

**Title: RCT of Brief Cognitive Behavioral Therapy for Chronic Pain**

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## Background.

**Chronic pain is highly prevalent and disabling among Veterans in VA primary care.** Pain has a significant impact on the VA healthcare system with 50% or more of Veterans in primary care reporting pain<sup>1,2</sup>. Chronic pain has been associated with a range of disabling health outcomes, including diminished functional status and quality of life, as well as increased psychological distress and healthcare utilization<sup>1,3-5</sup>. Patients with chronic pain have been shown to be more frequent utilizers of primary and specialty care, a key contributor to increased health care costs<sup>6-9</sup>. Because the majority of chronic pain is treated in primary care<sup>10</sup>, this setting is a critical target for offering a wider array of effective biopsychosocial care options to Veterans.

**Chronic pain management requires a biopsychosocial approach at all levels of VA care.** Efforts to promote biopsychosocial care for pain are reflected in the recent release of the National Pain Strategy<sup>11</sup>, as well as new guidelines from the Centers for Disease Control<sup>12</sup> and the American College of Physicians<sup>13</sup> that identified psychological therapies as a preferred front line treatment for chronic pain over opioid therapy. Within VA, the Stepped Care Model for Pain Management<sup>10,14</sup> is highly reflective of the biopsychosocial model which promotes inclusion of behavioral and psychological strategies that reinforce patient self-management and ultimately reduce disability. The VA's model includes the following: self-care in Step 1 (e.g., weight management, exercise); Primary care-based Patient Aligned Care Teams (PACT) in Step 2; Advanced consultation, such as multidisciplinary pain teams at Step 3, and tertiary, interdisciplinary pain centers at Step 4. The VA's PACT model, supported by Primary Care-Mental Health Integration (PC-MHI) programs, has the potential to improve the quality of care for chronic pain in Step 2. Primary care providers manage the majority of the biomedical aspects of pain, but they do not typically deliver evidence-based behavioral treatments deemed necessary for comprehensive pain care<sup>11,15</sup>. In contrast, PC-MHI providers work closely with primary care providers and are well-positioned to address the psychosocial aspects of chronic pain.

**PC-MHI can expand the scope of pain services in primary care.** The PC-MHI program has a significant infrastructure with over 1,100 providers who generated more than 1.1 million clinical encounters in fiscal year 2016<sup>16,17</sup>. PC-MHI services emphasize population-based, accessible treatment for mental and behavioral health concerns<sup>18</sup>. Typical PC-MHI services are brief (e.g., 15–30 minute appointments) and time-limited with a lower frequency and intensity than traditional psychotherapy<sup>19</sup>. PC-MHI providers offer assessment, brief interventions<sup>20</sup>, and care coordination<sup>18</sup>. PC-MHI has been shown to decrease wait times and no-show rates while improving same day access to mental health services<sup>21-23</sup>. Improvement in patient-level outcomes, such as depression symptoms or alcohol misuse, has also been reported<sup>21,24-27</sup>. Although PC-MHI providers have the potential to improve pain care, a critical barrier remains due to the lack of a well-accepted and evidencebased protocol for behavioral intervention for chronic pain that can be practically delivered in primary care.

**Cognitive behavioral therapy (CBT) for pain is effective but designed for specialty care.** CBT for chronic pain is an approach that encourages clients to adopt an active, problem-solving approach to cope with the many challenges associated with chronic pain<sup>28</sup>. CBT addresses the pain cycle, or the maladaptive changes in behavior that lead to increased distress, decreased activity, and a chronic course of pain. Abundant evidence suggests that CBT for chronic pain improves functioning for a variety of chronic pain conditions<sup>29</sup>.

The VA has endorsed CBT as the gold standard behavioral treatment for pain and has developed a treatment currently available as part of the Evidence-Based Psychotherapy Program. This particular protocol, developed by Dr. Murphy (Co-I), is effective at improving multiple pain outcomes, including pain intensity, catastrophic thinking, pain-related interference in activities, and overall psychological distress<sup>30</sup>. Despite its effectiveness, this protocol is typically delivered by pain management specialists in specialty care settings (e.g., multidisciplinary pain clinics outside of primary care) due to its time-intensive nature (i.e., 11-12 sessions of 50-minute each). Unfortunately, full-length CBT for chronic pain is not easily applied in primary care because PC-MHI uses a brief treatment model. Thus, our team has adapted the full length protocol into *Brief Cognitive Behavioral Therapy for Chronic Pain (Brief CBT-CP)* which is designed for use by PC-MHI providers.

**Brief CBT-CP provides essential components of treatment in less time.** Brief CBT-CP is significantly shorter in duration (~3 hours total) than the original protocol (up to 12 hours). Brief CBT-CP includes six, 30minute sessions. It retains core content from the full protocol: pain education, goal-setting, activities and pacing, relaxation training, cognitive coping, and relapse prevention. The session on sleep hygiene was eliminated because this content is not necessarily applicable to all patients. This protocol emphasizes the three key components of any CBT intervention: psychoeducation, skills development, and skill reinforcement through

at-home practice<sup>31</sup>. The content within each module has been abbreviated to ensure that it can be delivered within the 30-minute session structure of PC-MHI.

In designing a treatment that can be employed by PC-MHI providers, we considered several options but ultimately chose to modify the VA's full length CBT protocol<sup>32</sup>. First, CBT has the most well-established evidence base of psychotherapies for chronic pain<sup>31,33</sup> and has therefore been rolled out extensively in VA. Second, a recent trial comparing CBT to another form of therapy for chronic pain, mindfulness-based stress reduction, found that the effect of these treatments is equivalent<sup>34</sup>, indicating that mindfulness does not offer significant advantages over CBT. Third, six-session CBT for chronic pain groups have been shown to be cost effective for use in non-VA primary care<sup>35</sup>, suggesting the potential of a briefer version of CBT in the primary care setting. Fourth, our prior work has shown that a clear majority of PC-MHI providers self-report use of CBT techniques as part of their routine practice to address other mental health conditions<sup>36-39</sup>. Nationally, some PCMH providers play a role in delivering psychoeducational group interventions, or "pain schools", in primary care, yet the availability of these interventions is variable and the content is not standardized. Significantly, their overall effectiveness at improving patient outcomes appears marginal<sup>40</sup>, suggesting that pain schools may be insufficient as the principal approach to addressing the psychosocial aspects of chronic pain. Therefore, a standardized protocol would capitalize on therapeutic elements that have demonstrated effectiveness, match well with the PC-MHI treatment platform, and address a significant concern among primary care patients.

### **Significance**

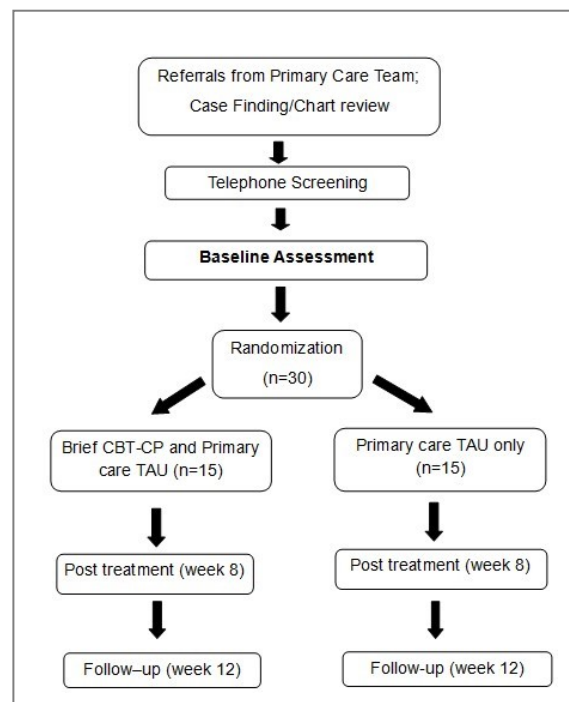
The long term goal of this research is to promote recovery and psychological wellness among Veterans with chronic pain. The proposed study will advance knowledge in rehabilitation research by providing preliminary data regarding the feasibility and effectiveness of Brief CBT-CP as a front line treatment. More immediately, this pilot study will provide the necessary information to develop a proposal for a full scale effectiveness trial. This intervention has been designed specifically for PC-MHI providers and therefore has clear implications for translation to clinical practice. The potential direct benefit to Veterans includes offering a safe, accessible, evidence-based, non-pharmacological treatment for chronic pain early in the trajectory of VA care.

### **Research Design and Methods**

**Conceptual framework.** The biopsychosocial model of pain<sup>41</sup> suggests that unchecked chronic pain can negatively impact activity engagement out of fear associated with movement. Limiting one's beneficial activities can result in physical deconditioning and avoidance of pleasurable events. Persistent pain and disengagement can lead to emotional distress and decreased motivation that result in further social/occupational role withdrawal. The subsequent state of disability is reinforced by maladaptive coping. Brief CBT-CP is aligned with this model and designed to target the biological (e.g., relaxation training), psychological (e.g., cognitive coping), and social (e.g., decreasing isolation) aspects of pain to improve long-term health outcomes. **Design considerations and overview.** This aim will evaluate the feasibility of Brief CBT-CP via a pilot randomized controlled trial (RCT). We will focus on feasibility outcomes because Brief CBT-CP has not been subject to prior research and documentation of the viability of study processes will provide critical information for future effectiveness studies<sup>42</sup>. We chose to randomize participants in order to have a realistic assessment of the stratified randomization procedure, retention of control participants, and assessment of the impact of our control condition on patient outcomes<sup>43</sup>. Primary care treatment as usual (TAU) was chosen because the long term goal of developing Brief CBT-CP is to improve upon usual care practices of PACTs by adding a behavioral protocol for PC-MHI providers. We considered but excluded the use of a pain psychoeducation condition because this approach would not reflect true usual care practices at our study site (and many other VA primary care clinics). A psychoeducation control would need to be developed specifically for this trial and its use is not as well suited to our study question about whether Brief CBT-CP improves upon primary care TAU. A psychoeducation control is better suited to answering the question about the impact of specific CBT components above the impact of education and supportive contacts with a therapist.<sup>44</sup> Similarly, use of primary care TAU will best serve the goal of conducting a future effectiveness trial in real world primary care.<sup>45</sup>

**Participants.** We will recruit 30 Veterans from the primary care clinics located at the Buffalo VAMC in Buffalo, NY. Thirty eligible participants will be randomized in a 1:1 ratio into either (1) Brief CBT-CP plus TAU or (2) TAU only. We will engage in recruitment during the second quarter of Year 1 through the end of the first quarter of Year 2. We aim to recruit and enroll 7-8 participants per quarter (or 2-3 patients per month) during that time frame. Post-treatment follow-up will be conducted at eight weeks and at 12 weeks.

**Eligibility and recruitment.** Two recruitment methods will be used. Veterans with chronic musculoskeletal pain who self-report functional impairment will be referred by their PACT, in response to a recruitment flyer posted in primary care, or by contacting the PI or study staff directly after hearing of the study by word of mouth or other sources, including ClinicalTrials.gov. This



*Figure 1: Recruitment and procedures.*

approach will be supplemented by a case-finding procedure in which study staff review electronic medical record data to identify potential patients. Initial eligibility criteria will target those Veterans who are age  $\geq 18$  years to 79 years, conversant in English, have an established history of VA primary care utilization (i.e., at least one primary care visit in the past year), and a diagnosis of musculoskeletal pain of  $\geq 3$  months. This pain definition is consistent with the consensus definition of chronic pain from the International Association for the Study of Pain<sup>46,47</sup> and is well-matched to the study goal of addressing chronic pain proactively. Veterans meeting these initial eligibility criteria will be sent a study invitation letter signed by their primary care provider. Following the letter, Veterans will be contacted by phone for additional screening in which they will first be asked to verify the presence of current musculoskeletal pain for  $\geq 3$  months. The PEG<sup>48,49</sup>, a validated 3-item pain measure<sup>48,49</sup>, will also be administered. Veterans must score  $\geq 4$  on the PEG pain intensity item and  $\geq 4$  on either of the PEG pain interference items to be included. Veterans will be excluded at this stage if they self-report current engagement

in behavioral health services that may include cognitive or behavioral interventions (i.e., behavioral medicine intervention, specialty mental health services, or standard PC-MHI). Veterans receiving only psychopharmacological intervention from a mental health provider will not be excluded. Veterans will also be excluded if they report uncontrolled medical conditions, scheduled/planned surgeries, or other interventions likely to impact pain/functional outcome ratings. Potential participants will not be excluded based on past/current/future use of chiropractic care or physical therapy.

In situations where the referring primary care provider and Veteran would rather directly connect to the study staff in-person, a letter will not be sent. Rather, and when feasible, study staff will be notified of the Veteran's preference to be screened at time of referral (or shortly thereafter) by study staff.

Veterans who meet telephone screening criteria will be scheduled for a face-to-face baseline interview. Following informed consent and HIPPA authorization procedures, assessment measures will be administered. Veterans will be screened for active suicidal ideation based on responses to the Patient Health Questionnaire9 (PHQ-9)<sup>50</sup>. Veterans will be excluded from participation if they score  $>0$  on PHQ-9 item 9 and also endorse imminent suicide risk (i.e., in response to additional questions that will differentiate suicide risk versus

nonsuicidal morbid ideation). Veterans will be excluded on the basis of probable substance use problems (e.g., alcohol, cannabis, opioids, benzodiazepines) if they score positive ( $\geq 8$ ) on the Alcohol Use Disorders Identification Test<sup>51</sup> (AUDIT) or score positive ( $\geq 3$ ) on the Drug Abuse Screening Test<sup>52</sup> (DAST-10). Veterans will also be excluded if their baseline administration of the BPI is  $< 4$  on the pain intensity items and  $< 4$  on pain interference items. Participants will also be excluded if they are unwilling to have their treatment sessions audio recorded.

Electronic medical record review will be used to identify if the patient is currently prescribed relevant pain or psychiatric medications. If relevant medications are prescribed, study staff will supplement this review by asking the patient to verbally verify if the medication(s) identified in the chart are 1) currently in use by the patient, 2) what the current schedule/frequency of use of that medication, and 3) if there have been changes in the past 2 months. Veterans will be excluded if relevant medications have been modified in the past 2 months. Use of over-the-counter (OTC) analgesic medications/topicals will not be considered an exclusion criterion, even if these agents are recorded in the patient's medical record by a VA provider. Similarly, routine or PRN use of prescribed anti-inflammatory medications (i.e., acetaminophen, aspirin, ibuprofen, naproxen) or topical agents will not be considered an exclusion criterion.

Patients will be excluded if chart review indicates either of the following: 1) unstable psychiatric status (e.g., active psychosis, current mania) or 2) major or minor neurocognitive disorder (e.g., dementia). Patients will also be excluded if chart review reveals uncontrolled medical conditions, scheduled/planned surgeries, and medical or other interventions likely to impact pain/functional ratings. Potential participants will not be excluded based on past/current/future use of chiropractic care or physical therapy.

**Procedures.** As shown in Figure 1, upon completing baseline measures, eligible participants will be randomly assigned to (1) Brief CBT-CP plus TAU or (2) TAU only. Assignment to Brief CBT-CP will be stratified based on degree of pain interference as measured by West Haven-Yale Multidimensional Pain Inventory – Interference (WHYMPI-I)<sup>53</sup>. Participants will be classified as average interference and below (WHYMPI-I score  $\leq 4.4$ ) or as above average interference (WHYMPI-I score  $> 4.4$ )<sup>28,53</sup>. All participants will complete a telephone-based follow-up with the study coordinator, who will be blinded to participants' condition, at 8 weeks (post-test) and at 12 weeks (follow-up) from randomization for re-administration of study measures. Participants will be compensated \$40 for the initial assessment and \$30 for each of two follow ups (total \$100 for Aim 1). We will replace dropouts who do not meet minimum treatment completion requirements of attending  $\geq 4$  sessions. Attending, at minimum, sessions one through four will provide patients with essential education and core CBT self-management skills. Although some dropout is planned, we predict that we will replace only a small number of participants ( $\sim 3$ -4) prior to our final 12-week follow-up assessment. This prediction is informed by Dr. Funderburk's (Co-I) current clinical trial (IIR I01HX000909) of a brief behavioral intervention for depression conducted at the Buffalo VAMC primary care clinics which used similar methodology. At 90% completion, this study has evidenced only 11.3% participant drop out at 12-week follow-up.

To assist with recruitment throughout the study, study staff will conduct reminder phone calls for all appointments 48-24 hours ahead of time reminding participants of the time and location of the meeting. Reminder letters containing date, location, and purpose of study contact will be sent prior to baseline, 8-week, and 12-week follow-up. Reminder letters will be sent for therapist appointments on an as-needed basis (e.g., when requested by participant). At least two phone attempts will be made (and one letter sent) to reach participants who do not show for scheduled contacts.

Participants will be provided with a behavioral health resource sheet at the end of their participation (or as needed during the trial) should they wish to access additional VA or community services.

**Measures of feasibility.** Our study measures focus on indicators of feasibility of trial processes<sup>43,54</sup>. To assess feasibility of participant screening, recruitment, and retention, study staff will track the number of potential participants identified by primary care team referral as well as our case finding procedure. We will document the number of potentially eligible participants who are sent study invitation letters, the number completing/refusing a screening call, and number who agree/refuse to be scheduled for baseline interview. We will track the number of participants who are randomized to compute actual enrollment rate (vs. planned enrollment), including time to reach full sample accrual. Within the Brief CBT-CP plus TAU condition, we will monitor treatment retention by assessing number of sessions attended, as well as the number of patients completing a full course of treatment. We will attempt to ascertain the reason for drop-out, when applicable,

during follow-up assessment calls. To assess the suitability of our measures of patient outcome measures, we will examine item response rates, including the number of missed responses and multiple responses, and time required for completion. We will also document any questions or comments raised by the participant during measure administration. To assess fidelity of service delivery, the study interventionist will complete an adherence checklist after each session. Checklists map on to each of the six sessions of Brief CBT-CP and will be designed to capture key content and procedures. All intervention sessions will be audio recorded with the participant's permission. The PI will randomly select 25% of the audio recordings for review by Dr. Murphy (study Co-I) using an adapted version of the CBT-CP Rating Scale<sup>55</sup>. To examine the precise nature of participants' service utilization during the trial, we will conduct a chart review at 12-week follow-up. Chart review will assess participants' engagement in primary medical care (i.e., PACT encounters), PC-MHI encounters, and other VA services to assist with assessing feasibility of TAU only as a control condition and will assess any changes in pain or psychotropic medication initiated since baseline assessment. **Aim 1 Measures of patient outcomes.** Patient outcome measures will be assessed at baseline, post treatment (eight weeks), and follow-up (12 weeks). Administration of all study measures will take about one hour at each time point.

- **West Haven-Yale Multidimensional Pain Inventory - Interference (WHYMPI-I).** The WHYMPI-I is a validated 9-item subscale that evaluates pain-related interference in daily activities and social and occupational functioning<sup>53</sup>. It is among the core assessments included in the full-length CBT for Chronic Pain<sup>32</sup> and is the primary patient outcome for this trial.
- **Brief Pain Inventory - Short Form (BPI-SF):** The BPI-SF is a psychometrically validated 9-item measure that assesses pain level (current and average), pain related functional impairment, and activity interference. The BPI-SF asks participants to indicate the extent of their pain as well as any interference with various activities and other aspects of life (i.e., mood, relationships) using a scale ranging from 0 (no pain/interference) to 10 (worst pain/complete interference). This measure is included in order to further assess pain outcomes in response to Brief CBT-CP.
- **Patient Health Questionnaire-9 (PHQ-9).** This measure is a 9-item measure of depressive symptoms validated for use in primary care<sup>50</sup>. Respondents are asked to rate symptoms experienced over the past two weeks on a four-point scale ranging from not at all (0) to nearly every day (3). The PHQ-9 is included because depression, as an indicator of emotional functioning, is a core outcome domain for all pain clinical trials<sup>56</sup>.
- **Generalized Anxiety Disorder-7 (GAD-7).** This measure is a 7-item measure of anxiety symptoms validated for use in primary care. Respondents are asked to rate symptoms experienced over the past two weeks on a four-point scale ranging from not at all (0) to nearly every day (3).
- **Pain Self-Efficacy Questionnaire (PSEQ).** This validated measure includes 10-items related to pain-related self-efficacy<sup>57</sup>. Respondents rate how confident they are in engaging in specific activities despite being in pain on a seven-point scale ranging from 0 (not at all confident) to 6 (completely confident). Sample items pertain to accomplishing goals and becoming more active.
- **Pain Catastrophizing Scale (PCS).** This validated 13-item measure assesses pain-related cognitions such as pain magnification and perceived helplessness<sup>58</sup>. Items are rated on a scale of 0 to 4, with scores of 0 corresponding to "not at all" and 4 indicating "all the time." Sample items include statements such as, "When I'm in pain... I feel I can't go on." The PSEQ and PCS are included because they measure constructs that are important mediators of the impact of CBT on activity interference outcomes<sup>59</sup>.
- **World Health Organization Quality of Life - BREF (WHOQOL-BREF).** This 26-item abbreviated version of the full-length WHOQOL measure<sup>60</sup> evaluates quality of life in several domains such as social relationships and satisfaction with person-environment interactions<sup>61</sup>.
- **Ability to Participate in Social Roles and Activities – short form (APSRA).** This 8-item measure was developed to evaluate one's perceived ability to perform usual social roles and activities. Negatively worded items about social role engagement are rated on a scale from 1 (always) to 5 (never) such that higher scores represent fewer limitations. This measure has been shown to have excellent psychometric properties and clinical utility<sup>62</sup>. The WHOQOL-BREF and APSRA are included in order to assess if Brief CBT-CP impacts recovery of social/occupational role engagement.

- **Working Alliance Inventory – Short Form Revised (WAI-SR):** The WAI-SR is a 12-item self-report measure that asks participants about their perceptions of their therapist (i.e., my therapist and I respect each other) and the therapeutic services they receive (i.e., what I am doing in therapy gives me new ways of looking at my problem). Participants indicate on a scale from 1 (seldom) to 5 (always) how well each statement describes their own experiences in therapy. This instrument is included in the current protocol in order to examine potential differences in treatment outcomes as a result of the participants' rapport with their study therapist.
- **Demographics Form:** This form requests standard information on patient demographic background, including the following: age, gender, race, living arrangements, marital status, education, and occupation.

### **Aim 1 Study conditions.**

Brief CBT-CP plus TAU: Brief CBT-CP is a manualized protocol that includes six, 30-minute sessions over the course of 6 weeks. Brief CBT-CP session outlines and patient handouts are included in the appendix. Session one focuses on foundational pain education and the development of treatment goals. Session two emphasizes balanced engagement in physical activity and pleasurable events. Session three emphasizes skills training for easily implemented relaxation techniques. Sessions four and five focus on recognizing and modifying unhelpful thoughts that negatively impact pain. Session six focuses on relapse prevention and independent implementation of CBT-CP skills following treatment. Brief CBT-CP will be delivered by a masters-level interventionist either at the Buffalo VA Medical Center or by telephone depending on the preference of the participant. The interventionist will be trained by Drs. Murphy (Co-I) and Beehler (PI) in how to apply the protocol. Training will include at least 20 hours of didactic explanations of the principles of each intervention, role play and feedback exercises, discussion of case examples, and skill rehearsal. Audio recordings of sessions will be reviewed by Dr. Murphy. If the interventionist has deviated significantly from the protocol based on CBT-CP Rating Scale<sup>55</sup> scores, or related measures, s/he will be provided with corrective feedback and assigned training cases until deficiencies are corrected.

TAU only: Participants assigned to TAU only will receive standard medical care from their primary care provider including pain medications, brief advice (e.g., use of relative rest, application of heat or ice, other selfcare strategies), or referral to pain-related adjunctive interventions (e.g., physical therapy), as indicated. Participants in TAU only will not receive behavioral intervention from the primary care clinic PC-MHI provider.

### **Aim 1 Analysis plan.**

Sample size: We will recruit and randomize 30 participants (approximately 2-3 participants per month for 12 months). Based on prior research in these clinics, we estimate that about 225 unique patients per month will report for primary care with a chronic musculoskeletal diagnosis. Previous work by our team indicates that this figure is highly feasible.

Primary feasibility outcomes: Feasibility outcomes will be assessed using descriptive statistics. We will calculate the percentage of patients who met preliminary eligibility criteria (identified via chart review) who were reached for telephone screening, including refusal rate. We will calculate the proportion of patients who screen eligible and either 1) refuse, 2) consent to and complete the baseline interview, but are not randomized for failure to meet study criteria, or 3) consent to and complete the baseline interview and are randomized. Refusal and recruitment rates will 1) indicate if our initial inclusion criteria and our screening methods are in need of modification, and 2) assist with estimating the total number of patients who will need to be screened to account for failures or refusals. Retention will be evaluated by computing the rates of withdrawal from the trial, or percentage of those randomized who do not complete all study procedures. Low retention rates will suggest that patients are facing barriers to completing the treatment (e.g., Brief CBT-CP may need to be abbreviated further). The feasibility and acceptability of patient assessment measures will be assessed through item response rates. This information will assist with assessing participant burden and will indicate which measures are highest in utility (i.e., easily completed by participants and show change over the study period). Assessment of treatment fidelity indicators will include analysis of session checklists completed by the interventionist, which will indicate the percentage of Brief CBT-CP content delivered (i.e., dosage). Scores on the checklists will be compared to the adherence ratings from the modified CBT-CP Rating Scale<sup>55</sup> for a subsample of recorded sessions to determine if these data sources show appropriate convergence.

Exploratory analysis of patient outcomes: Means, standard deviations, and confidence intervals (CIs) at each of the three measurement times per condition will be calculated. We will also generate a preliminary effect size at post-treatment and follow-up based on the WHYMPI – I. Effect sizes will be calculated by dividing the mean difference between intervention and control conditions by the pooled standard deviation. Then, 95% CIs will be calculated on the effect size by using the non-central *t*-distribution method<sup>63</sup>. While this study is not adequately powered to detect small changes in patient outcomes, the mean WHYMPI-I score in each condition at post treatment will be compared (while adjusting for the baseline score) using analysis of co-variance (ANCOVA). Adjusting for baseline pain interference reduces the residual variance of the ANCOVA model thereby increasing power, and attributes potential differences between conditions at post treatment to the condition, not the baseline score (regression to the mean). Stratifying the randomization scheme according to baseline pain interference will also decrease the likelihood of regression to the mean, and using ANCOVA minimizes its effect at post treatment<sup>64</sup>. A similar analysis will be conducted at follow-up and will be repeated with the remaining patient outcome measures. As an alternative to ANOCVA, we will also explore the use of multi-level modeling approaches. Multiple imputation will be used for any missing data<sup>65</sup>. **Risks and data security** Potential Risks

Across study aims, one possible risk to participants is that of potential disclosure of sensitive information. Several steps will be taken to minimize risk of breaching confidentiality including educating research staff about confidentiality and ethical issues in regard to the study. All electronic and paper self-report data collected will be identified by a unique study identification number rather than individually identifiable information. Identifiable voice recordings will be stored separately and in accordance with the data security and privacy procedures below. Identifiable information for informed consent, payment, and enrollment status will be stored separately from study data and will also comply with the data security and privacy procedures. Data security and privacy procedures (below) are designed to minimize this risk.

It is also possible that some patients may find the assessments and intervention uncomfortable or emotionally sensitive. There is minimal risk that participation in this protocol will produce psychological distress (i.e., embarrassment, discomfort) to participants when asked to share sensitive information about themselves (e.g., distress associated with experiencing chronic pain) with the research staff. Participants will be assessed for safety risk according to an established suicide protocol.

#### Recruitment and Informed Consent

Participants will be scheduled for a baseline interview session that will begin with informed consent procedures. Research staff will provide prospective participants with a copy of the informed consent and HIPAA documents to review independently, and staff will then thoroughly explain the contents of each document. Next, staff will ask participants questions about the main points of the informed consent document (i.e. main study purpose and procedures, limits to confidentiality) to verify participant understanding. Staff will reiterate that participation is completely voluntary and may be discontinued at any time with no penalty. Veterans will be informed that participation (or lack of participation) in the research study will not impact their eligibility for care at the VA. Only participants who understand these documents and choose to sign and enroll will be included in the study. Participants will be provided copies of both the informed consent document and HIPPA document.

#### Protection Against Risk

All research staff will be current on all required VA and IRB trainings in the responsible conduct of research including privacy, confidentiality, HIPAA regulations, recruitment procedures, informed consent, and data management. Additionally, the PI will provide study-specific training in those topics as well as appropriate conduct of the telephone screenings, interviewing skills, collection of self-report data, intervention delivery, and data entry/management and analysis. Only approved research staff will have access to the data. We will protect against breaches of confidentiality by coding participant data with an identification number and keeping the master list linking names and numbers in a separate password protected electronic file. Only project staff will have access to the master list of identification numbers. Computer data files will be password protected and stored on the VA SharePoint site managed by our local research office. Any necessary hard copy data will



be stored in a locked cabinet in the PI's office. Only authorized study staff will have access to study files. Data will be stored in accordance with official VA records retention policies.

All in-person research sessions will be conducted in private rooms. For telephone calls, researchers will conduct calls in private rooms, review the purpose of the telephone call, request that Veterans be in a location where they feel comfortable discussing those topics (e.g., scheduling, conducting phone assessments, etc.), and reschedule if Veterans are not in an appropriate location at that time. Multiple procedures will be in place to minimize psychological risk including: (1) participants will be reminded that they can choose not to answer any question that they are uncomfortable with, (2) participants will be reminded that they can choose to withdraw from the study at any time, and (3) licensed psychologists will be available to speak with Veterans who report significant distress during any study procedure. To further minimize risks for participants, it will be emphasized throughout the protocol that participation is voluntary and may be discontinued at any time. Participants will be told that stopping their participation will not adversely affect the care they receive at the VA. They will also be notified that they can choose to be referred to behavioral health services as an alternative to their participation in the research. Participants will be informed that study personnel may choose to discontinue their participation at any time if it is deemed inappropriate for the participant (e.g., participant evidences psychotic symptoms). Limits of confidentiality and importance of Veterans' safety will be outlined. During the informed consent process, participants will be notified that should they report anything that threatens their safety or the safety of someone else, Dr. Beehler will contact them to discuss this concern. In cases of imminent risk and child/elder abuse, mandated reporting and referrals to appropriate mental health services will take place. We will monitor participants for adverse events at each study contact. Any adverse event will be reported to the local IRB.

In the unlikely event that an individual becomes acutely distressed, or evidence risk of harm to self or others, he/ she will be evaluated and referred for emergency mental health services. Study staff will have a specific protocol to follow regarding emergency care (suicide assessment protocol) and will have the support of Drs. Beehler and King, licensed psychologists with significant prior experience in addressing patient safety concerns.

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