 (CBT-CP = 2)
South/East South Central	38,651	28	Black = 45 Hispanic = 2 Asian = 0 Native Am = 0	12.8	3 (primary care = 1, CBT-CP = 2)
South/West South Central	130,528	38	Black = 26 Hispanic = 8 Asian = 1 Native Am = 1	12.8	3 (primary care = 1, CBT-CP = 2)
South/West South Central	104,183	43	Black = 22 Hispanic = 14 Asian = 1 Native Am = 0	15.8	3 (CBT-CP = 3)
South/West South Central	61,250	37	Black = 15 Hispanic = 4 Asian = 1 Native Am = 3	12.3	2 (CBT-CP = 2)
West/Pacific	102,201	35	Black = 10 Hispanic = 5 Asian = 3 Native Am = 1	12.9	4 (primary care = 2, CBT-CP = 2)

^aUnique patients in fiscal year 2020 obtained from the outpatient encounters cube (VSSC).

One primary care clinician from a Northeastern site with a pain clinic talked about the advantages of having one place to go, which often led to better coordination with the veteran's pain care:

I think for the patient to go to the pain clinic, one of the advantages is that it is coordinated. The social worker or the psychologist on the team will follow-up with the patient and say okay, 'we made these 12 recommendations, which ones are you following through with?'. They'll follow-up with them and that helps with coordination.

However, patients may not be ready to act on recommendations immediately and that can hamper follow-up and cause gaps in veterans' care. As one CBT-CP clinician from the Northeast said:

What can happen is if the veteran isn't sure, wants to process a little bit more, they get a copy of their recommendations in the mail. Their PCP gets a copy as well and their mental health clinician is copied on the note too so everybody can be on the same page. But sometimes the veterans don't take us up on referrals right away. Sometimes there can be a lull in follow-up.

Another CBT-CP clinician from the Midwest noted a similar experience with the pain clinic and the frustration both the veterans and clinicians had with the referral process:

Some veterans say, 'I went to that pain clinic and nothing ever came of it'. And then you go back in their [medical] record

and you realize that they said ‘well, maybe, maybe, maybe, maybe’. No referrals were made. They got the recommendations in the mail and then we don't necessarily follow-up with them again unless they're referred to one of the five of us on the team for something individualized or to pain school and we don't see them again; we don't necessarily follow-up.

Some clinicians also said that the pain referral pathways were too complicated, with too many different pain care routes in one hospital. A primary care clinician from the South noted:

We have a pain clinic which primarily is involving things like pain injections and prescribing medications for pain, specifically with a pain specialist. We also have a multidisciplinary pain clinic, which is for patients who have not responded to standard pain interventions.

Limited clinician knowledge of biopsychosocial interventions may limit referrals to CBT-CP

Clinician knowledge regarding biopsychosocial interventions for chronic pain and other conditions varied substantially across sites. Many physicians admitted they had little knowledge of biopsychosocial interventions such as CBT-CP, and in these instances, clinicians decided to refer a veteran directly to the pain clinic rather than directly to CBT-CP, as they felt the pain clinic had better knowledge of biopsychosocial pain care treatment. One CBT-CP clinician from the Midwest spoke about the need for more CBT-CP education among primary care clinicians:

Overall, I'm not sure some primary care clinicians are even aware of CBT for chronic pain. I should be out there doing more education about CBT for chronic pain.

Another CBT-CP clinician from the Southeast concurred about the need for expanded education to increase CBT-CP referrals:

I think there's a lot of variability. Because some (clinicians) are more familiar than others, and even though we've done some education, some are still more open than others.

A CBT-CP clinician from the South also described the challenges of getting primary care clinicians to refer to CBT-CP:

Within the clinic that I'm working with we have maybe like 1.5 providers that are really comfortable with referring for CBT for chronic pain. I have one who's really good and just about everyone he sees he offers it just as an additional resource. It's been kind of slow to get some of the others to send referrals. Sometimes I'll get some primary care referrals but there's very few and far in between.

Some primary care clinicians were knowledgeable about CBT-CP, but worried that their colleagues in primary care were less knowledgeable and left decisions about pain care to the pain clinic. When describing referrals for CBT-CP, one primary care physician from the Midwest explained that the decision to refer was “clinician dependent”, based on the primary care clinicians knowledge of CBT-CP and ability to explain its benefits:

I would say many of us, and I hope many of us, go to CBT early in the flow of how we care for chronic pain. Others probably punt that discussion to the Pain Clinic. It probably comes in different varieties, depending on the patient, and depending on the provider's willingness to engage in that fairly lengthy discussion about the benefits of CBT-CP.

Clinicians find it challenging to identify suitable candidates for CBT-CP

Clinicians spoke at length about which veterans they believed would benefit most from CBT-CP. A range of beliefs were expressed. A primary care clinician from the Northeast explained:

Probably people that have already been through the pain program and have chronic pain and are consciously managing it through tai chi or acupuncture, things like that. I would think this could be a good adjunct to help them along to manage it. I imagine CBT would help those patients.

Another psychologist from the South stated:

I think people tend to get referred to mental health to help with the transition off of opioid usage and come up with other strategies, and so I think that that's where a lot of the referrals that I've been seeing from that team in particular, is veterans that are being tapered off opioids are being sent then to the CBT-CP, to kind of help with new strategies for pain management.

Conversely, a primary care clinician from the Northwest noted:

The ones who have PTSD, depression, and anxiety that's all untreated. Those are the people who would definitely benefit from CBT for chronic pain. Versus the 40-year-old whose got chronic back pain but is otherwise working and he doesn't have any mental health diagnoses. That's somebody who I probably wouldn't be as eager to send to the mental health, even though they would probably also benefit from it.

Other clinicians spoke of the importance of veterans being committed to trying CBT-CP, and if the commitment was not there, it was hard for CBT-CP to be effective. One primary care clinician from the Northeast explained:

I've had the experience where a veteran agreed to do CBT for chronic pain, then ended up going to see a spine specialist who recommended surgery. He decided he wanted to do surgery. But he said, 'I'll still do CBT for chronic pain in the meantime'. And what I found in working with the veteran is that he kept putting all of his eggs into, 'the surgery is going to fix-it' basket. And I think he was less motivated to come to the CBT for chronic pain group. He wasn't really as invested in trying out the skills.

Growing preference for telehealth pain care options during the COVID-19 pandemic

Many VA clinicians spoke about the increasing comfort that veterans feel when engaging in remote pain care. For some veterans who live rurally, remote options are ideal and save them a trip to the VA. One CBT-CP clinician from the South noted the challenges of frequent appointments for pain care for rural veterans:

They have to go to the CBOCs [community-based outpatient clinics], and even for some of them, the CBOCs are still an hour, 90 minutes away, and you're talking about weekly treatment to get there, and so that can provide a significant hardship among our veterans.

A primary care clinician from the Northwest concurred:

There are a lot of patients who, for one reason or another, come from further away to be seen here rather than go to a closer clinic like one of the CBOCs for example. The

ability to do things like CBT remotely, either from the comfort of their home or from, you know, their closest CBOC would be great.

One CBT-CP clinician from the South spoke of the success of CBT-CP telehealth approaches:

I'm finding that a lot of the veterans, especially with chronic pain, a lot of them are responding really well. I'm seeing huge improvements and actually following through with the protocol, just from offering it via telehealth.

Another psychologist from the Northwest agreed with the strength of the telehealth option for chronic pain:

I've been doing chronic pain treatment through VVC [VA Video Connect, a secure online telehealth platform like Zoom] for 5 years now, and I feel like it's just as effective as in-person. The results and trying to do the program has been just as well received as if it was in-person. I see absolutely zero issues with it, because everything I've done with chronic pain, training, or implementation, has been virtual.

Several clinicians reflected on how the COVID-19 pandemic shifted pain care from in-person to videoconferencing or telephone appointments. Clinicians noted that the VA was already a leader in telehealth, and the pandemic only further strengthened VA's ability to provide remote care. One CBT-CP clinician from the South noted:

I think is wonderful about how the VA has responded to the pandemic. We had the infrastructure in place and were doing quite a bit of telehealth before the pandemic. I think we're one of the telehealth leaders in the country. We do a lot. I was doing some telehealth even before the pandemic and so, for me, it was just about enrolling more patients in it and educating patients about it.

Finally, a CBT-CP clinician from the Midwest spoke about how videoconferencing, specifically, has improved care for veterans during the pandemic:

I feel that that'll benefit people more because you can actually look at the patient. You can look at their expressions to get a feel for where they're at. You know, I think that it is something that is worth doing, especially with COVID-19. We don't know when we're gonna get back to normal operations. If this works well, the reach is so much wider. It's exciting.

DISCUSSION

This formative evaluation examined pain care referral practices and clinician-reported barriers and facilitators that affect the use of CBT-CP across nine VA facilities participating in a randomized pragmatic trial examining a synchronous and asynchronous version of CBT-CP. Our findings identified several themes, which mapped onto Consolidated Framework for Implementation Research domains. Overall, pain care referral pathways were complex and varied by site (Inner Setting). Referring clinicians lacked knowledge about CBT-CP and expressed differing standards for identifying suitable patients for referral (Characteristics of Individuals Involved). Our findings also revealed a perception of the relative advantage of telehealth or remotely delivered CBT-CP in addressing patient travel barriers (Intervention Characteristics), a perception that grew after COVID-19 began and more patients used telehealth successfully.

Although each site had its own referral pathway to CBT-CP, often a pain clinic served as a hub for patients' referral to CBT-CP and other specialty pain care rather than directly from a primary care clinician to CBT-CP clinician. The VA has adopted the Stepped Care Model of Pain Management (Stepped Care Model),^{17,18} which endorses primary care management of chronic pain with stepwise referral to higher levels of care for patients as needed. VA endorsement of the Stepped Care Model provides outer setting support for comprehensive and organized pain care, but it does not specify referral pathways, the timing of referrals, or the sequence of treatments (all inner setting matters). A study conducted in VA found that despite adoption of this model, primary care clinicians expressed a need for a more specific pathway or algorithm to guide referral of patients with chronic pain.¹⁹ Absent evidence to guide such an algorithm, referrals often depend on clinician knowledge of treatment availability, their own preferences and the patient's real or perceived preference. Clinician's reliance on a pain clinic likely reduces uncertainty and shifts referral choices to those specializing in chronic pain care. However, a drawback noted by interviewees included delay or disruption in receiving recommended care especially when patients did not accept pain clinic recommendations during their pain clinic visit, which necessitated post-visit care coordination that may not be available at all sites.

Our interviews revealed two barriers to accessing CBT-CP involving characteristics of referring clinicians: (1) referring clinician's lack of knowledge about CBT-CP and (2) referring clinician's difficulty identifying suitable patients for referral. Though there were clinicians who were knowledgeable about CBT-CP and indicated clear reasons for referring (e.g., catastrophizing or fear of movement, opioid tapering), many clinicians were unaware of its availability, indication, or when to refer patients. In interviews, some clinicians said that patients with mental

health diagnoses would be the primary group of patients who should be referred to CBT-CP, despite the evidence for any patient with chronic pain potentially benefiting from CBT-CP, and clinical guidelines encouraging CBT-CP and other nonpharmacological interventions as first line treatments.^{3,20} Limited clinician knowledge and negative attitudes about CBT-CP and nonpharmacological interventions generally has also been found in prior studies.^{21,22} Additionally, clinicians may anticipate or share patient skepticism of nonpharmacological interventions or preference for medications.²¹ These attitudinal barriers could be addressed through improved clinician and patient education about CBT-CP. Given that the rationale or benefit of CBT-CP is not intuitive for patients,^{8,9} it is particularly important that clinicians are knowledgeable about CBT-CP and able to communicate to patients the rationale, benefits and validity of CBT-CP and other nonpharmacological interventions. In light of the predominance of the biomedical model for understanding pain a large-scale population-based education or messaging campaign to explain and promote CBT-CP and other nonpharmacological interventions may be required to ensure widespread acceptance and uptake of these treatments.²³

Finally, referring clinicians noted that including remote or telehealth delivery of CBT-CP, as in the IVR-CBT-CP option, as a characteristic of the intervention may be favored by patients due to its potential to reduce travel burden. Even prior to the start of the COVID-19 pandemic, clinicians in the sample were supportive of these interventions and noted that some patients, especially those who experienced travel difficulties preferred technology-based treatments. In interviews conducted after the COVID-19 pandemic commenced, clinicians indicated the positive role that technology-based treatment played in allowing pain care to continue. Acceptance and greater experience with technology-based treatments gained in the pandemic will likely facilitate implementation of IVR-CBT-CP in the planned pragmatic trial and indicates that marketing and education to clinicians about the benefits of technology-based treatments may not be necessary. Clinician's positive assessments of telehealth and technology-assisted interventions for chronic pain is consistent with the growing literature showing positive treatment effects for patients using these interventions.^{11,24-26}

The results of the preimplementation formative evaluation informed adjustments made to the trial to support successful implementation of in-person and telehealth delivery of CBT-CP. The varied pathways to CBT-CP within the sites prompted us to tailor study referral pathways to each site's existing pathways (Inner Setting). At some facilities, referral to CBT-CP was made directly from primary care physicians to CBT-CP clinicians, while at other facilities, patients were referred to pain clinics, which served as gatekeepers for other pain treatments including CBT-CP. At sites where referrals were

made directly from primary care to CBT-CP, we installed an electronic medical record referral alert into the electronic health record. The alert fired for any patient with a musculoskeletal diagnosis code commonly associated with pain (e.g., back or neck conditions, osteoarthritis, joint pain) and repeated pain intensity ratings indicating at least moderate pain (see previously published protocol).¹⁴ The alert enabled a streamlined two-click referral to the study. At sites where the patient referral pathway to CBT-CP is through a pain clinic referral rather than directly from primary care, CBT-CP clinicians recruited from the pool of patients who were referred to CBT-CP through the usual clinical activity of the pain clinic (i.e., nontrial related).

To address the lack of clinician knowledge about CBT-CP and facilitate identification of suitable patients for CBT-CP (Characteristics of Individuals Involved), we included informational supports in the body of the referral alert tool. These updates were developed based on feedback gathered from primary care clinicians during a small pilot study. The alert states that CBT-CP is an evidence-based, first line treatment for chronic pain and includes a link to informational handouts about CBT-CP that referring clinicians can access or provide to patients. In response to clinician requests, the alert also provides language for introducing CBT-CP to patients (CBT-CP involves learning skills to help patients manage chronic pain (e.g., relaxation and increasing physical activity slowly) and improve their functioning). Proactive identification of patients who are eligible, which is enabled by the alert, is designed to promote referral of a larger and more representative pool of patients who could benefit from CBT-CP and to remind clinicians of suitability of many patients with chronic pain for CBT-CP.

Barriers and facilitators identified during this formative evaluation will continue to be assessed during a process evaluation conducted while the study is underway and a summative evaluation after the study is complete. In this way, we can monitor and reassess identified barriers and capture unanticipated barriers and facilitators during the conduct of the study. Additionally, we will assess use of the referral alert and referring clinicians experience and satisfaction with it. Another goal of upcoming evaluations is to solicit additional information from CBT-CP clinicians regarding the barriers they experience providing CBT-CP. For example, in the current interviews several CBT-CP clinicians noted a need to provide ongoing education to referring clinicians about CBT-CP, a task that may represent a barrier to uptake and a drain on CBT-CP clinician effort. Other potential barriers and facilitators include level of leadership support and professional effort available for CBT-CP provision relative to local demand. Finally, future assessments may incorporate questions about the Consolidated Framework for Implementation Research construct of culture. The culture of the health-care system is oriented toward the biomedical model rather than the biopsychosocial model that underpins many

nonpharmacological interventions including CBT-CP and may be a reason for clinician and patient skepticism for nonpharmacological interventions. Information from CBT-CP clinicians can be added to existing evidence about barriers and facilitators that has thus far focused primarily on patients and referring clinicians.

This study had several limitations. First, we used purposive sampling, which is a nonprobability sampling technique that could limit the representativeness of the sample. Second, interviews were conducted with clinicians only and other staff such as nurses or administrators may have offered differing views. Third, we used both telephone and videoconferencing interviews. Prior to the pandemic, we relied primarily on telephone interviews as videoconferencing interviews were less accepted in VA. However, interviews during the pandemic were conducted when videoconferencing options became more widely used in the VA. It is a possibility that the quality of the interactions with the participants were richer during videoconferencing rather than during phone interviews.

CONCLUSION

The need for accessible, low burden nonpharmacological interventions is particularly important to address the negative effects of painful conditions and support recommended changes in pain care. Although many nonpharmacological treatments for chronic pain exist, uptake of those interventions is limited and identifying barriers to use and, more importantly, implementation strategies to promote widespread uptake of nonpharmacological interventions is critical to closing this gap. This formative evaluation identified barriers to widespread implementation of CBT-CP, including complex referral pathways and lack of knowledge about CBT-CP and who clinicians should refer. Use of technology-based treatments or telehealth was endorsed as facilitating uptake. Simplifying processes for identifying patients for referral to CBT-CP, educating clinicians to accurately understand CBT-CP and helping them convey that understanding to patients, and using more virtual and technology-based approaches to deliver CBT-CP to patients could help VA reach more veterans to help them manage their chronic pain.

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CONFLICT OF INTEREST

No potential conflicts exist.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

DISCLAIMER

The opinions expressed here are those of the authors and do not represent the official policy or position of the US Department of Veterans Affairs or the National Institute of Health.

ORCID

Kristin M. Mattocks  <https://orcid.org/0000-0002-6012-3008>

Diana M. Higgins  <https://orcid.org/0000-0002-6885-266X>

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APPENDIX A

Pre-Implementation Qualitative Interview Guide for primary care/CBT-CP providers and leadership (v.8.24.18)

INTRDUCTION

Thank you for agreeing to be interviewed about the plan to implement a new chronic pain management program at [name of VA]. The program is called Cooperative Pain Education and Self-management or (COPEs).

We are preparing a NIH-funded multi-site comparative effectiveness study of COPEs that will be implemented at up to 20 VA facilities. COPEs is a phone-based, automated, remotely delivered cognitive behavioral therapy program for chronic pain. We will be comparing it to traditional on-site, therapist-delivered cognitive behavior therapy (CBT) for chronic pain program currently being used across VHA. In a VA-funded single-site comparative effectiveness study patients randomized to the COPEs obtained improvements in pain, functioning, sleep and physical activity that were comparable to in-person CBT for chronic pain. We now plan to test COPEs on a much larger scale and have identified your facility as a potential site for the trial. We are interested in your site for two reasons. First, you are involved in the Women's Health PBRN, and we want to enroll a large sample of women veterans. Second, your site has an established CBT for chronic pain program and trained providers.

The purpose of the interview is to learn from you about how this study and the remotely delivered COPEs program could be best implemented at your VA.

Interview: I'd like to ask you a few questions about plans to implement COPEs ExTRA at [name of VA].

GENERAL PAIN TREATMENT QUESTIONS: All respondents

1. From my initial discussions with others at your facility, my understanding is that your facility offers XXXX for pain treatment. [Describe what we know about interventions]. Is there anything that I missed or have wrong?

Probe: Any additional services/programs (e.g., medication, yoga, CBT for pain, telehealth, PT)?

2. Can women Veterans get this care in the women's clinic or do they have to go to mixed gender settings?
3. How often do you refer to these resources?
4. What were your experiences working with these resources and your patients' outcomes?
5. How well-coordinated are these services and are there any challenges when referring to these services?
6. On a scale of 1-10 (with 10 being the most support in terms of staffing, resources, and enthusiasm), how would you rate overall leadership support (e.g. facility

leadership or service line leadership) for pain treatment services?

- a. Please tell me a little more about why you assigned that score?
7. How have your pain care services changed or shifted over the past two years?
 - a. What brought about those changes (e.g., acupuncture)?
 8. What changes have you noticed in what patients are looking for in terms of pain treatments?

CBT-CP QUESTIONS: PC Clinicians and leadership only

The next few questions are about cognitive behavioral therapy for chronic pain or CBT-CP.

1. Are you familiar with cognitive behavioral therapy for chronic pain (CBT-CP)? *If not, explain. CBT-CP is a psychological treatment where patients learn pain management skills that they can do on their own. CBT-CP focuses on improving patient's function and encouraging them to set functional goals (exercise, socializing, being more productive).*
2. Now I would like to make sure I understand how patients are referred to CBT-CP at your facility. [Describe our understanding of the pathway]
3. Is there anything that I missed or have wrong?
4. Have you referred patients for CBT-CP?
 - a. How often?
5. Do you feel like you know enough about CBT-CP to refer a patient?
6. Do you think this is true for your colleagues too?
7. What kind of things do patients ask you about CBT-CP?
8. How comfortable are you answering patients' questions about CBT-CP?
9. What has been your experience when you refer to CBT-CP?

Probe: Did patients you referred receive CBT-CP if they were interested? If no, do you know what the barriers were?

QUESTIONS ABOUT COPEs ExTRA: All respondents

Explain COPEs ExTRA: Now that I have a better understanding of what is happening at your facility, I would like to tell you about the program we will be implementing. I am interested in your feedback about how this program would integrate into your facility, any problems you anticipate, and any suggestions you might have. COPEs allows patients to participate in CBT-CP from their home without needing to come to the VA for appointments. Each day patients receive an automated

telephone call that asks about their symptoms and functioning as well as treatment skills they've been using in their day-to-day life. This information is summarized into a weekly, individualized feedback message provided to patients by their COPES coach to support their pain management practices. We will be comparing the strengths and weaknesses of this treatment to CBT-CP delivered at the patient's local VA medical center by VA clinicians trained in VA evidence based psychotherapy version of CBT-CP.

1. How would you anticipate this program working at your facility?
2. What challenges might exist for how COPES might function in coordination with other existing programs? (refer to programs mentioned).

PC providers only

REFERRAL ALERT – We know that not as many patients are referred to CBT-CP as could benefit and we want to make it as easy as possible for providers to refer. That is why we plan to use a referral alert. *Show alert. Explain how it will work.*

1. What if any problems might there be with using this referral alert? What concerns might you have?
2. What would you want to know before adopting the referral alert?
3. An additional reason we want to use the alert is we want to flag patients who are eligible. We think more patients could be helped by CBT-CP, and there are really very few patients who aren't appropriate.
 - a. Is there a specific type of patient with pain that you would definitely refer?
 - b. Definitely not refer?
 - c. How do you decide which patients might be open to hearing about a program like COPES?
4. We will be offering the program to as many people as possible, with a few exceptions:
 - a. We will accept patients who have SUD/AUD unless they are within the first 72 hours of a medically assisted detox.
 - b. We will not be excluding patient with serious health concerns unless they are enrolled in palliative care or hospice.

Do you anticipate any problems with these exceptions?

5. Please tell me about when you feel it is best to refer patients with chronic pain to CBT-CP. Is it something that you recommend early or after they have tried other treatments? Say more about why that is?

6. What would motivate YOU to refer patients to CBT-CP or to a program like COPES ExTRA?

CBT-CP clinicians only

1. How many patients per week do you see for chronic pain?
2. How many women Veterans do you see per week for CBT-CP?
3. Are there a maximum number of patients with chronic pain that you can see?
4. What other clinics or activities are barriers to you seeing more patients for CBT-CP?

Now I would like to make sure I understand how patients are referred to CBT-CP at your facility. [Describe what our understanding is]

5. Is there anything that I missed or have wrong?
6. Who do you receive referrals from for CBT-CP?
Probe: (Primary care, mental health, pain clinic). Where do you receive most referrals from?
7. What barriers do patients experience in getting CBT-CP treatment at your facility?
8. We will be offering the program to as many people as possible, with a few exceptions:
 - a. We will accept patients who have SUD/AUD unless they are within the first 72 hours of a medically assisted detox.
 - b. We will not be excluding patient with serious health concerns unless they are enrolled in palliative care or hospice.

Do you anticipate any problems with that?

9. Are there any patients that you would not consider seeing for CBT-CP?
10. Do you think primary care clinicians at your facility feel comfortable referring patients to CBT-CP? Probe: (know enough about the treatment, know how to bring it up, know who might benefit)
 - a. If so, why do you feel they are so well informed?
 - b. Has there been training or outreach?
 - c. If not, can you say more about the specific barriers and do you have thoughts on how to address those things?

WRAP-UP QUESTIONS: All respondents

1. Is there anything that we haven't asked about that you think might be important for us to know (re: pain care and remote delivery)?
2. Who else at your facility should we be talking to? Who else knows a lot about pain care at your facility?