Developing an Online Therapeutic Intervention for Chronic Pain in Veterans

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Title of Study: Developing an Online Therapeutic Intervention for Chronic Pain in Veterans

Principal Investigator: Erin Reilly, Ph.D. VA Facility: VA Bedford Healthcare System

Sponsor of Study: Department of Veterans Affairs

We are asking you to choose whether or not to volunteer for a research study. This consent form will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is focused on assessing an online intervention, Veteran ACT for Chronic Pain (VACT-CP) with a waitlist control group, to evaluate whether VACT-CP is usable, acceptable, and potentially helps Veterans with chronic pain to improve their functioning and pain-related symptoms. This study is being funded by the Rehabilitation R&D within the Department of Veterans Affairs. In addition to online website use,study activities related to completing assessments will take place, depending on your preference, either virtually or at the Bedford VAMC.

2. WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

If you decide to participate in this study, you will be randomly assigned to an online therapeutic intervention or a waitlist control group. This process is like flipping a coin.

For this study, you will have 1 study visit to determine your eligibility for this study. This visit will involve an interview and several questionnaires. You will have the choice to complete this visit and these assessments in person, online, or over the phone.This visit will take about 2 hours of your time. If you are eligible for this study, you will be invited to participate in the research study, in either the group receiving the online VACT-CP program or the waitlist control group.If you are part of the VACT-CP program, you will participate in 7 20min online sessions. For both groups, there will be a midpoint assessment session where you wil take a series of surveys, which will take approximately 1.5 hours. After 7 weeks, both groups will fill out questionnaires and an interview that will take appximately 2 hours. One month later, we will ask you to answer several questionnaires on again. This follow-up study assessment session will take about 1 hour of your time. You will be given $60 for the first study visit.You will be paid $40 for the midpoint surveys. You will also be paid $60 at the end of 7 weeks, and a final $40 for the 1-month follow-up visit. You will be paid by a voucher that you can take to the agent cashier or by giftcard.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We cannot and do not guarantee or promise that you will receive any benefits from this study.

However, participating may benefit Veterans suffering from chronic pain by exploring a new and emerging technology, and providing feedback on the potential future directions online interventions. Receiving the VACT-CP intervention in this study may also benefit you by helping

you learn mood and stress management skills, value-based goal setting for activities, and gaining education around chronic pain and different treatment options.

4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is the possibility that answering some questions may be emotionally upsetting. You have the choice to not answer any question that makes you feel uncomfortable. You have the choice to not answer any question that make you feel uncomfortable. You have the right to speak to the study PI at any time by contacting Dr. Erin Reilly at (781) 687-4191.

5. DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. You may also discontinue participation at any time.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Erin Reilly of the VA Bedford Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 781-687-4191.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in a research study designed to evaluate a new, online therapeutic intervention to improve the functioning of Veterans with chronic pain called VACT-CP. You have been invited because you have chronic pain. With this research we hope to learn whether VACT-CP is helpful in improving the functioning and pain symptoms of Veterans with chronic pain.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. Your individual participation in the project will take 11 weeks.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

Intake and Interview Procedures. If you decide to participate in this research study, you will have an in-person or phone screening with a member of the research team and you will be asked to complete questionnaires. We will ask you about your health concerns, pain levels, and technology experiences. You will also be asked questions about possible current and past psychological or emotional difficulties and substance use. This is done because such problems

are sometimes associated with pain-related difficulties, and because such problems may affect your efforts to improve your functioning. These interviews and questionnaires will take about 2 hours of your time. We will also ask for the names, contact information, and a release of information for people that you know that would help us be able to get in touch with you. If you do not meet eligibility criteria during this in-person screening, you will be excluded from participation. If you meet eligibility criteria, you will be asked to participate in the initial research phase of the study.

Initial Research Phase. You will be randomly assigned (like a flip of a coin) to one of two groups (VACT-CP or Waitlist). The reason you will be randomly assigned to a group, rather than you choosing a group is so that researchers can determine the possible usefulness of the VACT-CP online intervention compared to a group who are not receiving this intervention. We expect that 40 people will be randomized in this study.

VACT-CP Group A: (20 participants)
If you are assigned to VACT-CP, you will receive access to the online modules, which you will have 7 weeks to complete. Each module will be available to use for a week, and there will be a total of 7 modules you will be asked to complete. The initial module is devoted to an explanation of the treatment rationale, initial psychoeducation on pain-related symptoms, pain interference, and focal concepts of ACT, and assessment of individual pain symptoms. Modules 2-4 will focus on values clarification, acceptance and willingness, mindfulness, with an emphasis on tolerance of pain-related experiences. Modules 5-6 will continue to this focus, and incorporate goal-creation and committed action exercises. Module 7 will consolidate and provide feedback on goal-related achievements, and will focus on planning for the future. All content will be presented interactively, through text-based conversations with Coach Anne that appear as short videos on your the screen. You will hear what Coach Anne “says”, and respond to her queries using forced-choice text options that will trigger different responses from Coach Anne as the conversation progresses, to allow the system to responsively interact in a personalized manner with you. During the course of VACT-CP, you will complete the following surveys at four time points: approximately 2 hours for baseline assessments, a total of approximately 2.5 hours to test the 7-module VACT-CP program and interview over 7 weeks, 1.5 hours for the mid-point survey at week 3, approximately 2 hours for the 7 week/post-intervention assessment, and approximately 1 hour for the 1 month follow-up surveys. The online modules will take about 20 minutes of your time each week (7 modules total), and you will complete online exercises related to you pain, mood, values, and setting goals for the next week. A research staff member will also briefly check in with you at weeks 3 and 6 (approximately 15 minutes) to see if you are experiencing any concerns or issues with the technology that we can assist with.

Waitlist Group B: (20 participants)
If you are assigned to the waitlist, you will wait 11 weeks to gain access to the VACT-CP online intervention – although it wil be your choice if you would like to use it at that time. During those 11 weeks, you will complete the surveys at different time points. The duration of these surveys are the following: approximately 1.5 hour for baseline assessments, 1.5 hours for the mid-point survey at week 3, approximately 2 hours for the 7 week assessment, and approximately 1 hour for the 1 month follow-up surveys (week 11). In addition, you will be provided with a list of

common pain treatment options and pain management resources at the VA Bedford Healthcare System that you may choose to engage in during this time. At the end of 11 weeks, you will be provided with your own username and password so that you can use the online VACT-CP system if you would like to. There is no requirement that you use the online VACT-CP system after your 11-week survey assessment. It is your choice to use VACT-CP if you are still interested in using the online program to learn about managing your pain. You wil not be required to take additional surveys if you choose to use the VACT-CP online website; however, a research staff member will also briefly check in with you at weeks 3 and 6 (approximately 15 minutes) to see if you are experiencing any concerns or issues with the technology that we can assist with.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

The intake, mid-point, and follow-up interviews and questionnaires will take time to complete. We estimate it will take approximately 6 hours total over the 11 weeks to complete interviews and study questionnaires.

You may be uncomfortable answering questions about substance use, emotional and pain-related problems. If you are uncomfortable with any part of the surveys or interview, you may skip the question or take a break. You will have the opportunity to take breaks to minimize fatigue and discomfort. Please let the research staff know if you become too uncomfortable. You can also contact the researchers if your symptoms bother you after you go home. If needed, we will contact the psychologist on this study to evaluate you by phone or in person to see if you need any more treatment.

Also, some questionnaires include questions about whether you have had thoughts of harming yourself or others. If the research staff is concerned about your safety during the study, a study clinician may evaluate you and refer you for further evaluation and/or treatment. If a clinician determines that you are a danger to yourself or others, you may be held in a hospital against your will. These actions are to insure your safety and the safety of others.

At any point during the study, we will discharge you if we are concerned that staying in the study may cause you physical or psychological harm. If the research team discharges you from the study, we will contact your regular clinician to coordinate and provide you with the most Department of Veterans Affairs appropriate care to address these issues. If you do not have a regular clinician, we will discuss possible sources of medical care and encourage you to seek treatment.

Confidentiality of Information:

Participation in this research may involve a loss of privacy. Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example,

social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data.

All research information collected will be kept in locked files or on VA secure server spaces. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all Veteran and non-Veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. A note on your enrollemnt in this study will be added to your medical record so your care providers are aware that your are participating. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulations that protect privacy of medical records will apply to your VA record.

Other risks:

There is a risk that you may not be able to improve your chronic pain. However, we will monitor you very closely and will take numerous safety precautions to ensure your safety and well-being.

Unanticipated risks:

If you have any unusual or uncomfortable feelings during the study, contact the PI or research staff. You can reach a study staff by calling a member of the research team during normal business hours. You can also come in to the Mental Health Clinic (Hours: Monday-Friday, 8:00 am-4:00 pm; Building 78, 2nd Floor; 781-687-4333). You may also come in to the Bedford VAMC Urgent Care Center during their main hours (Monday-Friday, 8:00 am-4:00 pm; Building 78, 1st Floor; 781-687-2654) or after hours. You may also call the doctor on call after hours (781-275-7500). If you become suicidal, hospitalization is possible.

Since we are concerned about your health and safety, there are some situations when we will contact your primary care physician or other clinical professional that is providing care for you, such as to inform him/her that:

• You need to be taken to Urgent Care for medical reasons
• You report suicidal thoughts or homicidal thoughts
• You are hospitalized
• You experience serious side effects that are a concern to you and/or the study team
• You experience an adverse event or reaction that occurs in the course of the study where the PCP has not already been informed
• You may be potentially harmed by continued participation in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Your participation may or may not be of benefit to you. The benefits to you include an online care pain intervention, and careful monitoring during treatment. However, we cannot and do not guarantee or promise that you will receive any benefits from this study. If you participation does not benefit you, it will be of benefit to others, as it will contribute to the effort to learn more about the treatment of Veterans with chronic pain.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You are free to decline entrance into or withdraw your participation in this study at any time. If you decline to participate or withdraw from the study, and you desire treatment elsewhere, you will be provided with information about alternative mental health treatment in the VA and in the community. Mental health treatments at the VA include medications and counseling. Similar treatments are available through treatments in the community. A decision not to participate in this study or to withdraw from this study will not affect your ability to participate in other VA treatment, including mental health treatment.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this research may involve a loss of privacy. However, numerous safeguards will keep electronic and hard copy data secure. Your research records will be kept as confidential as possible. All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.)

Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP) and the Government Accountability Office (GAO) may have access to the records.

Identifiers might be removed from the identifiable private information collected. After the removal, the information could be used for future research studies without additional consent from you.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of certain communicable diseases, physical or sexual abuse, child or elder abuse or neglect, or harm or risk of imminant harm to self or others. The Certificate does not protect you if you, someone in your family, or someone you know voluntarily releases information about you.

We will include information about your study participation in your medical record. A medical record will be created if you do not already have one. In addition to the research team, other

researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time without penalty or loss of benefits to which you are entitled.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

For data already collected prior to the participant's withdrawal, we will continue to review the data already collected for the study but cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Investigators may end your participation in this study if they feel it is in your best interest, and/or if you are not complying by program rules. The reason for your discontinuation will be explained to you. If you stop participating in the study for one of these reasons, you will have the option of obtaining mental health treatment in the Mental Health Clinic, through your other health care providers, or will be referred to local mental health treatment providers. If you withdraw at any point during the study, we will still use the data that has already been collected. However, you may choose to withdraw your study data if you indicate this to research staff. If you decide to withdraw, you may also continue to fill out questionnaires at each assessment point until the end of the study, and you will be compensated for your time and travel for your participation. If you decide to withdraw and decide not to fill out questionnaires, you will not be compensated and will be discontinued from the study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

The study team will inform you of any important information about your participation that may affect you or your willingness to be in this study.

Title of Study: Developing an Online Therapeutic Intervention for Chronic Pain in Veterans

Principal Investigator: Erin Reilly, Ph.D. VA Facility: VA Bedford Healthcare System

Sponsor of Study: Department of Veterans Affairs

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call **Dr. Erin Reilly at 781-687-4191 during the day or have the doctor on call (781-687-2000) paged after hours.**

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures. No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions about the research, you may contact Dr. Erin Reilly at 781-687-4191.

If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Reilly or study staff have explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

HUMAN SUBJECTS RESEARCH PROTOCOL

Project Title: Developing an Online Therapeutic Intervention for Chronic Pain in Veterans

Protocol Version and Date: v3.0 (9/30/2021)

Principal Investigator: Erin D. Reilly, Ph.D.

Co-Investigators: Megan Kelly, Ph.D., Karen Quigley, Ph.D.

Institution(s): VA Bedford Healthcare System

1.0 Objective and Specific Aims:

This qualitative study will collect feedback from chronic pain providers and content experts on a basic prototype of an in-development online chronic pain therapy intervention system – Veterans Acceptance and Commitment Therapy for Chronic Pain (VACT-CP). Pain has been identified as among the most frequent presenting complaints to healthcare providers, including those responsible for providing primary care for Veterans. Perhaps the most complicated to treat and debilitating - chronic pain - refers to self-reported pain lasting longer than 3 to 6 months, persisting beyond the healing of an initial injury or disease, and it can often last for years (Merskey, 1986; Dobscha et al., 2009). With over 20 years of empirical research supporting its efficacy, Acceptance and Commitment Therapy (ACT) has been shown to be particularly effective as a treatment for chronic pain in targeting functional and quality of life improvement in the context of continuing pain difficulties (Vowles, Wetherell, & Sorrell, 2009). However, ACT for Chronic Pain is often inaccessible to Veterans due to transportation barriers, time constraints, and a lack of trained therapists (Heapy et al, 2017). This suggests that the VA could benefit from the rapidly increasing field of online and mobile health technology for increased access to empirically supported chronic pain treatment. Web-based interventions in particular have been growing in popularity as a treatment-delivery method for many psychiatric and behavioral difficulties.

To this end, a group of psychologists, social science researchers, and interactive-web designers have begun to create an online program to deliver to Veterans an ACT for Chronic Pain online intervention (VACT-CP). However, often when such online interventions for Veterans are created, major stakeholders – clinicians, nurses, and other care providers – are not included in the iterative development and feedback process, although best practices suggest this is vital (Schueller et al., 2014). As these are often the primary source for potential Veteran referrals to such online programs, this is a major gap in much of the literature on developing, assessing, and refining such systems for use by Veterans. To address this gap and create a usable online intervention, and systematically include these providers in the ongoing VACT-CP development process, we will first conduct qualitative interviews with 10 - 12 current chronic pain providers (including social workers, physicians, PACT nurses, and psychologists) who provide treatment for chronic pain at the VA Bedford Healthcare System for formative assessment of the potential benefits, concerns, and institutional VHA dissemination issues for the VACT-CP intervention.

In addition, we will interview and gather feedback from Veterans (12 – 15) to for usability testing, to assess the delivery mode, and utilize an Integrated Technology Acceptance Model to iteratively assess feasibility and usability of the VACT-CP online treatment. This portion of the project will focus on refining the delivery mode, and revising chronic pain intervention content as necessary. Specifically, providers and Veterans will be shown the VACT-CP system for intervention and interviewed about their reactions in order to allow for system refinement and to allow for revisions to the system. **This project will thus aim to:**

Phase 1 Objective: To gather qualitative feedback on the VACT CP system from a sample of 10 - 12 chronic pain clinical-care providers, as well as explore and identify barriers and facilitators of VACT-CP referrals and implementation in the VA Bedford Healthcare System**.**

1. VA Bedford providers will be interviewed individually to aid in ongoing VACT-CP development, and to gather information on potential opportunities and barriers to referring Veterans to the online VACT-CP program.

    1a. Open-ended questions related to palatability of the intervention, feasibility of engagement with Veterans with chronic pain, interest or potential concerns with referring Veterans to such a program, and reactions to a short walk-through of the intervention.

    1b. Gather more general information from valuable stakeholders and potential referral-providers to discover possible benefits, barriers, referral concerns, and overall thoughts on online Veteran interventions.

2. Providers will be interviewed in the context of planning for a future pilot usability trial of VACT-CP (IRB application for this trial will be submitted separately in the future), to adapt the program and recruitment strategy to the Veteran needs and local context.

Secondary Aims: N/A

Phase 2 Objective: Conduct a Feasibility and Usability Assessment to pilot test VACT-CP components including format, ECA, and system usability via field-based iterative usability testing (3 rounds, *n* = 4-5 per round, total n = 12 – 15).

1. Gain further feedback on the VACT-CP treatment by gathering information from Veterans via usability testing (n = 12 – 15 total).
2. Assess Veteran interest, satisfaction, and usability of the online VACT-CP program.
3. Iteratively address any technological concerns.
    a. Utilize Veteran feedback, website revisions, and preliminary support that a small-pilot RCT is merited.

Phase 3 Objective: The goals of the feasibility pilot RCT study phase are to conduct a Stage 1b RCT pilot trial (total recruited n = 40 – 60 participants) **to:**

1. Explore relationships between Veteran traits, usability beliefs, and technology perceptions on intended and actual use of the VACT-CP system
2. Describe differences in VACT-CP versus a wait-list control group on pre- and post-test measures of pain acceptance, pain level, pain-related functioning, and quality of life, treatment satisfaction with the VACT-CP system and ACT-related outcomes including pain acceptance, valued living and experiential avoidance;

3. Evaluative the relative feasibility and acceptability of the VACT-CP intervention procedure and waitlist control, including ease of recruitment, retention in each condition, treatment receptivity, attrition and retention in each condition, sustained participation, and the assessment process.

A maximum of 40 Veterans will be enrolled and randomized to test the VACT-CP system within their home; we will recruit up to 60 participants in order to meet this randomization goal.

2.0 Background and Significance

2.1 Background

Pain has been identified as among the most frequent presenting complaints to healthcare providers, including those responsible for providing primary care for Veterans (Kerns et. al., 2003). Perhaps the most complicated to treat and debilitating - chronic pain - refers to self-reported pain lasting longer than 3 to 6 months, persisting beyond the healing of an initial injury or disease, and it can often last for years (Merskey, 1986; Dobscha et al., 2009). Chronic pain is a highly prevalent problem - an estimated 126.1 million U.S. civilian adults report some pain in the previous 3 months and 25.3 million adults (11.2%) suffer from daily, chronic pain (Nahin, 2015). In an effort to reduce pain in these patients, pharmacological treatments such as long-term opioid therapy are often prescribed (Boudreau et al., 2009). Unfortunately, although patients with chronic pain report some relief from short-term use of opioids, there have been concerns about the effectiveness of traditional medical interventions and long-term opioid use (CDC, 2013). In fact, there is no evidence of the long-term efficacy of prescription opioids in chronic pain treatment, and they can lead to substance use, abuse, and death (Chou et al., 2009; Martell et al., 2007; Yu et al., 2003). To adequately address pain for suffering patients, it is imperative to look beyond pharmacological treatments and address the behavioral factors that can assist with self-management of chronic pain.

As behavioral treatment for chronic pain can be labor intensive and potential clinics less accessible to Veterans outside of major VA settings, many Veterans do not have access to therapists trained in chronic pain treatment (Trafton et al., 2010). In fact, less than half of Veterans prescribed opioids for chronic pain treatment receive mental health treatment, and half of VA facilities do not have any pain-focused psychological services utilizing behavioral therapeutic orientations (Trafton et al, 2010). This suggests that the VA could benefit from the rapidly increasing field of online and mobile health technology for increased access to empirically supported chronic pain treatment. Web-based interventions in particular have been growing in popularity as a treatment-delivery method for many psychiatric and behavioral difficulties (Ybarra & Eaton, 2005). Online interventions have the potential to reach Veterans who might otherwise not have access to VA clinical care, as 85% of adults have access to either the Internet at home or wireless mobile devices (Rainie, 2012).

Technology-assisted support and treatments are increasingly appealing to potential consumers and appeal to health centers because telehealth delivery methods can improve their ability to reach patients, are cost-effective, and can increase overall impact (Heapy et al., 2017). Following the initial program development, at-home and web-based behavioral interventions are relatively easy to implement within clinical and health settings compared to in-person individual or group interventions, since they do not require training new practitioners to implement a treatment model or monitor treatment fidelity (Ybarra & Eaton, 2005). Once developed, an at home, technology supported self-management can assist with multiple issues related to chronic pain. For instance, Heapy and colleagues (2017) found that an interactive, automated voice response (IVR) self-management system for chronic back pain, and found it

to be non-inferior to in-person CBT for Veterans. In addition, participants receiving both in-person and IVR interventions reported physical functioning, sleep quality, and physical quality of life at 3 months.

Although technology-supported programs are increasing in popularity and are often non-inferior to in-person treatment, sustained engagement and retention of consumers in mobile, at home treatment continues to lag (Heapy et al., 2017). In addition, a recent systematic review of web-based interventions for pain suggested that technology supported treatments can be efficacious, but more research is needed to investigate the best kinds of formatting and tailoring necessary for at-home technologies (Martorella et al., 2017). Consequently, there is still room to improve this online treatment and create a more Veteran-centered and engaging experience.

To address engagement and motivational difficulties with mobile pain interventions, our research group (the Social and Community Reintegration Research Program – SoCCR at the VA Bedford Healthcare System) has been collaborating with Dr. Tim Bickmore at Northeastern University, and Dr. Reilly has received a Rehabilitation Research and Development Career Development Award to develop and pilot an online Veteran-centric ACT for Chronic Pain program. We are currently writing and developing a detailed 8-session VACT-CP protocol for individual online treatment, with treatment techniques based on previously-developed ACT treatments for chronic pain, as well as additional ACT training. This program will also utilize embodied conversational agents (ECAs), or virtual guides, previously developed by Dr. Bickmore to engage Veterans more fully in the program. The purpose of this study, to gather provider feedback and perspectives on this program, and online interventions in general, that will be used to further develop and refine the VACT-CP system, as well as gather valuable information on potential opportunities and barriers to this program for Veterans with chronic pain, in pursuit of an online intervention that can be tested as a randomized clinical trial with Veterans.

2.2 Preliminary Studies

Dr. Kelly, in collaboration with researchers at the Fred Hutchinson Cancer Research Center in Seattle, WA has evaluated the receptivity of an ACT web-based tobacco cessation intervention for individuals with PTSD that targets negative affect as an obstacle to quitting. This research showed that participants with clinically significant symptoms of PTSD (n=694) were more satisfied with the ACT web-based tobacco cessation intervention and felt like it was more useful for quitting than participants without clinically significant symptoms of PTSD (n=622). These results provide evidence that a targeted, web-based ACT intervention for chronic pain, that also targets negative affect as a barrier to coping with chronic pain, may also be perceived as useful and acceptable for Veterans. The ECA for the current project will be based on this prior work (see Figure 1), as well as the intervention platform, and will be modeled from this project and other preliminary studies and findings from Dr. Timothy Bickmore, creator of Nurse Annie Fox on his online interventions. ECAs are already being developed, assessed, and used to provide assessment and care. In addition to the Nurse Annie Fox project, two ECA-based substance use screenings have been validated in the Boston VAMC. On the basis of these pilot studies, an ECA has also been designed to conduct screening, brief intervention, and referral to treatment (SBIRT) for alcohol misuse in the Veteran population, and is currently being evaluated in a RCT at VA Boston, with the ECA intervention participants reporting higher working alliance ratings compared to neutral, and participants' attitudes towards the ECA.

Figure 1. Nurse Annie Fox ECA

2.3 Significance

The information from the proposed qualitative study will provide valuable information for both VACT-CP intervention refinement, and provider perspectives on referring Veterans with chronic pain to online treatments. Using provider perspectives to refine and center the VACT-CP program on both Veteran goals and provider feedback, the proposed program will provide an accessible, home-based treatment for Veterans with chronic pain, which is highly prevalent in Veterans and associated with serious functional and quality of life issues. The potential for such a program within the VA is of particular importance to Veterans and VA programs focused on behavioral treatment of chronic pain in Veterans, with a particular emphasis on increased impact and access of chronic pain behavioral treatment. Overall, it is expected that this program will 1) assist with the development and refinement of the VACT-CP system, 2) identify providers' overall interest, concerns, and perspectives on online behavioral treatment referrals, 3) plan for a future feedback and usability study utilizing the VACT-CP online treatment with Veterans, and 4) provide preliminary information on the usability, feasibility, acceptability, and describe the potential impact of the VACT-CP system through a 40 person RCT (VACT-CP intervention versus waitlist control).

3.0 Research Design and Methods

3.1 Drug/Device Information

Not applicable

3.2 Type of Study

Phase One: We will first finalize the design of a mock-up of the VACT-CP website, and some finalized portions of the VACT-CP treatment that will be shown during usability interviews to elicit feedback and further refine the online program and website. For Phase 1, we will conduct semi-structured interviews with a maximum of 12 providers at the VA Bedford Healthcare System, who report working at least partially on issues of chronic pain. These interviews will be audio-recorded for formative assessment of the potential benefits, concerns, and institutional VHA dissemination issues for the VACT-CP intervention, using a semi-structured interview guide and a "think-aloud" strategy for intervention review. Providers will also be shown the VACT-CP system for intervention and interviewed about their reactions to the site, and queried regarding the potential benefits, barriers, referral concerns, and overall thoughts on the VACT-CP system. These interviews will be audio recorded. We will also ask participants to complete a very brief (5 minute) questionnaire related to their work background and general demographics in order to describe our provider sample. The generated information and themes will be utilized for development and refinement of the VACT-CP intervention and to learn from major stakeholders the important areas for potential revision during development and inform development of the full-VACT-CP system.

Phase Two: We will conduct semi-structured interviews with a maximum of 15 Veterans with chronic pain. The goals of Phase 2 are to: 1) gain further feedback on the VACT-CP treatment by gathering information from Veterans via usability testing to; 2) assess Veteran interest, satisfaction, and usability of the online VACT-CP treatment; 3) iteratively address any technological concerns. For purposes of feedback and iterative program development, the Veteran will be provided with portions of the VACT-CP intervention, which they will access on a personal computer, during which time their use of the system will be recorded using either VA Skype for Business or Cisco WebEx. Approximately 4 - 5 Veterans will be recruited and participate in this usability testing at a time, with 3 different usability testing arms, in order to allow for time to iteratively address any functionality issues or concerns with

the user interface. Participants will also be provided with measures of demographics, usability and health information technology use, including a retrospectively worded version of the Usability Survey items (e.g., I enjoyed using the VACT-CP program) and a semi-structured qualitative exit interview. Participants will receive $40 for their research session, which should take approximately 2 hours.

Phase Three: We will assess the feasibility and acceptability using a Stage 1b RCT pilot test comparing VACT-CP (n = 20) to a wait-list control group (n = 20), including ease of recruitment, retention in each condition, treatment receptivity, attrition and retention in each condition, sustained participation, and the assessment process We will also describe preliminary data on the impact of VACT-CP vs. the control condition on pain-related functioning related to social, occupational, and physical functioning, emotional functioning, mental health, and quality of life. Participants will receive $60 for the baseline assessment, $40 at the midpoint testing visit/3 weeks, and, $60 for the end of treatment (Session 7/7 weeks) and $40 for a one-month follow-up (total; $200 total). Participants assigned to wait-list control will have the option to use the VACT-CP online system after their one-month follow-up.

3.3 Study Procedures

a. Sub-Study Participation

N/A

b. Study Related Procedures

General Procedures
Phase One: All Primary Aims will be assessed through a qualitative interview with a research staff member at the VA Bedford Healthcare System. Subjects will be VA clinical care providers.
Upon obtaining IRB approval, research project staff will provide study information to VA staff and clinicians within clinics serving Veterans with chronic pain such as social work, Primary Care and Behavioral Health, etc. Providers may also call the listed research staff contact number on the informational materials if interested in study participation after seeing a flyer or hearing about the study. Sampling for this group will also be based on a reputation-based snowball design. Research staff will then coordinate with the provider to answer any questions about the study and provide a time to complete informed consent and the qualitative interview, which should take approximately 1 -1.5 hours total. Confidential and private spaces at the VA Bedford Healthcare System
will be used for the qualitative interview, and the website prototype will be shown on one of the computers within this room. A total of 10 – 12 providers who identify as treating patients with chronic pain will be enrolled.

Phase Two: Usability testing procedures: We will conduct usability testing with 12 - 15 Veterans who meet eligibility criteria. We will first complete a phone screen, to assess whether Veterans are eligible according to our inclusion/exclusion criteria. After the intake assessment, eligible participants will be scheduled for usability testing (a one session procedure). The intake assessment may be completed remotely VA Skype for Business or Cisco WebEx, depending on their system eligibility, as both are approved for current use in VA research.

Usability testing will be conducted in three waves, with 4-5 participants in each wave. The choice of 4 - 5 participants per wave was based on the finding that approximately 80% of usability problems can be

detected using a sample of 4 to 5 participants (Virzi, 1992). Usability testing will take about 2 hours to complete and will be video-recorded. Participants will participate remotely, using VA Skype for Business or Cisco WebEx. We will invite Veterans to participate in a Skype/WebEx conference call, which is behind the VA firewall. We will then give the Veteran the VACT-CP website to take a look at. We will interview the Veteran as s/he is looking at the website and interacting with the virtual ACT coach (Coach Anne). We will then record the Veteran's responses using SkypeWebEx and save it directly to a secure location on the PI's L drive, which will be password protected.

Participants will be asked to interact with the virtual ACT coach (Coach Anne). Participants will be instructed to "think aloud" as they complete the task and provide their first reactions to the program. We will assess VACT-CP usability along four dimensions: (a) usefulness—whether users can successfully complete designated tasks on the site, (b) effectiveness—the ability to accomplish tasks quickly and easily, (c) learnability—the ability to meet pre-determined site navigation goals within a specified period of time, and (d) satisfaction—the users' feelings and opinions about the website. Objective measures include usability scales, and interview questions will be related to subjective measures are ratings of usefulness, visual appeal, and overall satisfaction. Satisfaction with the program will be assessed using an 8-item questionnaire used in our prior work. In addition, we will conduct qualitative interviews with participants to identify which aspects of the program were the most or least helpful and review any suggested changes. These usability testing procedures are consistent with best practices and procedures used for other behavioral health intervention websites (e.g., WebQuit). After each round of testing, we will work with the Northeastern University programming team to make changes to improve the usability of the program.

Retention and Non-completion. As study participation will require only a single session to show the VACT-CP components, and engage in the qualitative interview, we do not anticipate severe difficulties regarding retention. However, as the study will take place for 1 - 1.5 hours for Phase One, and approximately 2 hrs for Phase Two, it is possible that some participants will not be able to complete all study procedures in one sitting, or may have to be scheduled for two separate study sessions that total 1 - 1.5 hours each. For Phase Three, the total goal for enrollment and randomization is 40 participants (n=20 per group) for the 7-week VACT-CP intervention or waitlist control group; assuming an attrition rate of 30% after randomization. We will recruit up to 60 participants in order to meet our goal of 40 randomized participants.

VACT-CP Treatment Content and Structure. The following components will be emphasized in VACT-CP based on previous manualized ACT-chronic pain treatment by Vowles and Sorrell[37] *Life with Chronic Pain: An Acceptance-based Approach Therapist Guide and Patient Workbook* and utilizing ECA technology to create a personalized, therapeutic experience. Creation of the intervention will entail modification of the ECA image, creation of the intervention scripts and programming for the online user-experience. The main areas of intervention in this treatment are as follows (Table 1).

Table 1. VACT-CP Timeline and Intervention Description.

TIMELINE	*MODULE FOCUS*	*INTERVENTION DESCRIPTION*

Week 1	*Introduction to VACT-CP and the Treatment Agenda*	Assess the Veterans experience of chronic pain, past experience with acceptance and mindfulness, the nature of their pain and past treatments for pain, while providing information on ACT and it purpose. Veterans will be asked to identify efforts to control or avoid pain-related symptoms and internal experiences and how this is problematic for functional living. Letting go of fear-based decisions and pain-related experiences will be emphasized. Veterans will also make distinctions between primary and secondary pain to distinguish physiological and psychological consequences of pain.
Week 2	*Behavioral Change and Triggers*	Veterans will also register and make distinctions between primary and secondary pain (to distinguish physiological and psychological consequences of pain, as well as being introduced to the behavioral model and concepts of behavioral change when experiencing cognitive barriers to change. Internal (e.g., thoughts, feelings, bodily sensations) vs. physiological pain triggers and concerns will be identified, and their role as a perceived obstruction for living a meaningful life will be discussed.
Week 3	*Values Clarification*	The Veteran will be introduced to goal setting and committed action, which will be explicitly linked to both values and functional goals, as well as invited to explore additional activities for pain management included on the site (e.g., stretching, yoga, progressive muscle relaxation). Veterans will clarify their values and goals for treatment, using a personalized values-assessment.
Week 4	*Acceptance*	Veterans will be encouraged to face pain-related experiences with mindful acceptance. Veterans will engage in acceptance exercises (e.g., willingness to experience painful sensations, rather than avoid them) that are linked to previously identified values. Veterans will also participate in mindfulness exercises in order to practice nonjudgmental acceptance of internal pain-related experiences.
Week 5	*Cognitive Defusion*	Veterans will be introduced to be pacing vs. activity cycling while getting psychoeducation on the nature of language and cognitive barriers to committed action. The Veteran will be helped to learn that they are not their thoughts related to pain, anxieties, or fears, and practice mindfully observing and accepting these internal experiences, rather than try to avoid them.
Week 6	*Committed Action (Behavioral Activation)*	This module will provide metaphors and discuss willingness to experience discomfort as a means to pursue important outcomes. Veterans will be asked to incorporate more pleasant events in their lives to replace pain-avoidant behaviors used to fill idle time. Veterans will also be asked to identify a behavioral, functional goal over the next week that will potentially cause them some discomfort, but is aligned with a valued life area.
Week 7	*Willingness and Wrap-Up*	The final session will focus on overviewing and reinforcing progress made so far in terms of the Veteran's committed actions, to plan for relapses and setbacks for the "lifelong assignment" of fully engaging in one's life.

Participants will receive 7 online modules, provided as weekly sessions that will feature an ECA (virtual therapist) as a treatment guide. The initial module is devoted to an explanation of the treatment rationale, initial psychoeducation on pain-related symptoms, pain interference, and focal concepts of ACT, and assessment of individual pain symptoms. Modules 2-4 will focus on values clarification, acceptance and willingness, mindfulness, with an emphasis on tolerance of pain-related experiences. Modules 5-6 will continue to this focus, and incorporate goal-creation and committed action exercises. Module 7 will consolidate and provide feedback on goal-related achievements, and will focus on planning for the future. All content will be presented interactively, through text-based conversations

with Coach Anne that appear as short videos to Veterans on the screen. Veterans will hear what Coach Anne "says", and respond to her queries using forced-choice text options that will trigger different responses from Coach Anne as the conversation progresses, to allow the system to responsively interact in a personalized manner with the Veteran.

Phase Three: Following recruitment, a research associate not otherwise involved in the study will screen participants prior to enrollment. Veterans will be randomized in a 1:1 ratio, with a research staff member utilizing and keeping the schedule. Veterans randomized to VACT-CP (and online website that includes 7 online-module based weekly sessions of treatment) via personal computer or provided laptop at the Bedford VAMC. Veterans in the waitlist control will be provided with a list of common pain resources at the Bedford VAMC. The VACT-CP program will be housed on a secure web server through Northeastern University, with no Veteran private health information collected by the system. Veterans in both conditions will complete the assessment battery (see Table 2 for specific schedule) at baseline, either in-person or remotely (via a phone call or online using the VA-approved Qualtrics survey platform) depending on the participant's preference. In addition, the full battery of primary outcomes and process measures will be taken at mid-point of the intervention phase (3 weeks) and at the end, immediately following the treatment (7 weeks). Veterans will be tracked in terms of their post-referral treatment engagement (e.g., enrolling in any of the pain-resource options on the handout). In addition, a research associate will call the Veteran at weeks 3 and 6 and conduct a brief safety assessment with Veterans assess for potential suicidality, usability issues, and participant health and well-being.

Justification for Wait-list Control Condition. The use of a waitlist, control group is often a standard practice in trials of new treatment regimens for psychological conditions; however, there is debate as to whether wait lists are appropriate comparisons for different treatment conditions. According to the World Medical Association (WMA) update regarding the use of non-active treatments in clinical trials where an effective treatment is available, the suggestion has been made that the benefits, risks, and effectiveness of a new method should be tested against those of the best current therapeutic methods, though this does not exclude the use of "no treatment" groups where no proven therapeutic method exists. In effect, though we are adapting an effective treatment for chronic pain (ACT for chronic pain), there is no proven "best" current treatment for ECA-guided online interventions for chronic pain as a comparison point; consequently, the treatment being piloted has no appropriate active, efficacious online treatment as a comparison, suggesting that a waitlist condition is an appropriate comparison.

3.4 Data Collection

Phase 1 Data Collection: Data collection after enrollment and during the demo session will consist of 1) a short survey which will not be audio-recorded and 2) a qualitative interview, which will be audio recorded. Confidential and private spaces at the VA Bedford Healthcare System will be used for the assessments. The questionnaire and qualitative interview will take approximately 1 - 1.5 hours total. Demographic questions will be asked regarding age, ethnicity, race, gender identity, and education , as there is research suggesting that personal comfort with technology relates to individual's interest in referring other to specific technologies (Hilty et al., 2006), and that comfort with technology can be impacted by demographic factors (Czaja et al., 2006; Jackson et al., 2008). The purpose of these questions is to gather information from valuable stakeholders and potential referral-providers on VACT-

CP system to address refinement of the program, possible benefits, barriers, referral concerns, and overall thoughts on the VACT-CP system (see Qualitative Interview Protocol for specifics).

Quantitative Measures

1. **Demographics questionnaire**: will gather basic, non-identifying information including participant age, ethnicity, race, and education (2 minutes).
2. **Work-history survey:** using questions created specifically for this study, we will gather basic information related to working with patients who have chronic pain, including provider's current position, past experiences as a health or mental-health provider specific to working with chronic pain, length of time in current position, past specialized training on treating chronic pain, and information related to making referrals to online or tech-mediated health interventions or resources (4 minutes)

Qualitative Data Gathering

This interview will include open-ended questions related to palatability of the intervention, feasibility of engagement with Veterans with chronic pain, interest or potential concerns with referring Veterans to such a program, and reactions to a short walk-through of the intervention. Questions for palatability (Table 1) are based on the "organizational perspective" components of the Practical, Robust Implementation and Sustainability Model (PRISM: Feldstein & Glasgow, 2008). Interviews will be audio recorded and transcribed.

Table 1. Provider Assessment Interview Structure.

GENERAL INTERVIEW GOALS	
Part 1. Descriptive questions: demographics, history of clinical work with Veterans, past experience with Veteran referrals for chronic pain and inclusion of technology (i.e., mobile apps.) in treatment.	
Part 2. Present the participant with a walk-through of the VACT-CP website prototype and user interface. Using a "think aloud" strategy, ask them to give their immediate thoughts out loud as they interact with the system. Ask clarifying questions as appropriate.	
Part 3. Open-ended questions related to palatability from a current provider or as a potential referral source perspective will be asked.	
PROVIDER ELEMENT	**OPEN-ENDED QUESTIONS FOR PROVIDERS**
General	What do you think about online programming for Veteran support for chronic pain in general? What are your overall thoughts on VACT-CP?
Patient centeredness	How do you think Veterans could benefit from the program online?
Provides patient choices	For what reasons might you refer Veterans to this program as an option for CP treatment? Are there any Veterans that you would not refer to this type of program because you don't think they would engage or benefit?
Addresses patient barriers	In what ways might you feel comfortable referring a Veteran to this program? What might be some barriers to referring a Veteran to this online program?
Additional program elements	Do you think the provided handout on this intervention would give you enough information to refer Veterans to this intervention? What would you change

	about these materials?
Burden/Barriers	What do you see as potential barriers to referral, or for Veterans to sign up for this online treatment?
Feedback of results	Would you be interested in hearing about VACT-CP results after the study ends?

VACT-CP Revision: Following data collection, we will: 1) gather feedback regarding acceptability and potential usability of the platform in other settings (e.g. at the Veteran's home), 2) gather and analyze provider feedback on the VACT-CP system, 3) address any technological or system-specific concerns as, and 4) use this data to modify potential plans for a future VACT-CP usability pilot. Modifications to the interface and protocol will be based upon: 1) acceptability and feasibility of the VACT-CP platform and potential treatment components, and 2) qualitative feedback obtained from providers. We will not be gathering information on the usefulness of treatment as part of this study.

Individual feedback sessions at the end of the full study will be analyzed together to gather information for refining the treatment to make it acceptable to patients. After receiving the totality of information from 10-12, the researchers will amend the program with a potential solutions i.e, adding VA-specific pain information, text size or text color being altered. Some platform usability and intervention-specific challenges will be addressed with introductory handouts/tutorial materials/orientation to the program at the beginning of the intervention session.

Phase 2: Data Collection:
Qualitative Combined Usability and Contextual Interview. We will focus on usability and feasibility for Phase 2. During the 2 hour at-home usability sessions, participants will assess the usability of the VACT-CP intervention using a "think-aloud protocol", verbalizing their thoughts as they navigate the website and Coach Anne. After a period of exploration with the site, the research staff will use a pre-created protocol to ask Veterans to interact with Coach Anne through one of the VACT-CP modules (i.e., responding to her queries, entering therapy goals, completing in-session assessments, interacting with the virtual therapist generally). As the participant navigates the intervention website on their computer, their actions will be recorded through a screen-share recording electronically, and the Veterans comments will be recorded via the audio. Dr. Reilly will observe the actions in real-time during the session via the same technology platform.

Usability Assessment Procedures
Eligible Veterans will first complete baseline demographic and health measures provided over the phone (approximately 30 mins). Following the baseline assessment, Veterans will be provided with a quick overview of the site and interaction system to help Veterans access and understand different portions of the user interface and treatment set-up, during which time they will be asked questions and recorded as a usability interview. Next, Veterans will be provided with verbal instructions for use, and begin their walk- through of a portion of the treatment (approximately 10 mins). During this time, the Veterans will take part in a contextual interview wherein Veterans move through the system unguided and are observed and asked questions about their experience (approximately 30 minutes). After this, additional, usability items (25 mins) and open-ended questions will be asked regarding Veteran preferences (approximately 20 minutes).

For purposes of feedback and iterative program development, the Veteran will only be provided a portion of the VACT-CP program during this time, during which time their use of the system will be recorded. Approximately 4-5 Veterans will be recruited and participate in this usability testing at a time, with 3 different usability testing arms, in order to allow for time to iteratively address any functionality issues or concerns with the user interface. Following this walkthrough, participants will be provided with measures of demographics, usability and health information technology use, including a retrospectively worded version of the Usability Survey items (e.g., I enjoyed using the VACT-CP program) and a semi-structured qualitative exit interview. Participants will receive a $40 gift card for their virtual research session, which should take approximately 2 hours.

Assessment Measures At Beginning of Session

A broad range of reliable and valid measures will be used to provide an assessment of chronic pain difficulties, demographic information, and technology use, technology interest, and comfort.

Demographics, functional health, and pain measures. Demographic measures will include pain-related information regarding type and duration, age, gender, race and ethnicity, and education. Well-being measures will include psychological depression, Patient Health Questionnaire-9 (PHQ-9), and PTSD Check List (PCL-5), as well as pain interference (Brief Pain Inventory), and the Veteran's RAND 36 Item Health Survey (VR-36). These measures will be used to describe the sample and will take approximately 30 minutes).

Media and Technology Usage and Attitudes Scale (Rosen et al., 2013): A 16-item measure of different attitudes toward technology using a 10-point frequency scale from Never (0) to All the Time (10) that assess comfort level, attitudes towards new technology, and usage patterns for mobile technology. Completed before usability/platform interaction session.

Post-Website Usability Interaction Measures

Intrinsic Motivation and Perceived Usefulness Scale (ITAM; Venkatesh, 2000): The usability survey items were adapted from an existing set of usability questions to make the questions specific to the VACT-CP online treatment. The items form 2-4 item subscales that will be used to address relationships between elements of our modified Integrated Technology Acceptance Model. We will assess antecedent conditions that are proposed to influence health-technology acceptance and use, including satisfaction with medical care, preferences for seeking information, health care needs, internet dependence, and health care knowledge. In addition, we will assess intrinsic motivation, perceived ease of use, and perceived usefulness of each health-technology. Prior versions of the subscales have shown good internal consistency reliability for each subscale (Cronbach's alphas > 0.7 for all but information seeking preference which was 0.60).

System Usability Scale (SUS; Brooke, 1996): a 10-item measure, scored on a 5-point Likert scale, that assesses human-computer interaction. A SUS score above 58 is regarded as above average, and a SUS score above 80 is regarded as high and a score above which participants are likely to recommend the product to friends. The SUS generates a subjective evaluation score using a globally accepted scale and to understand if the system in its current form is sufficiently usable.

Qualitative Combined Usability and Contextual Interview: Veterans will be observed while interfacing with the VACT-CP system, recorded, and asked questions by the interviewer. This will consist of specific questions related to the different parts of the system the veteran interacts with (e.g., the virtual coach design, structure of the modules, feedback system) as well as more open-ended questions when not provided with specific cues (e.g., what are you trying to get to from this page, what could be better about how this is set-up, etc.). Questions will be open-ended in nature, and address the extent of any problems with accessing and using the VACT-CP treatment online, how they might perceive the usefulness or importance of VACT-CP focal areas of treatment, whether they would recommend this treatment to a fellow Veteran, and any problems or concerns they may have with using the VACT-CP program.

Using this additional, open-ended interview protocol, we will also inquire as to whether they would be interested in using the VACT-CP treatment at home beyond this session, and the role of their virtual coach in the patient's interest in the treatment, and about past strategies or tools the patient used to address their chronic pain or tools the patient used to address their chronic pain issues and whether the VACT-CP treatment might seem more useful than prior options or strategies. Finally, participants will be asked to indicate what, if any, changes they would make to the treatment to assist in self-management of their chronic pain. This will also include assessing their interests in complementary and alternative methods of pain management (stretching, yoga, progressive muscle relaxation, etc.) to assess if it would be useful and feasible to add these options to the platform later if desired. The interview will be video-recorded and coded to look for similar themes, difficulties, revisions, and strengths of the system.

Intervention Revision

During each wave of testing, Veterans will interact with the VACT-CP online treatment to: 1) gather feedback regarding acceptability and usefulness of the treatment, 2) gather and analyze complementary data from SUS-8, 3) address any technological issues as they arise, and 4) examine preliminary data from this phase of the study. Modifications to the website will be based upon: 1) acceptability and feasibility of the online treatment, and 2) qualitative feedback obtained from patients, therapist, and mentors. Individual feedback sessions at the end of Phase 2 will be held to gather information for refining the treatment intervention and make it acceptable to patients.

We anticipate that our Veteran intervention reviewers might miss bugs or other user interface problems and anticipate that some revisions to the online system and program may need to be made. For instance, one potential issue that may arise might be an inability for the Veteran to read the text on the screen. After receiving this information during an initial feedback round, the researchers will amend the program with a potential solution, i.e., text size or text color being altered, with the revised version then being piloted in the next round of Veteran user testing. Some usability challenges will be addressed with introductory handouts/tutorial materials/orientation to the program at the beginning of the intervention session. In addition, large organizational issues will be discussed before moving on to platform refinement.

Phase 3: Data Collection

Callers will be initially screened by phone. Eligible participants will be scheduled for an in-person assessment or phone-conference with research staff. At this assessment, research staff will confirm study eligibility and obtain informed consent and administer the Structured Clinical Interview for DSM-5

(SCID-5) to assess for potential psychosis, substance use disorders, or clinically-significant suicidality. Eligible subjects will then complete self-report measures. Participants with additional, co-morbid pain diagnoses will not be excluded. Data will be collected at baseline, the study midpoint (approximately 3 weeks), end of treatment/7 weeks, and at the one-month follow-up period. Self-report baseline and post-baseline assessments will be administered either in-person or online by Qualtrics, a VA-approved platform and vendor. Length of time for assessments will take approximately 2 hours for baseline assessments, 1.5 hours for the mid-point survey, approximately 2 hours for the 7 week/post-intervention surveys, as well as approximately 1 hour for the 1 month follow-up surveys. See Table 2 for the measurement schedule:

Table 2: Measurement Schedule for Phase 3

MEASURE	BASELINE	MIDPOINT	INTERVENTION END /7 WEEKS	1-MONTH FOLLOW-UP
Demographics	X			
MEAQ	x		x	x
CPVI	x	x	x	x
PHQ-9	x	x	x	x
VR-36	x	x	x	x
POQ-SF	x	x	x	x
SCID-5	x			
BPI	x			
CPAQ	x	x	x	x
Usability survey*			x	
SUS*			x	
WAIS-S*			x	
CSQ-8*			x	
Qualitative Interview			x	

**will only be assessed in invention group*

Demographics, functional health, and pain measures. Demographic measures will include age, gender, race and ethnicity, and education. We will also include questions related to medications currently being used for the management of physical or psychological conditions, self-reported using a single-item listing diagnoses, and at baseline and 7 weeks conduct a CPRS record review for such information. These measures will take approximately 10 minutes.

Feasibility and Acceptability Measures: Feasibility outcomes will include recorded information on recruitment rates, retention rates within each condition, measure completion rates, how often Veterans access the website, and any reported problems with the website. This information will be collected by the research team.

Quality of Life. *The Veteran's RAND 36 Item Health Survey (VR-36)*[43] is 36-item measure of health including physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It is often summarized into (physical functioning components and mental functioning components, and is one of the most widely utilized and valid measures of physical and psychological well-being. This survey will take approximately 15 minutes.

Usability Survey. The usability survey items were adapted from an existing set of usability questions to make the questions specific to the VACT-CP online treatment. The items form 2-4 item subscales that will be used to address relationships between elements of our modified Integrated Technology Acceptance Model.[35] We will assess antecedent conditions that are proposed to influence HIT

acceptance and use, including satisfaction with medical care, preferences for seeking information, health care needs, internet dependence, and health care knowledge. In addition, we will assess intrinsic motivation, perceived ease of use, and perceived usefulness of each HIT. Prior versions of the subscales have shown good internal consistency reliability for each subscale (Cronbach's alphas > 0.7 for all but information seeking preference which was 0.60). The usability survey should take the average user about 5-7 minutes.

System Usability Scale (SUS; Brooke, 1996) a 10-item measure, scored on a 5-point Likert scale, that assesses human-computer interaction. A SUS score above 58 is regarded as above average, and a SUS score above 80 is regarded as high and a score above which participants are likely to recommend the product to friends. The SUS generates a subjective evaluation score using a globally accepted scale and to understand if the system in its current form is sufficiently usable.[44] This survey will take approximately 3 minutes.

Pain-related Measures. At the beginning of each module, the Veteran will be asked to rate their current level of pain using a 11-item pain intensity scale. In addition, the following two assessments will be provided pre- and post- intervention: *Pain Outcomes Questionnaire – Short Form (POQ-SF)*[47] is a is a 20-item inventory that assesses patient's ability to engage in functional activities related to daily living that may be impacted by pain interference; and *The Chronic Pain Acceptance Questionnaire (CPAQ)*[48] is 20-item survey measuring recognition of pain as not negating the ability to live valued life. We will also assess pain interference, again using the Brief Pain Inventory. This battery of pain -related measures will take approximately 25 minutes.

Mental Health Co-Morbidity Measures. To assess for important psychological co-morbidities in chronic pain treatment, we will administer the 9 – item Patient Health Questionnaire-9 (PHQ-9)[61] to asses for depressive symptoms, and 20-item PTSD Checklist-5 (PCL-5).[41] These surveys will take approximately 7 minutes.

Valued Living. *The Chronic Pain Values Inventory (CPVI*) is a 12-item self-report measure of the extent to which the patient is living in accordance with their values in areas such as work, health, and family, which is related to lower perceived disability and pain-related anxiety, as well as greater reported patient functioning even in the context of high levels of pain.[62] This survey will take approximately 3 minutes.

Behavioral Avoidance. The *Multidimensional Experiential Avoidance Questionnaire (MEAQ)* is a 62-item self-report measure of experiential avoidance, including subscales on Behavioral Avoidance, Distress Aversion, Procrastination, Distraction & Suppression, Repression & Denial, and Distress Endurance.[50] This survey will take approximately 12 minutes.

Patient Satisfaction with Treatment*:* *Client Satisfaction Questionnaire-8.(CSQ-8*)[51] This 8-item scale measures global satisfaction, perceived quality, and effectiveness of the proposed mental health treatment. This scale has been used in mental health and other health centers, and has acceptable internal consistency (α=.83-.93). This survey will take approximately 2 minutes.

Therapeutic Alliance: *Working Alliance Inventory-Short Form (WAI-S)*[52] This 11-item scale will be administered to obtain both an early and a late alliance assessment between the Veterans and VACT-

CP virtual ECA therapist that will walk patients through the treatment. It has acceptable internal consistency (Cronbach's α=.83-.98) and predictive validity related to therapy outcome**.** This scale will take approximately 2 minutes.

a Storage

Data collected online via Qualtrics will initially be stored on the Qualtrics platform. This platform is HIPAA compliant and has been approved by the VA FedRAMP's process for data collection and storage. After collection is complete, this data will be transferred from the Qualtrics platform directly into password protected files on a VA sharepoint site: https://vaww.visn1.portal.va.gov/sites/mirecc/vactcp/ that is designated and accessible for this study only.

b Collection of PHI

Data collected online will be stored on the FedRAMP approved, HIPAA compliant platform, both on the Qualtrics platform and when transferred to a VA platform. Only members of the approved research staff will have access to this data.

3.5 Analysis Plan

Phase One:

Primary analyses. We will gather feedback from semi-structured interviews on system interest, concerns, issues, and suggestions for improvement to VACT-CP so that we are better suited to move forward with completed development and future pilot testing at VA Bedford. Preliminary analyses will include assessment of qualitative data for transcription errors. As only 10 - 12 subjects will participate in quantitative surveying on workplace history and general demographics, only aggregated information will be reported.

Qualitative Interview Analysis: The audio recordings and notes made by Dr. Reilly during the qualitative interview will be transcribed and analyzed using Excel or NVivo software available through the Bedford VAMC. A modified consensual qualitative research (CQR) approach will be utilized to code the transcribed audio, which Dr. Reilly has been trained in and utilized in past peer-reviewed publications. CQR can be particularly useful in allowing for a team of coders to identify themes arising in both structured and more open-ended interview moments. Dr. Reilly will develop an initial codebook for using in coding based on the key activities and questions in the semi-structured interview protocol.

Dr. Reilly and another research staff member will then employ the codebook in identifying usability-themes within the audio, with an additional research staff identified to act as a code auditor. According to CQR, the following processes occur to allow for depth and breadth in describing the shared experiences of participants: (b) two coders utilize the initial codebook throughout the data analysis process to foster multiple perspectives, and revise the codebook as needed; (c) consensus is researched between coders about the meaning of the data; (d) at least one auditor must check the work of the

primary team of judges and minimize potential bias; and (e) domains and themes are reported in terms of the frequency of arising themes.

Themes will then be categorized according to the following CQR groupings: general (include all or all but one of the cases), typical (include more than half of the cases up to the cutoff for general), and variant (at least two cases up to the cutoff for typical). Specifically, the themes generated by this qualitative data will be used to identify potential user issues, concerns, intervention opportunities, and general trends and categories of provider's perceptions' of the VACT-CP system. Using this method, we will classify all general comments regarding usability as necessary to include in iterative development and refinement, while variant and typical will be discussed within the research group to decide upon potential ways to incorporate this feedback into intervention refinement. Research staff will then summarize suggested changes, obtain input from the full research team, then meet with the VACT-CP programmers to implement potential changes. Results will be published to inform other researchers about development and implementation findings related to referrals to online behavioral interventions for pain, preferred user interfaces, provider interest, and perceptions of behavioral intervention content and needs.

Phase Two:

Similar to Phase One of the research, the video recordings and notes made by Dr. Reilly during the qualitative portion of user testing will be transcribed and analyzed using coding software options (e.g., NVIVO or Excel) available through the Bedford VAMC. A modified consensual qualitative research (CQR) approach will be utilized to code the transcribed videos, which Dr. Reilly has been trained in and utilized in past peer-reviewed publications. CQR can be particularly useful in allowing for a team of coders to identify themes arising in both structured and more open-ended interview moments. Dr. Reilly will develop an initial codebook for using in coding based on the key activities and questions in the user-testing protocol. Dr. Reilly and the research associate will then employ the codebook in identifying usability-themes within the videos, with an additional research staff identified to act as a code auditor. According to CQR, the following processes occur to allow for depth and breadth in describing the shared experiences of participants: (a) two coders utilize the initial codebook throughout the data analysis process to foster multiple perspectives; (b) consensus is researched between coders about the meaning of the data; (c) at least one auditor must check the work of the primary team of judges and minimize potential bias; and (d) domains and themes are reported in terms of the frequency of arising themes.

Themes will then be categorized according to the following CQR groupings: *general* (include all or all but one of the cases), *typical* (include more than half of the cases up to the cutoff for general), and *variant* (at least two cases up to the cutoff for typical). Specifically, the themes generated by this qualitative data will be used to identify user performance measures, errors, and difficulties, and tasks that do not meet acceptable criteria, and general trends and categories of users' behavior, such as how well users can complete an assigned task on the VACT-CP system and where they are encountering problems. Using this method, we will classify all general comments regarding usability as necessary to include in iterative development, while variant and typical will be discussed within the research group to decide upon potential ways to incorporate this feedback into intervention refinement.

In addition, Veterans will complete a series of brief usability questionnaires following user testing and the qualitative interview. Usability Survey and SUS data will be input into an excel spreadsheet and reported descriptively using SPSS software, and used to describe Veteran's general perceptions and opinions of the technology's usability, both within the controlled testing setting and for future use within their home. This feedback will then be triangulated with qualitative data and used to iteratively refine the VACT-CP program between the three waves of user testing. We will complete this process with 4-5 Veterans per round; Dr. Reilly will then summarize suggested changes, obtain input from the full mentoring team, then meet with website staff to implement potential changes.

Phase 3:
Data management procedures described for Phase 2 will be used in Phase 3. The PI will direct data management and analyses in consultation with CDA-2 mentors Drs. Megan Kelly, Molly Waring, and Karen Quigley.

Power analysis. Consistent with the recommended stage model for development of behavioral therapies, the aim of this stage I Pilot Study is to inform future treatment development and evaluation plans. Given that prior investigations of ACT have reported effect sizes within the large to medium range, we expect VACT-CP will also produce a medium treatment effect. In order to have .80 power to detect differences at a two-tailed alpha level of .05, a medium effect would require n=125. This is beyond the scope of a CDA-2 award, and is more appropriate for a stage II trial. A total sample size of 40 is feasible (n=20 per group) and consistent with Rounsaville et al.'s[53] recommendation of 15 to 30 subjects per condition for stage I behavioral treatment development.

[Primary Analyses and Hypotheses, Aim 3a:

Hypothesis One: Given prior usability research, we predict that both perceived ease of use and perceived usefulness will be strongly correlated with behavioral intention and actual use of VACT-CP.

Hypothesis Two: We predict that higher behavioral intention, perceived system usability, and intrinsic motivation to use VACT-CP will correlate positively with actual use (number of modules completed).

We will focus on usability of the VACT-CP system in home setting to test Aim 3a. Usability will be primarily measured via the Usability Survey Subscales for antecedent user features (e.g., health care need). The Usability Survey Subscales and System Usability survey will assess for acceptability features at both pre- and post-intervention (e.g., perceived ease of use, perceived usefulness, intrinsic motivation, and system usability) We will then assess if these usability factors relate to intended and actual use statistically using bivariate correlations.

To address Aim 3a, we will first compile descriptive statistics for each of the ITAM measures, determine Cronbach's alphas for each of the ITAM component subscales, and compute bivariate Pearson's correlations to assess relationships between acceptability, antecedent and intention and actual use factors of the ITAM. Next, where we have sufficient data from participants receiving the same intervention we will use multiple linear regression models for VACT-CP use to model which acceptability features (intrinsic motivation, perceived ease of use, perceived usefulness, system usability) are most strongly related to behavioral intention to use modules and with actual use.

Additional data will be provided by the semi-structured qualitative interviews and tracking of any calls to research staff with concerns. Analysis of post-intervention interviews will be done using notes taken by one of the team members during the exit interview; interviews will also be audiotaped for later use if needed. Dr. Reilly and research staff will apply CRQ qualitative analytic techniques (see Phase 2 Data Analysis plan) to these data (e.g., coding for and extracting major themes) to assess both barriers and facilitators to use of the VACT-CP system, and individual demographic user factors that impact use. Finally, we will behaviorally assess feasibility by measuring the proportion of individuals who successfully complete the 8 week trial with at least 5 completed modules, which would be 71% of the program completed and slightly above the mean number for percentage of completed sessions found in previous online behavioral interventions.[58]

Secondary Analyses, Aim 3b.

Hypothesis One: We will observe increases in the means scores on pain acceptance, functioning, behavioral avoidance, mental-health symptoms (PTSD and depression), and values-oriented living given past ACT-based chronic pain interventions research for VACT-CP participants.

Hypothesis Two: We predict that there will be small- to no-change in means on pain levels, given research suggesting that behavioral intentions do not change pain levels overall.[58]

To address Aim 3b, we will describe the outcome variable scores from pre- to post-intervention using subjective pain-related outcomes and quality of life measures. Because we have proposed a rolling design where changes in the delivery of VACT-CP intervention can be made with each wave of participants, the number of participants given the same version of the self-management program may be too few to test these outcome effects at a conventional level of significance. We will thus describe differences by reporting means and standard deviations pre- and post-levels of outcomes (pain acceptance, pain levels, pain functioning, behavioral avoidance, mental-health comorbidities, and values-oriented living). We will also use mental health measures to describe our sample and explore if groups are equivalent based on these measures.

Based on the intent-to-treat principle, all subjects enrolled in the pilot study treatment will be included in analyses, and the PI will conduct preliminarily analyses and descriptively report on the pilot RCT outcomes of the VACT-CP intervention in order to inform further refinements to VACT-CP. Additional outcomes of interest, including working alliance and treatment satisfaction will also be reported and described in terms of their means and standard deviations. Due to imprecise estimations due to small sample size, we will not report estimates of effect sizes as a specific hypothesis or aim; however, we will explore and report on descriptives (means, standard deviations) between pre- and post-scores.

Secondary Analyses, Aim 3c.

To evaluate the feasibility of recruiting the necessary sample for a larger randomized controlled trial by determining the effect size for future studies. Leon and colleagues[59] point out that a pilot study does not necessarily provide the meaningful effect size estimates necessary for planning subsequent larger studies due to the imprecision inherent in data from small samples. However, it will provide feasibility and acceptability data.

Hypothesis One: We anticipate acceptable exclusion/inclusion criteria for recruitment, acceptable retention rates for randomization, and equivalent retention rates within each condition.

Hypothesis Two: We anticipate that Veterans within the VACT-CP condition will report higher rates of treatment satisfaction compared to the wait-list control.

We will specifically utilize this information to design the large efficacy trial for the Merit Review application. For example, if recruitment rates are low, we will plan to add another VA site. If a higher-than-acceptable number of Veterans are excluded due to exclusion criteria, we will re-examine whether that eligibility criterion is necessary. If retention rates are lower than acceptable, the PI and research team will discuss how to retain more Veterans before moving to the efficacy trial, and build retention rates into your sample size calculation. For the purposes of a future Merit Review application sample size estimation, we will calculate sample size requirements results of previous adequately-powered chronic-pain behavioral interventions, and we will secondarily consider the impact of our intervention on reported pain-acceptance and functional improvement in this small pilot RCT.]

4.0 Human Subjects

4.1 General Characteristics

Phase One: We will aim to recruit a maximum of 12 clinical care providers at the VA Bedford Healthcare System who work with Veterans with chronic pain, over the course of 3 to 6 months. Dr. Reilly or another member of the study team will send emails to providers who have been identified as working with patients with chronic pain to invite them to join the study, as identified by study staff. The general features of this participant sample will be clinical-care providers (nurses, doctors, psychologists, psychiatrists) over the age of 18 who work at the Bedford VAMC and currently provide pain-management care treatment to Veterans. In order to ensure a representative mix of clinical-care pain providers at the VA Bedford, we will aim to ideally recruit 2-3 psychologists, 2-3 nurses, 2-3 MDs, and 2-3 psychiatrists total, and may engage in more targeted recruitment in order to meet the **minimum goal of two providers in each area**. Interviewing and incorporating provider feedback is important at this development stage, so that chronic-pain clinical providers have their perspectives included into the creation of this VA platform. As content experts and future clinicians who would likely refer Veterans to this program, they should be able to provide input related to improving the system and adding potential important treatment options to the site. This project will allow for feedback and preliminary usability information to revise the developing chronic-pain treatment platform.

Providers and staff at various VA Bedford clinical sites will be identified using a reputation-based snowball design, wherein persons who are recruited will be asked to pass along recruitment information (flyers, initial email) to other chronic pain providers they believe might be interested in this study. We may make presentations to groups of providers who are likely to care for patients with chronic pain issues at their team meetings to tell them about the study. A small group of individuals interested in discussing online interventions for pain will initially be identified with the help of local providers, researchers and administrators, and only research staff will recruit these persons via an IRB-approved email and potentially a corresponding phone call.

Interested individuals will be briefly screened by phone for eligibility. No individually-identifiable data will be captured from the brief phone screening; data will be saved ONLY for purposes of tracking screening eligibility rates and reasons for ineligibility. This will inform our future referral strategy and resource planning for a future small pilot usability study on VACT-CP. The racial and ethnic characteristics of the sample are likely to reflect that of clinical-care providers at the VA Bedford. In addition, we may post flyers in approved locations around the facility and affiliated ambulatory services including community-based outpatient clinics (CBOCs) and share flyers with clinical staff who are most likely to have contact with other chronic-pain care providers who might be interested in the study.

Phase Two: We will aim to recruit a maximum of 15 Veterans recruited from the Bedford VA. Veterans at the Bedford VAMC will be identified as having a chronic, non-cancer pain diagnosis using CPRS chart review, hear about the study from providers, or are self-referred. Veterans from the community may contact us by learning about the study from posts in the community (e.g., craigslist). A 2019 review revealed that there were 2,605 Veterans who were seen over the past year (i.e., having had at least two appointments for pain) at the Bedford VA with chronic, non-cancer pain concerns, so we should have no difficulty recruiting the proposed number of participants.

Potential participants will be pre-screened by phone to determine whether basic study eligibility criteria are met. Individuals who remain eligible after the phone pre-screen will be scheduled for the research session. At the beginning of the research session, we will provide participants with detailed information about the study and obtain verbal informed consent. Following informed consent, participants will complete study assessments and engage in a usability testing. Participants will have a $40 gift card mailed to their home following the research session.

Phase Three: We will aim to recruit up to 60 participants over fifteen months total to allow for the desired final 40 participants screened as eligible and randomized into the pilot RCT study, specifically aiming for recruiting 3-4 participants per month. Subjects for the proposed study will be recruited over the course of approximately 15 months and be screened according to their presence of chronic pain and other inclusion/exclusion criteria. First, potential participants will be pre-screened by phone to determine whether basic study eligibility criteria are met. Individuals who remain eligible after the phone pre-screen will be randomized in a 1:1 ratio. Veterans randomized to VACT-CP will receive 7 online-module based weekly sessions of treatment via personal computer or provided laptop with wireless accessibility at the Bedford VAMC. Veterans in the waitlist control will be provided with a list of common pain resources at the Bedford VAMC. Subjects will be paid $60 for the baseline assessment, $40 at the midpoint testing visit/week 3 for waitlist control, and, $60 for the end of treatment (Session 7)/end of week 7 for control group participants and $40 for a one-month follow-up (total; $200 total).

4.2 Inclusion of Vulnerable Subjects and Special Populations

Phase One: This study will include VHA medical and mental-health care providers who may feel pressured or also be vulnerable to coercion or undue influence to participate in research. Special considerations have been taken to protect this group and these employees, by ensuring that their supervisors will not be informed of their participation by study staff, as well as assurances that their participation will be kept confidential and all data collected will be anonymized and deidentified.

Phase Two and Phase 3: Vulnerable participants include those with chronic pain disorders, as these individuals can often have comorbid mental health concerns. Another population to be included is that of the Veterans themselves. They are accustomed to taking and following direct orders, thus introducing a further need for researchers to prevent coercion either directly or indirectly. Veterans will be given ample time to read and consider informed consent, with other treatment options presented by investigators. Family members, significant others, and primary treatment teams may also be involved in the decision-making process if the Veteran wishes. They are also informed that refusal to participate will be accepted without hesitation at any time and will not change their eligibility for VA services, treatment, disability payments, or other related VA benefits. Research staff will evaluate each subject at the end of the phone screen and/or usability testing session to ensure that they have not experienced significant distress or exacerbation of their symptoms as a result of their participant. The evaluation will consist of asking the subject about (1) feelings of distress and (2) desire for additional support because of distress. Anyone experiencing distress and desiring support will be provided with informal support, and if necessary taken to formal providers

4.3 Inclusion of Incompetent Subjects

Not applicable.

4.4 Inclusion/Exclusion Criteria

Phase One:

Inclusion Criteria

1) Currently working at the VA Bedford Healthcare System or one of its affiliated CBOCs in a clinical capacity, including mental health, physicians, nursing, pharmacists, or primary care/behavioral health staff
2) Currently seeing Veterans to assist in their management of chronic pain

Exclusion Criteria.

1) Any cognitive or physical impairment that would interfere with study participation of using a computer and providing verbal feedback.

Phase Two:

Inclusion Criteria

1) Current diagnosis of non-cancer chronic pain
2) Competent to provide written informed consent
3) Ages 18 and older
4) Access to the internet at least weekly through a computer

Exclusion Criteria

1) Any cognitive or physical impairment (e.g., auditory or sight issues issues) that would interfere with study participation of using a tablet/computer and providing feedback.

Phase Three:

Inclusion Criteria

1) Current diagnosis of non-cancer chronic pain, defined as 1) at least one pain-related diagnosis indicated by an ICD-9 or -10 code related to either Musculoskeletal pain or Joint Problems/Osteoarthritis or 2) presence of chronic pain of at least mild to moderate severity as indicated by two or more NRS pain scores of ≥ 4 at three separate VA outpatient visits in past year based on a CPRS record review;
2) Has a working, high-speed wireless internet connection at home, or is willing to access sessions either at the Bedford VAMC by using a provided laptop in a secure space
3) Competent to provide written informed consent
4) Ages 18 and older.

Exclusion Criteria

1) Any current or lifetime DSM-5 psychotic disorder
2) Current or recent (within 1 month of study entry) DSM-5 alcohol or drug use disorder
3) Current use of any other chronic pain-related behavioral or psychological treatment
4) Any cognitive impairment that would interfere with study participation
5) Clinically significant suicidality within the past year
6) Presence of any clinical features requiring a higher level of care (inpatient or partial hospital treatment)
7) Any cognitive or physical impairment that would interfere with study participation of using a laptop/computer and providing feedback]

4.5 Recruitment Procedures

Phase One:

Subjects will be a total of 10 - 12 clinical care providers who work at the VA Bedford Healthcare System and identify as working with Veterans to assist with their treatment of chronic pain. There will be two recruitment methods:

1) We will post flyers in approved locations around the VA Bedford facility and affiliated ambulatory services in areas that serve Veterans with chronic pain. Interested individuals who reach out to study staff will be screened by phone for eligibility. The recruitment procedures will be conducted by the research staff in areas of the hospital such as social work, mental health, and PCBH.

2) Providers and staff at various Bedford VA clinics will be identified using a reputation-based snowball design, wherein participants who receive the initial flyer or email are encouraged to pass along study information to other providers they believe could be interested in participating. A small group of individuals interested in discussing online interventions for pain will initially be identified with the help of local providers, researchers and administrators (Drs. Megan Kelly, Tu Ngo, Charles Drebing, etc.). These persons would provide names and emails of potential participants, and then Dr. Reilly would email these persons separately using IRB-approved email language (see attached document). These subjects will be recruited directly, via an email from Dr. Reilly (see attached for the proposed content of this initial contact). If there is no response to the email after 48 hours, a second attempt would be made in the form of a phone call, which would be explained in the initial email. Another email will not be sent. Contact will stop after the phone call if there is no response after the second attempt. We will inform potential participants that they are free to decline without fear that their supervisor or any of their co-workers will know about it. Respective Service Chiefs and union

leadership will be contacted if needed for permission to interview providers, but they will not be told which employees decide to participate or who declines to participate. We will also request that those people participating be excused from their clinical duties for the time of their participation. If providers and administrators are unable to be excused from duties or if they prefer to participate outside of their tour, they will be scheduled for an appointment after their work tour. At the end of the interview we will ask for the names of other individuals who may be appropriate for interviews and we will contact those individuals using the process above. Clinic leadership will not be involved in the recruitment process and will not be made aware of who is participating.

Phase Two: and Phase 3 Subjects for Phase 2 will be approximately 12 - 15 patients primarily recruited by referral from the Primary Care Behavioral Health clinic at the VA Bedford Healthcare System. Subjects for Phase 3 will be approximately 40 – 60 patients. The PI will not be a current provider of services to any participant recruited into the study. The PI will not call participants prior to enrollment, unless they contact the PI or research staff and express interest in the study or they do not call after receiving a letter about the study to indicate that they are not interested in the study (see below).

<u>The recruitment process will include the following:</u>

1.) We will ask providers to mention the study to potential participants if they think it might be of interest to the participant, and provide a brochure or flyer if they are interested. We will ask providers to tell participants to call us if they are interested. Providers are not recruiting study participants, only providing information about the study. Although we will specifically target providers from the Mental Health Clinic (MHC), the Veterans Mental Health and Addictions Program, Primary Care Behavioral Health (PCBH), the Community Residential Center (CRC), and the VASH program, we will provide information to any clinicians who are interested in learning about it.
2.) We will also provide information to veterans and providers at a Crossroads event at the VA Bedford Healthcare System, where information (e.g., flyers) about the present study and other investigators' studies will be distributed at a table in a highly frequented area of the Hospital.
3.) We will also distribute flyers and brochures throughout the hospital, with research staff study contact information.
4.) To increase recruitment, we will also employ previously successful recruitment strategies of posting the study on popular websites, letters to health professionals, and online resources (such as Craigslist.org). See attached media posting that would be displayed on these sites, which contains contact information for research study staff.
5.) The names of veterans from a medical record review coming to the following clinics for appointments: the Mental Health Clinic (MHC), the Veterans Mental Health and Addictions Program, Primary Care Behavioral Health (PCBH), the Community Residential Center (CRC), and the VASH program. These names will be obtained by searching CPRS for entry/provider codes associated with these programs.
    a. The research staff will access these patients' medical records only to determine whether they meet the study inclusion criteria for psychiatric diagnosis, and obtain address and phone contact information. We will also access SSNs ensure that we are identifying the right patient for contact. We will not open flagged records.
    b. We will then send a letter to the patient to invite him/her to learn more about the study (attached to this application). The letter will contain contact information for the research

team so the patient can contact the research team for more information. It will state that if we don't hear from the patient within two weeks, that we will call them about the study. It will also state that if patients do not want to be called, they can call our research staff and let us know. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA.

It is expected that recruitment will be enhanced by the Bedford VAMC's extensive treatment networks, recognition for expertise in pain management treatments, lack of competing studies, and subject payment. If continuous review of recruitment data suggest imbalance in gender distribution, we will target our recruitment toward clinics that serve higher numbers of women (e.g., women's clinics).

We expect that most of the recruitment for this study will be done from the Bedford VAMC and that they will be recruited through advertising. For those subjects who learn about the study from clinic staff, physicians, or other VA staff (e.g., handed a flyer for review by a clinician) and the Veteran indicates that they are interested in participating, the Veteran will be informed that they can call the number on the brochure to contact study staff to learn more about the study.

We will call a potential participant three times, and if we do not hear back from them from any of these attempts, we will discontinue contact attempts. However, if a potential participant does call back and leaves a message, we will reinitiate the three-call rule (i.e., call them three more times and discontinue if we do not hear from them). If potential participants are not available, we will leave a message, saying *"My name is Dr./Mr./Ms. and I am calling from the Bedford VA Hospital. We are calling about a research study and would like to check if you are interested in participating in this study. If you would like more information, please give us a call back at 781-687-xxxx. Thank you."* If we reach someone by phone who is not the potential participant, we will ask the person to write down our contact information for the potential participant (name and number), but will not indicate where we are from or the purpose of our call to maintain confidentiality.

4.5.1 Subject Identification and Pre-Enrollment Screening:

Screening Procedures.
Phase One: Callers will be screened by phone and providers who have given their name and number and asked to be called will be called by study staff. During the screening, providers will also be informed about the study design and information. If the provider is interested in the study and meets inclusion/exclusion criteria via participant screening, the trained research staff will then schedule the participant to come into the Bedford VAMC for the approximately 1 - 1.5 hour interview session at a mutually convenient time.

Phase Two: All potential participants will be screened by phone. Potential participants will be identified via self-referral, information is provided by clinical providers or VA staff. Veterans may be provided information on the study by providers and those Veterans tell providers they would like to be contacted by study staff. In addition, Veterans may be identified via a medical record search of potential candidates with a non-cancer chronic pain disorder that come to the clinics listed above. If potential research participants call us about their interest in participating in the study, we will use the attached screening tool and script to assess their eligibility for the study. Patients who are initially screened via

prescreening through the VA Medical Records System, CPRS will be sent a letter regarding their interest, and then called after two weeks if they do not opt out. We will call Veterans to determine their interest in the study, and conduct a screening with the attached screening tool and script. For participants that have indicated to their providers that they would like to be called about the study, and providers have passed on this information to research staff, then research staff will contact them for an initial prescreen for the study (see attached phone script and screen).

Potential subjects will initially be pre-screened by phone to determine whether basic eligibility criteria are met for the study (e.g., age, diagnosis, computer Internet access). Phone pre-screens will be scripted and completed by trained interviewers. Individuals who remain eligible to participate after completion of the phone pre-screen will be invited to participate in usability testing.

Phase 3: We will utilize the same screening procedures as Phase 2 (phone screen for Phase 3 will be different. See attached document).

4.5.1a HIPAA Authorization for Recruitment and/or Screening:

Phase One: We will only ask potential participants if they currently work at the Bedford VAMC, and if they treat Veteran patients for chronic pain concerns. Participants will not be asked for any information regarding their person health or health care.

Phase Two and Phase Three: A request to use identifiable information in the conduct of this research study under a waiver of authorization for recruitment and screening was submitted with this protocol. The identifiable information being requested is:

<u>To use during the recruitment process:</u>

- To conduct brief screenings with veterans who express interest in the study after learning about it through study presentations, brochures, letters, phone calls, or providers. This will involve asking the veterans questions based on study inclusion/exclusion criteria (i.e., chronic pain diagnosis). These are included on the study screening form.

- The names of Veterans coming to the following clinics for appointments: Veterans Community Care Center (VCCC), Mental Health Clinic (MHC), the Community Stabilization Program (CSP), Primary Care Behavioral Health (PCBH), the Community Residential Center (CRC), and the VASH program. These names will be obtained by searching CPRS for entry/provider codes associated with these programs.

    - The research staff will access these Veterans medical records only to determine whether they meet the study inclusion criteria for chronic pain diagnosis, and obtain address and phone contact information. We will also access SSNs to ensure that we are identifying the right patient for contact (e.g., patients with the same name but different SSN). We will not open flagged records.
    - We will then send a letter to the patient to invite him/her to learn more about the study (attached to this application). The letter will contain contact information for the research team so the patient can contact the research team for more information. It will

state that if we don't hear from the patient within two weeks, that we will call and contact them about the study. It will also state that if patients do not want to be called, they can call our research staff and let us know. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA.

The identifiable information will be used or disclosed only by members of the research team. This information will not be disclosed to anyone outside the VA.

The proposed study poses minimal risk to the privacy of the subjects because:

a. The identifiable information will be protected from improper use or disclosure by:

- For screening purposes only, this study will maintain a contact log. This log will contain the identifying information for veterans who are identified by research staff via medical record review or who contact research staff after learning about the study. It will contain the patient's name, social security number, contact information, and status (No Response, Screened In, Screened Out, Pending, No-Show, Chose not to participate). This log will be password protected and stored on our designated secure server space. This log will be used until the end of the recruitment period in order to prevent ineligible or uninterested veterans from being contacted again by letters from research staff. All information will be kept according to VA Records Retention Policy.

- Study screening forms will be coded, and will not contain the participant's name, social security number, or date of birth.

- All identifying information will be maintained in locked file cabinets in locked offices or on a VA secure server.

- Only identifying information for candidates who meet the diagnostic eligibility criteria will be recorded.

- Identifying information for these patients will be recorded electronically on a VA server space, and will be password protected.

- If patients are not interested, we will transfer their information to a log of non-interested participants which will also be recorded electronically on a VA server site with password protection on file.

    - This log will be used until the end of the recruitment period. This will be done to prevent uninterested patients from being contacted again by letters from research staff. All information will be kept according to VA Records Retention Policy.

- This information will be only be used for scientific research purposes.

- Only Bedford VA study team members will have access to this information.

- The study team will not identify, directly or indirectly, any individual participant in any report of such research or otherwise disclose participant identities in any manner.

4.5.1b Consent for Recruitment and/or Screening:

Phase One: A waiver of consent is requested only for the recruitment process.

We will conduct brief phone screenings with interested providers to enable the research staff to more efficiently achieve the enrollment goal and assess eligibility before the in-person study visit. Screening script is included with this protocol.

Phase Two: A waiver of consent (along with a HIPAA waiver) was requested for the recruitment process. We will conduct brief screenings with interested Veterans will enable the research staff to more efficiently achieve the enrollment goal.

> This recruitment method is the only way we will achieve sample size goals and the goal of a representative sample of veterans who are eligible for this study. It is essential that we specifically offer the study to all patients who meet criteria for the study in order to obtain a representative sample, rather than relying solely on self or provider referrals. If the research team relies on provider identification of eligible patients, it is likely that they will fail to identify all patients who meet diagnostic criteria for the study. Just relying on provider and self-referrals may result in a biased sample, as it is likely providers would only refer veterans to the study who they considered good candidates for this study, rather than all candidates who are eligible for the study. By having the research team identify potential candidates beforehand and then sending letters to potential candidates to use to contact the patient, and following up for those who do not opt out, we can ensure that the largest sample of veterans possible can be invited to participate in the study. The inclusion criteria for the study are very broad and were expressly designed to allow greatest access possible to the study. For this study, it is important that we recruit our sample from a broad population of patients with chronic pain, not just those identified only by providers or themselves as eligible.

All Veterans who decide they want to participate will complete an Informed Consent process prior to entering the study. This consent will provide detailed information about study procedures and potential risks and benefits.

Mail: We will mail interested potential participants the information sheet form and study letter explaining the information sheet. Interested individuals will contact study staff, and non-responders to the mailer will be contact via phone to confirm disinterest or interest. Interested individuals will be screened via a non-recorded phone call with study staff, and eligible participants will be scheduled for a study session.

Verbal Consent: At the beginning of scheduled study sessions, study staff will review the information sheet with them over the phone. After the potential research subject has reviewed it and continued to indicate interest in participating, and before any information is collected, or any questionnaires answered, a study staff member will speak with the Veteran by phone or using HIPAA-compliant Skype/Cisco and will review the informed consent with them. We will go over all the elements of informed consent and make sure they are aware of each component. We will then verbally consent Veterans who will then complete the usability portion of the study remotely which will greatly reduce the time Veterans will have to wait to participate and will also allow for better usability data, as at-home usability sessions in real time with a participant who is remote is considered particularly helpful in identifying system issues and real-world implementation concerns (Bastien, 2010). We will request a waiver of documentation of informed consent from the IRB so that we may use verbal informed consent through an information sheet.

Phase Three:
A waiver of consent (along with a HIPAA waiver) was requested for the recruitment process. We will conduct brief screenings with interested Veterans will enable the research staff to more efficiently achieve the enrollment goal.

> This recruitment method is the only way we will achieve sample size goals and the goal of a representative sample of veterans who are eligible for this study. It is essential that we specifically offer the study to all patients who meet criteria for the study in order to obtain a representative sample, rather than relying solely on self or provider referrals. If the research team relies on provider identification of eligible patients, it is likely that they will fail to identify all patients who meet diagnostic criteria for the study. Just relying on provider and self-referrals may result in a biased sample, as it is likely providers would only refer veterans to the study who they considered good candidates for this study, rather than all candidates who are eligible for the study. By having the research team identify potential candidates beforehand and then sending letters to potential candidates to use to contact the patient, and following up for those who do not opt out, we can ensure that the largest sample of veterans possible can be invited to participate in the study. The inclusion criteria for the study are very broad and were expressly designed to allow greatest access possible to the study. For this study, it is important that we recruit our sample from a broad population of patients with chronic pain, not just those identified only by providers or themselves as eligible.

All Veterans who decide they want to participate will complete an Informed Consent process prior to entering the study. This consent will provide detailed information about study procedures and potential risks and benefits.

Mail: We will mail interested potential participants the information sheet form and study letter explaining the information sheet. Interested individuals will contact study staff, and non-responders to the mailer will be contact via phone to confirm disinterest or interest. Interested individuals will be screened via a non-recorded phone call with study staff, and eligible participants will be scheduled for a study session.

Verbal Consent, for participants who are consented and enrolled remotely: At the beginning of scheduled study sessions, study staff will review the information sheet with them over the phone. After the potential research subject has reviewed it and continued to indicate interest in participating, and

before any information is collected, or any questionnaires answered, a study staff member will speak with the Veteran by phone or using HIPAA-compliant Skype/Cisco and will review the informed consent with them. We will go over all the elements of informed consent and make sure they are aware of each component. We will then verbally consent Veterans who will then be randomized 1:1 via a previously created randomization schedule to VACT-CP or into Wait-list control.

4.5.2 Enrollment

Phase One: 10-12 subjects will be enrolled in the study by study research staff. A subject will be considered enrolled in the study after the informed consent process.

Confidential and private spaces at the Bedford VA will be used for informed consent process, and for the single in person study visit. Interviews and questionnaires done in person in the VA will be completed with the door closed. A white-noise machine will be used whenever possible to further decrease the risk of participant information being overheard outside of the assessment room.

Phase Two: A maximum of 15 subjects will be consented in the study for usability testing. We assume that for every 3 people we consent, 2 will meet eligibility criteria and participate. For participants eligible for the usability testing session, a subject will be enrolled in the study after the informed consent process if they meet eligibility criteria.

Phase Three: A maximum of 6o subjects will be consented in the study. We assume that for every 3 people we consent, 2 will meet eligibility criteria and become enrolled in the study. For participants eligible for the usability testing session, a subject will be enrolled in the study after the informed consent process if they meet eligibility criteria.

4.5.2a HIPAA Authorization

Phase One: Not applicable. We are not asking providers about their health or healthcare, therefore HIPAA does not apply to this study.

Phase Two: We are requesting a HIPAA waiver from the IRB, as it may be impracticable to obtain a signed HIPAA document from subjects as all research activities will occur remotely. If they do not send back a written HIPAA document we would not be able to use their data.

Phase Three: We are requesting a HIPAA waiver from the IRB, as it may be impracticable to obtain a signed HIPAA document from subjects as all research activities will occur remotely. If they do not send back a written HIPAA document we would not be able to use their data.

4.5.2b Informed Consent:

Phase One: All subjects participating in interviews will be provided with an informed consent sheet that would explain the study and contains all needed elements for informed consent. We will not be asking for any private health information. Dr. Reilly or the interviewer will go over the elements of informed consent including the purpose of the study, the expected duration of their participation (1 to 1.5 hours), the intended use of the data, and who is funding the study. Because we wish to record the interviews,

we would make that clear in the informed consent. The informed consent process will take place privately in person, and without the influence of clinic supervisors.

Phase Two: Verbal informed consent will be obtained from each participant prior to entering the study. The information sheet provided to Veterans will explain in simple terms, before the patient is entered into the study, the risks and benefits to the patient. Verbal consent will be obtained after a thorough explanation of the study by the PI or other study personnel (e.g., research assistant, postdoctoral fellow, PI), and an opportunity for the participant to ask questions about the study. This discussion will take place under conditions in which the participant has adequate time to consider the benefits and risks associated with his/her participation in the study.

Only participants capable of giving informed consent will be admitted into the study. Informed consent will be obtained by trained and highly qualified research personnel. The research staff member that conducts the informed consent process will ask each participant to verify that the information in the consent form is understood. The staff member will review understanding of the consent form, including information pertinent to study participation. During the informed consent process, we will assess whether the Veteran is competent to provide informed consent. We will determine whether the Veteran is oriented to time, place, and person. We will ask questions to understand whether the Veteran understands the basics about what the study protocol involves. We will assess whether the consequences of participating in the study are understood. We will also assess whether the Veteran is able to clearly and voluntarily express his or her preference for participating in the study. If the Veteran is not able to do these things, we will determine that the Veteran is not competent to provide informed consent and we will end the informed consent process. Only once all questions have been answered and the participant understands the purpose of the study and study procedures will the participant be asked to verbally provide consent.

A discussion of the study's purpose, research procedures, risks and potential benefits, and the voluntary nature of participation as part of the informed consent process will continue throughout the research experience.

It will be the responsibility of the PI to assure that informed consent is obtained from each participant prior to the performance of any protocol procedures, and in accordance with current state and federal regulations. A waiver of documentation of informed consent will be requested as individuals will be consented verbally. The informed consent process will be completed prior to the initiation of any study procedures. When obtaining consent, we will communicate basic facts about the study, such as the expected duration (30 minutes for baseline assessments and 1 hours to test the VACT-CP program and interview, and 25 minutes for post-usability testing surveys), the intended use of the data, and who is funding the study. We will review the information sheet and ask if they have any questions. We will assure the privacy of participants by asking them to use a private space, rather than a shared office or common area, to speak with us.

Phase Three: Verbal informed consent will be obtained from each participant prior to entering the study. The information sheet provided to Veterans will explain in simple terms, before the patient is entered into the study, the risks and benefits to the patient. Verbal consent will be obtained after a thorough explanation of the study by the PI or other study personnel (e.g., research assistant,

postdoctoral fellow, PI), and an opportunity for the participant to ask questions about the study. This discussion will take place under conditions in which the participant has adequate time to consider the benefits and risks associated with his/her participation in the study.

Only participants capable of giving informed consent will be admitted into the study. Informed consent will be obtained by trained and highly qualified research personnel. The research staff member that conducts the informed consent process will ask each participant to verify that the information in the consent form is understood. The staff member will review understanding of the consent form, including information pertinent to study participation. During the informed consent process, we will assess whether the Veteran is competent to provide informed consent. We will determine whether the Veteran is oriented to time, place, and person. We will ask questions to understand whether the Veteran understands the basics about what the study protocol involves. We will assess whether the consequences of participating in the study are understood. We will also assess whether the Veteran is able to clearly and voluntarily express his or her preference for participating in the study. If the Veteran is not able to do these things, we will determine that the Veteran is not competent to provide informed consent and we will end the informed consent process. Only once all questions have been answered and the participant understands the purpose of the study and study procedures will the participant be asked to verbally provide consent.

A discussion of the study's purpose, research procedures, risks and potential benefits, and the voluntary nature of participation as part of the informed consent process will continue throughout the research experience.

It will be the responsibility of the PI to assure that informed consent is obtained from each participant prior to the performance of any protocol procedures, and in accordance with current state and federal regulations. A waiver of documentation of informed consent will be requested as individuals will be consented verbally. The informed consent process will be completed prior to the initiation of any study procedures. When obtaining consent, we will communicate basic facts about the study, such as the expected duration (approximately 2hrs for the baseline assessments and a total of approximately 2.5 hours to test the 7-module VACT-CP program, 1.5 hours for the mid-point survey, and approximately 2 hours for the 7 week/post-intervention surveys, as well as approximately 1 hour for the 1 month follow-up surveys), the intended use of the data, and who is funding the study. We will review the information sheet and ask if they have any questions. We will assure the privacy of participants by asking them to use a private space when completing assessments virtually, rather than a shared office or common area.

4.5.2c Master List

A participant will be added to the master list of subjects when s/he is consented. This master list will be kept on the secure VA server this study. Only staff that are part of the study and have access to the server will have access to this master list.

4.5.2d

Specify if a VHA health record will be created or updated with research progress notes, and what it will include. Describe who will be responsible for making sure these items are entered in the health record if required.

A VHA health record will not be created and updated for this study..

4.5.2e Certificate of Confidentiality

We do not need a certificate of confidentiality for this research study.

4.6 Risk/Benefit Ratio

4.6.1 Potential Risks and Methods to be Used to Minimize Risks:

4.6 Risk/Benefit Ratio

4.6.1 Potential Risks and Methods to be Used to Minimize Risks:

Potential Risks:

This study does not require invasive procedures or investigational drugs. The major safety concern associated with this study is the disclosure of confidential information and is discussed in the confidentiality section below.

During the study assessments and study procedures, participants may experience some discomfort from discussing personal material and completing self-report questionnaires. Likewise, some participants may feel uncomfortable about having the study assessments and/or usability testing sessions videotaped and reviewed by others (which is necessary for usability testing analysis). Secondly, there is a possibility that study patients will not improve from the online intervention. In addition, The Columbia Suicide Severity Rating Scale will be used to assess and address any potential risk associated with participating in the study at each assessment session (i.e., baseline, post-treatment, etc.). Using results from this measure, study staff will be trained to immediately evaluate responses the Columbia and respond accordingly to the standard operating practice we have implemented in the protocol should the participant requires immediate crisis intervention.

There is a risk of breach of confidentiality and loss of privacy, which great care will be taken to prevent. As discussed below, we will take precautions to ensure that potential risks are minimized.

<u>Adequacy of Protection Against Risk</u>

Phase One: Potential risks are characterized as not greater than minimal. This study will pose no physical risk to subjects or investigators. The primary risk to individual subjects is that of a breach of confidentiality or that supervisors may view participation in this study as unfavorable. Appropriate steps will be taken to protect subjects' privacy and confidentiality. Interviews will take place in a confidential setting, behind a closed door, with just the participant and a research staff member at VA Bedford. Participation in the study is not anticipated to be associated with any substantial discomfort or

inconvenience. Minor inconveniences include time requirements, which may be viewed as frustrating and time-consuming. Providers may benefit from the knowledge that they helped to modify and test an implementation strategy that can be used as a tool for expanding treatment options for Veterans. These benefits outweigh the small risk of loss of privacy and confidentiality.

We will specifically guard against loss of confidentiality and supervisor influence in reference to interviews. Interviews will take place in a private room and will not involve clinic leadership or a participant's supervisor. No personally identifiable information (PII) will be collected.
All identifying information will be maintained in locked file cabinets in locked offices or on a VA-secured server. The electronic contact list will be password protected and stored on a VA shared drive and will only include names and phone numbers of interested providers. All information will be kept according to VA Records Retention Policy. This information will be only be used for scientific research purposes. Only VA study team members will have access to this information. The study team will not identify, directly or indirectly, any individual participant in any report of such research or otherwise disclose participant identities in any manner. Providers who decide they want to participate will need to sign an Informed Consent prior to entering the study. This consent form will provide detailed information about study procedures and potential risks and benefits.

Participants will be asked not to identify themselves or other staff by name in interviews and transcripts will have any names of individuals removed. Interviews will be digitally recorded and kept on VA servers behind the VA firewall and in accordance with VA policies. Each digital recording will be identified by a unique code that will NOT include subject identifiers. Transcription of digitally recorded material will take place on VA servers behind the VA firewall by a VA research assistant or using a VA-approved transcription service. Transcripts will be identified by a unique code that will NOT include subject identifiers. Only research staff members approved by the human subjects committee will have access to participants' research records. All research information will be kept behind VA firewalls or will be securely stored in locked file cabinets in locked offices.

Phase Two and Phase Three: Recruitment procedures have been described under Research Design and Methods above. Participants will be obtained from referrals from Bedford VA services and clinics, including primary care, the mental health clinic, and specialty services (e.g., MHICM, domiciliary, Women's Health Clinic, OEF/OIF program, Vietnam Veteran groups, LGBTQ program). We expect that some participants will be self-referred, whereas others will be referred by providers.

Verbal informed consent will be obtained from each participant prior to entering the study. The informed consent document will explain in simple terms, before the Veteran is entered into the study, the risks and benefits to the Veteran. The informed consent document will contain a statement that the consent is freely given, that the Veteran is aware of the risks and benefits of entering the study, and that the Veteran is free to withdraw from the study at any time. Consent will be obtained after a thorough explanation of the study by the PI or study staff member and an opportunity for the participant to ask questions about the study. This discussion will take place under conditions in which the participant has adequate time to consider the benefits and risks associated with his/her participation in the study. The IRB-approved consent form will be signed and dated by the participant and investigator and a witness. A discussion of the study's purpose, research procedures, risks and potential benefits, and the voluntary nature of participation as part of the informed consent process will continue throughout the research experience.

It will be the responsibility of the PI to assure that an informed consent form is obtained from each participant or legal representative and to obtain the appropriate signatures and dates on the informed consent document prior to the performance of any protocol procedures and in accordance with current state and federal regulations. Documentation of informed consent document will be retained within study records.

Data Storage and Privacy

All information about subjects will be protected by the research team who will follow all guidance provided in the following VHA HANDBOOKS and DIRECTIVE:

- VHA HANDBOOK 1605.1, PRIVACY AND RELEASE OF INFORMATION (May 17, 2006)
- VHA HANDBOOK 1907.01, HEALTH INFORMATION MANAGEMENT AND HEALTH RECORDS (August 25, 2006)
- VHA HANDBOOK 6500, INFORMATION SECURITY PROGRAM (September 18, 2007)
- MEMORANDUM, SUBJECT: Protecting Information Security and Privacy (February 27, 2009)
- VHA HANDBOOK 1200.12, USE OF DATA AND DATA REPOSITORIES IN VHA RESEARCH (March 9, 2009)

All data collected will be the property of the Department of Veterans Affairs whether in paper or electronic form and will be secured utilizing the following methods.

Paper:

- All paper documents will be stored on VA property unless authorized by the Director, Information Security Officer, and Privacy Officer in writing.
- All paper documents will be locked in an approved file cabinet with only members of the research team having access.
- Paper documents will be stored at the Bedford VA in Building 5.

Electronic:

- All information in electronic form will be stored on VA servers at the VA Bedford Healthcare System behind the VA firewall.
- Electronic Data Associated with this study will be located on secure VA servers.

The people or agencies that will have access to the information are the principal investigator and the co-investigators. No information related to this research will be released to any third party or disclosed outside of the VHA – except as required or permitted by law. Subjects' identity will not be revealed in any reports or publications resulting from this study.

Risk of injury: We do not anticipate any injuries associated with this study. However, as mentioned in the informed consent, no money has been set aside for compensation in case of injury as a result of participating in this study however subjects have the right to file any legal action.

Adequacy of Protection Against Risks:

Phase One: To ensure protection of confidential information, all data will be coded and stored in locked files to ensure confidentiality. Each digital recording will be identified by a unique code that will not include subject identifiers. Transcription of digitally recorded material will take place on VA servers

behind the VA firewall and by a VA-approved research assistant. Transcripts will be identified by a unique code that will not include subject identifiers. Completed quantitative information will be kept at the data management site at VA Bedford Healthcare System and stored in password protected files on a VA secure server folder, designated for this study only. Only the PI and the PI's research team will have access to the computerized data. Research staff working on this study will be educated about the importance of strictly protecting subjects' rights to confidentiality.

In addition, The VA Bedford Healthcare System has an institutional policy requiring all clinical investigators and their key personnel to undergo mandatory training in human research subject's participation. The program includes all clinical researchers regardless of their source of funding. Researchers typically fulfill this requirement by completing VA mandated research trainings. Dr. Reilly and other staff have successfully completed this education in human subjects research.

Phase Two: To protect Veterans against risk the following steps will be taken:

1) In order to minimize anxiety during the study assessments and usability testing, the PI and study staff will make every attempt to help participants feel comfortable when discussing sensitive material or talking aloud during the usability testing procedure. The PI is a licensed clinical psychologist with 10 years of clinical experience, particularly with regard to treating anxiety, depression, PTSD, mood-related issues due to serious health conditions.

2) Initial and continuing participation of the participant in these protocols will be strictly voluntary; the participant will remain free to terminate participation at any time.

3) Data will be collected directly from the participants. All data will be used specifically for the research purposes described in this application. No identifying information will be associated with any information provided by participants as a function of their participation in this study, including their names, addresses, or phone numbers. Each participant in the study will be assigned an arbitrary study number at random and this number will be used for all data for subsequent analyses. Although the screening log will include the name of each participant, it will be filed separately from the actual data files for each participant. To ensure protection of confidential information, all data will be coded and stored in locked files to ensure confidentiality. Video and audio data within the recordings of usability testing will be kept at the data management site at the Bedford VA and stored on a secure VA server for this study. Upon completion of the study and data entry and analysis data will be stored according to VA regulations and destroyed 6 fiscal years after the close of the study. Only the PI and the PI's research team will have access to the computerized data. Names will not be included on videotaped portions of the study, in computerized data files, or in any published reports. Case records will be reviewed only by study personnel or, if necessary, by institutional, state, or federal regulatory personnel. Research assistants and others working on this study will be educated about the importance of strictly protecting participants' rights to confidentiality.

5) Numerous safeguards will keep electronic data secure. Each subject will be assigned a code number so that should any non-study personnel gain access to the data, they will not know to whom the data belong. A secure password is required to access computers at each site, and computer networks are on secured servers that meet or exceed federal confidentiality standards. All connections to this website will be made using the secure sockets layer (SSL). Participant usage data are maintained on a server in a locked server room at Northeastern University, where the VACT-CP website is hosted. Full access to

the server is restricted to two staff members. VACT-CP will store participant usage data. **No participant identifiers will be transmitted to this database server. The VACT-CP website will only store data related to site usage during usability testing.**

6) The Bedford VA has institutional policies requiring all clinical investigators and their key personnel to undergo mandatory training in human research participant's participation. The program includes all clinical researchers regardless of their source of funding. Researchers typically fulfill this requirement by completing Bedford VA research trainings. All research staff have successfully completed education in human subjects research through the Bedford VA.

Phase Three: To protect Veterans against risk, the same steps as Phase 2 will be followed. In addition, we will take the following steps during the research process:

1) Potential study participants will be screened initially over the phone for eligibility. For screening purposes only, this study will maintain a contact log. This log will contain the identifying information for veterans who are identified by research staff via medical record review or who contact research staff after learning about the study. It will contain the veteran's name, social security number, contact information, and status (No Response, Screened In, Screened Out, Pending, Chose not to participate). This log will be password protected and stored on a VA shared drive. This log will be maintained until the end of the recruitment period in order to prevent ineligible or uninterested veterans from being contacted again by letters from providers or by research staff. The identifiable information will be used only by members of the research team. This information will not be disclosed to anyone outside the VA. The proposed study poses minimal risk to the privacy of the subjects because all data will be stored on secure servers, the intervention website (VACT-CP) will not collect any PII or PHI, and all assessments will take place using a secure space at the VA, our VA-approved Qualtrics system for surveying participants, or using a VA-approved secure teleconferencing system (MS Teams, Cisco, WebEx, phone calls, etc). Study screening forms will be coded, and will not contain the veteran's name, social security number, or date of birth. All identifying information will be maintained in locked file cabinets in locked offices or on a VA Shared Drive.

2) There is a possibility that study participants will not improve from use of the VACT_CP online intervention. All participants who fail to respond to treatment and request more assistance from research staff, or withdraw prematurely, will be referred for alternative chronic pain therapeutic treatment with the VA..

3) Participants in both conditions – intervention and waitlist control- will be regularly monitored for suicide risk throughout the treatment and will receive safety plans as necessary (e.g., VA standard of care for suicide prevention). Thus, all participants will continue to receive the standard of care they would receive were they not enrolled in the study. Assessment of suicide risk will be conducted by a study staff at weeks 3 and 6. Staff will conduct a brief safety assessment and qualitative interview with Veterans assess for potential suicidality, usability issues, and participant health and well-being. During the course of the study, some Veterans may be identified as being at imminent risk for suicide, in which case study staff will follow the suicide risk management plan laid out by the Bedford VA.Given that some study participants may present with numerous vulnerabilities (e.g., history of traumatic brain injury, current or past suicidal ideation or behavior), all study staff members will be trained by Drs. Reilly and Kelly, licensed clinical psychologists, in procedures for conducting risk assessment and crisis

interventions. For participants who in the PI judgment pose a substantial current risk of suicide but do not consent to having a provider contacted, we will breach confidentiality and contact their provider while notifying the participant of this and explaining our rationale (concern for their safety). At the beginning of the study and each subsequent assessment, participants will be told that the information they share is confidential unless the participant appears in jeopardy of harming themselves or someone else. For actively suicidal participants, or other participants who appear at high risk, who are not currently receiving mental health treatment, we will strongly encourage the participant to obtain mental health treatment. In addition, we will make every effort to find treatment for the participant and facilitate their obtaining treatment in a timely way.

Telephone Risk Assessments. Risk assessment will be conducted with all participants during the initial eligibility screening. Elements of risk assessment will include level of suicidal ideation and suicidal intent, using questions from the University of Washington Risk Assessment Protocol (UWRAP). If the Veteran endorses either of these items, further questions will be asked, including presence and level of specificity of a plan, access to weapons and other means, presence of known risk factors (e.g., recent loss, substance misuse, chronic pain or other serious medical problems), and presence or absence of deterrents. The PI will be notified of all such occurrences immediately. Following the procedures of the Bedford VA, if a Veteran is at imminent risk of suicide at the time of a phone screen, the psychology technician will direct the Veteran to Dr. Reilly, or their clinician designee via warm telephone transfer. The psychologist will conduct a suicide risk assessment over the telephone in order to determine the Veteran's level of risk. If the psychologist deems the Veteran to be at imminent risk, s/he will call the police and request emergency services via a warm transfer. The psychologist will stay on the line with the Veteran until s/he makes contact with emergency services and care is transferred. In the unanticipated event that a licensed clinical psychologist is not available, and study staff are unable to reach the emergency room at the VA, they will conduct a warm transfer to the Veterans' Crisis Line. If they believe that the Veteran is not at imminent risk, but may need a welfare check, s/he will coordinate with VA police and the suicide prevention team. We will coordinate with credentialed, clinical research staff at each study site to ensure that there is constant coverage by a licensed clinical psychologist. As necessary, the study team will collaborate with the local suicide prevention coordinator to facilitate care and clinical follow-up. If a potential participant is hospitalized, they will remain potentially eligible and will be invited to participate during or after their hospitalization.

Face-to-Face/Telehealth Assessments. The Columbia Suicide Severity Rating Scale will be used to assess and address any potential risk associated with participating in the study at each assessment session (i.e., baseline, midpoint, etc.). Using results from this measure, study staff will be trained to immediately evaluate responses the Columbia and respond accordingly to the standard operating practice we have implemented in the protocol should the participant requires immediate crisis intervention (see below).

Research Sessions. All research staff will complete VA required research trainings. Study staff will contact Dr. Reilly or their clinical designee if other concerning information regarding the participant's safety or the safety of others is identified during administration of the protocol. Study staff will have emergency contact information available at all times for the PI or designee, as well as crisis management and emergency services (e.g., VA National Veterans Crisis Line, Psychiatric Emergency Services, 911).

If contacted, Dr. Reilly or her clinical designee will conduct a more thorough risk evaluation and will initiate appropriate follow-up procedures. Follow-up procedures for high risk are detailed below:

- *High Risk Procedure.* If a participant is judged by Dr. Reilly or her clinical designee to be at imminent suicide risk during treatment sessions, the participant will be escorted to the Bedford VA Mental Health Walk-In Clinic for evaluation of risk and potential need for hospitalization.

In order to ensure the safety of the participant, we will ask the participant to provide contact information for themselves and 3 other parties who 1) know how to get in contact with the participant, and 2) the participant gives consent for study staff to contact. If the participant does not show up for an appointment, we will contact them. If we cannot reach the participant repeatedly, we will attempt to get in touch with the contacts the participant has provided. If we still cannot reach the participant, study staff will coordinate with the suicide prevention team to locate the participant and ensure their safety. Participants will be made aware of these procedures at the start of the study.

4.6.2 Data and Safety Management Plan:

4.6.2.1 Data Security

How/where informed consent documents and study data will be stored:

All data collected for recruitment and for screening purposes will be filed separately from any potential identifying information for each subject. All data will be filed securely under lock and key in file cabinets at the Bedford VA Hospital (Building 5, Room 135b). Data files related to study participation, including participant data and informed consent documents, will be stored directly on a VA-secure server designated for this study only by anonymous subject study number, will be securely maintained, and will be assessable only to research staff directly involved in this project. Upon completion of the study and data entry and analysis, all data and files will be stored and archived indefinitely under lock and key, or on the designated secure server. All hard-copies of non-sensitive study documents will be secured in locked file cabinets within locked SoCRR (Social & Community Reintegration Research) offices in Building 5 (Room 135b) at the Bedford VAMC.

Electronic files and data will be de-identified and labeled with the study ID number, and then stored in a password-protected file on a VA server folder ((\\R04BEDNAS21.v01.med.va.gov) (specific to this study. Storage will be in accordance with VA Research Data Security and Privacy requirements. De-identified data will be labelled only with a non-identifying study subject number. Data files will be securely maintained, and will be accessible only to research staff directly involved in this project. All video recordings will be stored on the server and accessible only to study personnel for fidelity monitoring purposes.

De-identified questionnaire data for this study (if not collected by Qualtrics) will be stored in a database called REDCap (Research Electronic Data Capture), which is housed on a VA-secured, VA Informatics and Computing Infrastructure (VINCI) server at the Austin Information Technology Center (AITC). To ensure the protection of Veteran data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources are approved in accordance with the requirements of National Data

Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. All data transferred from VINCI is subject to audit for compliance. VINCI has multiple layers of security and disaster recovery to prevent data loss. Study data is kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1 (RCS 10-1). REDCap is only accessible via a VA network connection and via a VA-secured computer.

For Phase 3, participants will have the choice to complete assessments in person at the Bedford VAMC, via a telephone call with staff, or online via VA-FedRAMPs approved, HIPAA compliant Qualtrics platform. If participants choose this option, this data will initially be collected and stored on the Qualtrics platform. At the close of the data collection period, all data will be transferred to a VA-secure share drive accessible only to approved research staff. Transfer will occur using a direct download using a VA-secure computer and behind the VA firewall. This data will be downloaded and stored (download will be FIPS 140-2 compliant and data will be fully de-identified in accordance with HIPAA deidentification standards) on an encrypted VA server in password protected files on our secure VA server space that is designated and accessible for this study only.

The collected data will contain PHI but will be de-identified. All the data collected will remain in an electronic folder that can only be accessed by the research team who are identified on the protocol submitted to the IRB. Access to the study data on the VA server will be restricted to the members of the research team, where each research team member will have their own username and password. Upon completion of the study and data entry and analysis, all data and files will be stored and archived indefinitely under lock and key, or on the designated server and the REDCap database.

Procedures to ensure the *privacy of subjects*:

Phase 2: Subjects will screened via a private phone call, and usability testing sessions will be conducted using Skype/Cisco, which is a secure VA approved platform for communication with Veterans. Veterans will be asked to complete all phone and Skype/Cisco communications in a secure room, alone, with the door closed.

Phase 3: Subjects who request to complete study activities (assessment, online website use) at the Bedford VAMC will be asked to come to the PI's program offices, which are located in Building 5, away from busy patient areas. Use of the website (VACT-CP) and any study questionnaires will be completed in the PI's program offices, with the door closed. A white-noise machine will be used to ensure that information from the subject will not be heard outside of program offices**.**

Procedures to maintain the *confidentiality of data/information*:

All data will be used specifically for the research purposes described in this application. No identifying information will be associated with any information obtained from questionnaires or interview data, including names, addresses, or phone numbers. All data will be kept in accordance with VA regulations. Each participant in the study will be assigned an arbitrary study number at random and this number will be used for all data for subsequent analyses. All data are filed securely under lock and key in file cabinets at the VA Bedford Healthcare System (in Building 5). Upon completion of the study and data entry and analysis, all deidentified data and files will be stored and archived indefinitely under lock and

key. All computers are password-protected. All audio files will not contain identifiers and will be downloaded after being recorded to password-protected files on VA computers. Information will not be made available to any party without the written informed consent of the subject and at the subject's request.

How/where data will be stored (location with room number):

Data will be stored in locked file cabinets in Building 9, a Bedford VA building that is locked during non-business hours. Computerized data files will be stored in password-protected files on a secure VA server designated for this study, and accessible by study staff, only. For Phase 3, participants will have the choice to complete assessments in person at the Bedford VAMC, via a telephone call with staff, or online via VA-FedRAMPs approved, HIPAA compliant Qualtrics platform. Data that is collected in pers or by phone will be input to RedCAP. If participants choose the Qualtrics (online survey) option, this data will initially be collected and stored on the Qualtrics platform. At the close of the data collection period, all data will be transferred to a VA-secure share drive accessible only to approved research staff. Transfer will occur using a direct download using a VA-secure computer and behind the VA firewall. This data will be downloaded and stored (download will be FIPS 140-2 compliant and data will be fully de-identified in accordance with HIPAA deidentification standards) on an encrypted VA server in password protected files on our secure VA server space that is designated and accessible for this study only.

The collected data will contain PHI but will be de-identified. All the data collected will remain in an electronic folder that can only be accessed by the research team who are identified on the protocol submitted to the IRB. Access to the study data on the VA server will be restricted to the members of the research team, where each research team member will have their own username and password. Upon completion of the study and data entry and analysis, all data and files will be stored and archived indefinitely under lock and key, or on the designated server and the REDCap database.

Who will have access to the data/codes:

Only Dr. Reilly and authorized study personnel will have access to the data/codes. Once a research staff member is no longer working on this protocol, they will no longer have access to data and codes.

What will happen to the data when the research is complete:

All data will be kept in accordance with VA regulations. Upon completion of the study and data entry and analysis, all deidentified data and files will be stored and archived indefinitely under lock and key.

How data will be archived:

The data will be archived. Data will be archived on VA authorized storage media on the VA server, and hard copies of data (i.e., questionnaires and interview data) will be stored in locked file cabinets in Building 5, Room 135b.

Will data with identifiers be released?

Data with identifiers will not be released, transferred, or shared.

Coordination with Other Sites

How/where data will be stored:

All participant website usage data in the lab will be managed by Northeastern University under the guidance of Dr. Timothy Bickmore, the lead for the creation of the VACT-CP online program. **No PHI or PII will be transmitted to or from Northeastern University.**

Numerous safeguards will keep electronic and hard copy data secure. Each subject will be assigned a code number so that, should any non-study personnel gain access to the data, they will not know to whom they belong. Only study staff associated with the VACT-CP study will have access to these codes. All hard copy data will be kept in a locked file cabinet accessible only by authorized research staff approved this study. A secure password is required to access computers at each site, and computer networks are on secured servers that meet or exceed federal confidentiality standards.

All connections to the VACT-CP website will be made using the secure sockets layer (SSL).

Participant usage data are maintained on a server in a locked server room at Northeastern University. Full access to the server is restricted to two staff members of Northeastern University.

There is deidentified data from the website that includes information about engagement in the website (e.g. Veteran responses to Coach Anne questions, time spent on the website, etc), but no clinical information per se that will be accessed by Northeastern University for analysis. **Northeastern University will not have access to patient usability testing data that is recorded for Phase Two or Phase Three.**

What will happen to the data when the research is complete:

All data will be kept in accordance with VA regulations. Upon completion of the study and data entry and analysis, all de-identified data and files will be stored and archived in accordance with VA regulations.

How data will be archived:

The data will be archived. As mentioned above, any hard copy data will be archived on VA authorized storage media and hard copies of data (i.e., questionnaires and interview data) will be stored on the VA server or in locked file cabinets in Building 5, Room 135b. However, de-identified digital site usage data will be archived in accordance with VA regulations by Northeastern University.

Will data with identifiers be released?

Data with identifiers will not be released, transferred, or shared by Northeastern University, as they will not have any PHI or PII.

We will retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule

(RCS) 10-1. All disclosures and data transmission will meet privacy and security requirements per VA Directive 6500, VA Handbook 6500, and VHA Handbook 1605.1.

All of the above listed practices are designed to minimize risks to subjects while being consistent with sound research design. Furthermore, the risks are reasonable in relation to anticipated benefits.

4.6.2.2 Data Safety Monitoring

A DSMB is not required because multiple clinical sites will not be used, the study is not blinded, and interventions are not particularly high risk or vulnerable populations are not included.

Data and safety monitoring plan:

Dr. Reilly will be monitoring adverse events involving data loss and adverse events related to the study. Adverse events will be monitored in the following ways:

1) Many elements of the research plan are intended to minimize the risks of study participation. Co-investigators will be available to subjects in the event of an emergency. In the event that serious medical or mental health complications should occur, consultation from emergency clinical services is immediately available at the Bedford VA Hospital.

2) Weekly meetings will be held between Drs. Kelly and Reilly. We will discuss and resolve any safety issues more frequently if necessary, as such issues arise, possible participant withdrawal from the study, or any safety concern.

3) Drs. Kelly and Reilly will observe and ensure that data are locked in designated file cabinets and data stored electronically are password-protected and not moved outside the VA. Data integrity and confidentiality will be safeguarded as discussed in the Data Management section of the application and under Protection Against Risks above.

4) Data integrity and confidentiality will be safeguarded as discussed in the Data Management section of the application and under Protection Against Risks above. We will report data security incidents to the IRB, privacy, and information security (e.g., theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls) as soon as we learn of these incidents.

Reporting Adverse Events: Reporting of adverse events will occur as follows:

Local Research Deaths. The IRB will be notified immediately upon becoming aware of any local research death that is both unanticipated and related to the research. A written notification to the IRB will be submitted within
5 business days of becoming aware of the death. If the death does not appear to be both unanticipated and related to the research, it will be recorded and reported at continuing review.

Local SAEs. The IRB will be notified in writing within 5 business days after becoming aware of any local Serious Adverse Event or Serious Problem that is both unanticipated and related to the research. If the serious adverse event or serious problem does not appear to be both unanticipated and related to the research, it will be recorded and reported at continuing review. We will reach out to the local research office if we have any questions.

Serious Problems Involving Information Security. The ACOS/R&D, Information Security Officer (ISO), Privacy Officer (PO), and relevant investigators will be notified immediately (i.e., within one hour) upon becoming aware of information security incidents related to VA research that appear to represent a serious research information security problem, including any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI. The ACOS/R&D will be notified in writing 5 business days of becoming aware of any of these incidents.

Apparent Serious or Continuing Noncompliance. The IRB will be notified, in writing, within 5 business days after becoming aware of any apparent serious or continuing noncompliance with IRB or other human research protection requirements.

4.6.3 Potential Benefits:

There is no direct benefit to the clinical-care providers or Veterans participating in this study. However, participating may benefit by exploring a new and emerging technology, and providing their input on potential future directions for its usage. Moreover, this research will help to understand better what potential areas for pain self-management interventions may best be suited to this platform or at-home care from the perspective of clinical care providers. The feedback gained from this study will provide direction for refinement of the VACT-CP system, as well as inform methods for a future research studies on the utilization and programming of VACT-CP. Because these anticipated benefits are very important to the field, the fairly minimal risks that the study poses are reasonable. Therefore, to improve knowledge about the potential effectiveness and usability of the VACT-CP system, it is important that these aims of this study be addressed and that providers – key referral sources, content experts, and stakeholders - have the opportunity to provide feedback on the technology. This study has the potential to not only improve the treatment of Veterans with chronic pain, but also advance the field of at-home tech supported mobile interventions by further exploring usability and interest of Veterans in this platform for chronic pain management. In addition, this suggests that the VA could benefit from the rapidly increasing field of online and mobile health technology for increased access to empirically supported chronic pain treatment. Web-based interventions in particular have been growing in popularity as a treatment-delivery method for many psychiatric and behavioral difficulties. Online interventions have the potential to reach Veterans who might otherwise not have access to VA clinical care, as 85% of adults have access to either the Internet at home or wireless mobile devices.

Online health and clinical treatments are increasingly appealing to potential consumers and appeal to health centers because telehealth delivery methods can improve their ability to reach patients, are cost-effective, and can increase overall impact. Following the initial program development, web-based behavioral interventions are relatively easy to implement within clinical and health settings compared to in-person individual or group interventions, since they do not require training new

practitioners to implement a treatment model or monitor treatment fidelity. Once developed, a self-guided, web-based ACT intervention for Veterans with chronic pain would provide primary care physicians and clinicians with a new referral option--one that requires no knowledge of ACT.

4.6.4 Alternative Procedures.

There are no alternative procedures available, as this is not a treatment study. Participants are free to decline entrance into or withdraw their participation in this study at any time. However, if Veterans decline to participate or withdraw from the study, and they indicate that they desire pain management treatment, they will be provided with information about treatments in the VA. Chronic pain treatments at the VA include individual and group counseling, telephone counseling, complementary and alternative interventions (e.g., acupuncture), and pharmacological options. A decision not to participate in this study or to withdraw from this study will not affect the participant's ability to participate in standard VA treatment.

4.7 Costs and Payments

Phase 1: There will be no payment to providers who are subjects.
Phase 2: Participants will receive $40 for their research session, which should take approximately two hours. This will be provided in the from of a $40 CVS gift card that is mailed to participants after their research session.
Phase 3: Subjects will be paid $60 for the baseline assessment, $40 at the midpoint testing visit, and, $60 for the end of treatment (Session 7) and $40 for a one-month follow-up (total; $200 CVS gift cards).

4.8 Providing for Reuse of Data

Data will not be reused.

4.9 Creation of a Tissue Bank

We will not be creating a tissue bank.

5.0 Resources

Funding for this study has been secured through an RR&D Career Development Award (PI: Dr. Erin Reilly), and will provide sufficient staff support for the conduct of this study and protection of human subjects and programming support for any interactive changes made to the VACT-CP system. The PI is research faculty within the Social and Community Reintegration Research Program and MIRECC, which provides space and staff for this study. The SoCRR and MIRECC program involves several researchers from the Bedford VA and VISN 1 that are community reintegration experts. Study activities will take place either remoted or in the offices of MIRECC in Building 5. VISN 1 MIRECC has purchased the use of the Qualtrics platform for collecting data.

6.0 Collaborations

We will work with Northeastern University, who will host the VACT-CP website and collect deidentified participate usage data during usability testing.

7.0 Qualifications of the Investigators

Dr. Erin Reilly is a research investigator at the VA Bedford Healthcare System. She has 10+ years of experience with educational technology research and self-report measures in research studies, and has been working over the past year with Veteran participants with social concerns, anxiety, and chronic pain. She has 17 publications, and has received multiple grants related to educational and clinical interventions assisted by mobile technologies, including the use of online learning management systems, technology-mediated health interventions, and the use of socially-assistive robotics for social and psychological interventions. She has received a Rehabilitation Research and Development CDA-2 to develop and refine an online ACT intervention for Veterans with chronic pain.

Dr. Megan Kelly, Ph.D. is the Bedford Site Director of the VISN 1 New England MIRECC, a research investigator in SoCRR, and an Associate Professor of Psychiatry at UMass Medical School. She completed a research fellowship in clinical psychology at the Alpert Medical School of Brown University. She has over 50 publications (published or in press). She has received a VISN 1 Career Development Award on developing an ACT intervention, and another three VA grants on the development of Veteran-specific ACT treatments, including the development on a web-based ACT tobacco cessation intervention for Veterans with mental health disorders. She is also a site PI of a NIDA-funded study to develop and evaluate an ACT-based online treatment for tobacco cessation.

Dr. Karen Quigley, Ph.D., is a Research Associate Professor of Psychology at Northeastern University and a Research Physiologist at VA/HSR&D at the Bedford VA Hospital. She is an expert on the integrating innovative technology into behavioral interventions, including the WatchPAT device for use in providing objective sleep assessment, the Fitbit One for assessing step counts and motivating self-generated goal setting for each week of the trial, and the VA's CBTI Coach app as self-management tools for Veterans.

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