Telehealth CBT to address social isolation in Veterans with chronic pain

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Abstract

Loneliness—a subjective emotional state characterized by the perception of social isolation—is a psychosocial stressor that is associated with increased mortality and chronic pain. Individuals who have chronic pain and report loneliness experience greater pain-related interference in activities, depression, and suicidal ideation. Importantly, there are potentially effective interventions that can be used to decrease loneliness; however, there are no studies that have directly intervened on loneness among Veterans with chronic pain. Cognitive-Behavioral Therapy for Loneliness (CBT-L) intervenes on loneliness by addressing negative beliefs that perpetuate loneliness, increase negative affect, and reduce one's ability to engage in social activities. For a Veteran with chronic pain, this is critical as addressing negative affect, and having a sense that one has social support and engages social support are key aspects of increasing functioning. While CBT for Chronic Pain (CBT-CP) comprises skills to promote social functioning, more robust efforts may be needed to better address lonely while also addressing functional impairment.

The proposed two-year study uses a novel application of a brief, phone-delivered, evidence-based intervention, CBT-L, to decrease loneliness by modifying socially-relevant maladaptive thinking patterns, increasing engagement in enjoyable and social activities, and improving problem solving skills. Participants will be recruited nationally using online advertising. The objectives of the current proposal are to adapt CBT-L to optimize its impact on Veterans with chronic pain, examine if the recruitment, retention, and treatment delivery is feasible and if CBT-L is acceptable to participants, and assess parameters of key outcomes among participants randomized to receive CBT-L versus CBT-CP to inform a subsequent larger clinical trial.

To achieve these objectives, we will adapt a manual through an evidence-based, iterative process then conduct one-arm trial of CBT-L (n=8) in Veterans with chronic pain reporting loneliness. After refining the manual and procedures following the one-arm trial, we will randomize a total of 40 participants to receive either CBT-L or CBT-CP. We will assess loneliness, the quality and quantity of social interactions, and pain outcomes such as pain-related interference, and pain catastrophizing at baseline and after the treatment period. We will also track participant flow, therapist adherence to the manual, participant homework completion and participant satisfaction with the treatment.

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Study Protocol

Protocol Title: Telehealth CBT to address social isolation in Veterans with chronic pain

1.0 Study Personnel

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2.0 Introduction

Loneliness—a subjective emotional state characterized by the *perception* of social isolation[1]—is a critical factor that has a significant public health impact. Loneliness is evident across the lifespan and can be experienced by anyone, although it occurs at higher rates among those with psychiatric disorders, people who are objectively isolated, and people with chronic illnesses.[1] Loneliness is characterized by a discrepancy in actual and desired social relationships. This discrepancy is what differentiates loneliness from objective social isolation (i.e., when people have few social contacts). Someone who is objectively socially isolated may not be lonely, and someone with many social contacts may be lonely.[2] A national study of adults ages 45+ found that over one-third reported loneliness.[3] Among Veterans, 44% of a cohort of over 25,000 reported past-month loneliness,[4] and over 70% of Veterans in primary care with probable major depression reported past-month loneliness.[5] Loneliness increases the risk for a constellation of chronic diseases, and can lead to the development and exacerbation of psychiatric disorders and suicidal behavior.[2,6] A meta-analysis of 70 studies found that loneliness increases odds of mortality by 29% after adjusting for key covariates.[7]

Loneliness is prominent and problematic in individuals experiencing chronic pain. Pain conditions affect over half the Veterans seen in the VHA,[8] are leading causes of disability,[9] have an estimated economic impact of over half a trillion dollars,[10] and are associated with higher rates of psychiatric disorders, substance use, and suicide.[8,11] Addressing loneliness in Veterans with chronic pain can have a profound impact on their psychosocial functioning and given its transdiagnostic nature, can impact comorbidities that are common among Veterans with chronic pain. Loneliness is highly prevalent among individuals with chronic pain, and pain is predictive of the onset of loneliness.[12] National survey data indicate that 40-50% of people with chronic pain report loneliness.[13,14] Younger adults with chronic pain experience higher rates of loneliness, and often identify being more withdrawn, isolated, and having fewer friends relative to peers without chronic pain.[15,16] The high rates of loneliness among people with chronic pain is extremely problematic. Social isolation and more social dysfunction predict longer duration of sick leave for people with low back pain.[17] People with pain who are more socially withdrawn or isolated were twice as likely to report suicide ideation.[18] Among nursing home patients with pain, loneliness is associated with lower life satisfaction, higher depression, less mobility, and lower ability to complete activities of daily living.[19] Among both university student and community samples, loneliness is associated with depressive symptoms and pain-related interference in activities.[20,21] Patients with pain who isolate also tend to over-identify with their pain and have lower levels of activity.[22] Problems have been exacerbated by the COVID-19 pandemic, which has increased loneliness, exacerbated problems related to social resources, and reduced access to quality pain care.[23]

Studies have sought to uncover key reasons why patients with chronic pain are lonely. Many indicate that pain negatively impacts socialization, and they do not feel understood by their social support network. Patients with chronic pain often feel like they have nothing in common with others and like they have few authentic and honest relationships.[24] Others report feeling “humiliated” and self-conscious about their difficulty engaging in activities, and that their

disability and negative mood prevent them from engaging in a broader range of activities.[25] Another study found that people with chronic pain want to avoid being self-pitied by others.[26] Some have separated themselves from other people because they "could not stand the laughter and happiness of others" making them feel more "miserable" and reluctant to start new relationships.[27] Researchers have also posited that pain catastrophizing (i.e., thinking the worst about pain) and fear avoidance behaviors in patients with pain can manifest themselves as social isolation.[28] Taken together, patients with pain experience significant suffering contributing to isolation and loneliness. This, in turn, contributes to behaviors that perpetuate loneliness because they are engaging in less activity and with fewer people who may lend support.

To date, there are no studies that have specifically focused on addressing loneliness among Veterans with chronic pain. Cognitive-Behavioral Therapy (CBT) is the best way to address loneliness in Veterans with chronic pain. Evidence-based psychotherapies for chronic pain, particularly CBT for Chronic Pain (CBT-CP), have modules that indirectly address social factors (e.g., increasing pleasant activities, using positive coping thoughts); however, research on loneliness interventions suggest that these approaches are likely not adequate. Some pain-focused treatments, such as physical activity interventions and peer led groups have found small effects on loneliness.[19,29] However, more intensive, loneliness-focused strategies are needed to address loneliness as an antecedent and consequence of chronic pain. A meta-analysis on randomized clinical trials (RCT) for loneliness found that cognitive-behavioral interventions significantly reduced loneliness (Hedge's g = -0.60) to a greater extent than other loneliness interventions (e.g., increasing opportunities for social intervention, social skills training; range of Hedge's g = -0.16-0.02).[30] Kall et al.[31] developed an 8-session CBT for Loneliness (CBT-L) and found that it decreased loneliness (Cohen's d = 0.77) and social anxiety and increased quality of life at the 2-year follow-up. CBT-L addresses negative beliefs and cognitive biases through identifying them, and generating more balanced, alternative thoughts.[31,32] Patients learn to approach avoided situations to assimilate new information to overcome fear and distress associated with social contexts. Utilizing these strategies can help replace avoidance of activity as viable alternatives to deal with the negative experiences associated with loneliness and to increase social support, which may help reduce pain interference. Research is needed to address loneliness among Veterans with chronic pain.

3.0 Objectives

The proposed study will provide critical feasibility and acceptability data on telehealth Cognitive-Behavioral Therapy for Loneliness and Pain (CBT-L/P) among Veterans with chronic pain who report loneliness. We will conduct a small single-arm trial (n = 8) for refinement of the intervention and study procedure. With the refined manual, Veterans with chronic pain reporting loneliness will be randomized to either CBT-L/P (n = 20) or CBT-CP (n = 20). The specific aims are as follows:

Aim 1: Refine the CBT-L/P manual by conducting a one-arm trial among Veterans with chronic pain reporting loneliness (n = 8). *We will deliver CBT-L/P as part of a small, single-arm trial. This trial will allow us to collect feasibility of treatment delivery, and treatment satisfaction and acceptability data to further refine the manual.*

Aim 2: Conduct a pilot randomized clinical trial to assess feasibility and acceptability among Veterans with chronic pain reporting loneliness. Participants will receive either CBT-L for Pain (n = 20) or CBT-CP (n = 20). *We will assess: (1) treatment acceptability, (2) participant adherence to treatment, and (3) therapist fidelity. We will also assess outcome measure completion percentage, means and standard deviations, and level of correlation of repeated measurement of social functioning and pain outcomes.*

4.0 Resources and Personnel

The study team consists of Drs. Ashrafioun, Allan, and Stecker, Park Bogan (coordinator), Anna Stephens (coordinator), Shelby Neureuter (RA), Bennett Kukla (RA), Monae James (RA) and research therapists (TBD) to deliver the intervention. Research therapists will have at least a master's degree in a counseling/health-related field and prior CBT training Drs. Allan, Stecker, and Ashrafioun will be in charge of executing the scientific objectives of this project. Mr. Bogan will serve as project coordinator with additional assistance from Anna Stephens. The coordinators will assist in IRB documentation, participant payment and tracking, advertising, and conducting eligibility screening. The coordinators and research assistants will also complete screening and consent procedures, and complete assessment packets by telephone with participants at baseline, post-intervention and the 30-day follow-ups. Study therapists will deliver the study interventions.

5.0 Study Procedures

5.1 Study Design

Study sample: We will initially recruit 8 Veterans who screen positive for loneliness and have functional impairment from chronic pain to receive CBT-L. Once these 8 Veterans have completed study procedures, we will recruit an additional 40 to be randomized to either CBT-L/P or CBT-CP. This cohort will be randomized 1:1. The study will take place at the VA Center of Excellence for Suicide Prevention.

Screening: Research staff will screen by phone following a script. Potential participants will provide verbal consent to complete the screening measures. Those individuals meeting eligibility who are interested in participating will be scheduled for a phone-based consent and baseline assessment appointment. Based on our past experience, we expect approximately 25% of all participants who complete the screening to be eligible to and interested in participating. Therefore, we expect to screen no more than 600 participants to reach our sample of 48.

Assessments and Intervention:

Participants will be enrolled following consent and will complete the baseline assessment. Participants will schedule a convenient time for their telehealth-based intervention sessions. Post-treatment and 30-day post-treatment follow-up assessments will also be conducted by telehealth (phone, Teams, Webex, VVC), depending on the phase of the study. Participants will be paid $40 each assessment completed. The post-treatment assessment will also include an exit interview for participants to describe acceptability of the intervention. Total compensation will be up to $80 for the pilot phase, and $120 for the randomized phase.

CBT for Loneliness and Chronic Pain (CBT-L/P):

The study team recently created a draft CBT-L manual (see **Appendix**) starting from a translation of the Kall et al. CBT-L manual as the base.[31] We then incorporated relevant content and worksheets from the VHA Brief CBT manual into the CBT-L base.[32] Pain-specific materials need to be integrated into the manual, which will be the focus during the refinement period.

The CBT-L adaptation for pain will use CBT-L strategies and account for impediments to functional improvement specific to Veterans with pain. Importantly, the approaches used will include those that anyone who is lonely might experience, but will also emphasize factors that are specific to people with chronic pain. To summarize some of the adaptations (see bulleted section below), participants will initially be presented with education on activating events that elicit thoughts, behaviors, and emotions that perpetuate loneliness, and in the case of chronic pain, continued impaired functioning related to pain. Sessions will then focus on identifying and changing unhelpful thoughts that contribute to loneliness. For example, if a participant states "I'm in so much pain that I'll just yell at everyone if I leave my room," or "It's not worth doing anything because I annoy my family and I'm in too much pain," they would be asked to estimate the accuracy of the thought and to dispute it. The original thoughts might be altered to "I could come out for a little bit and talk to people," and "There are plenty of things that I can and have done and my family hasn't been annoyed," respectively. Assertiveness training will help reinforce effective strategies to improve communication with friends and family members to increase the likelihood of positive (or less aversive) social interactions and to communicate needs. Exposure and behavioral activation are used to approach feared behaviors (e.g., social interactions, especially those involving physical activity) and to increase the participant's general activity level to improve mood. Loneliness contributes to avoidance thereby limiting use of adaptive coping strategies and reinforcing loneliness and negative affect. By increasing one's activity level, particularly pleasant social activities involving physical activity, the participant's mood may improve by decreasing avoidance, increasing the potential for social contact, reducing pain, and increasing self-efficacy to engage in activities. In the final sessions, the participant identifies barriers and ways to cope with loneliness-related problems by identifying strategies, evaluating the potential solutions, and selecting a plan to implement the strategies. This discussion will occur in the context of reducing pain flares, preventing a return to behavioral inactivation, and not allowing maladaptive thinking to drive poor coping, further maladaptive thinking, and lack of activity.

- Session 1: CBT Model & Goal Setting
    - Pain integrated into CBT model; goals also associated with addressing pain-related functional impairment
- Session 2: Identifying & Challenging Thoughts I
    - Pain-related thoughts perpetuating loneliness; loneliness-related thoughts perpetuating pain
- Session 3: Identifying & Challenging Thoughts II
    - Continued focus pain-related thoughts perpetuating loneliness; loneliness-related thoughts perpetuating pain
- Session 4: Assertiveness Training
    - Teaching effective communication and conflict resolution

- Session 5: Exposure & Behavioral Activation I
    - Incorporating physical activity into exposure and behavioral activation related to social activities
- Session 6: Exposure & Behavioral Activation II
    - Incorporating physical activity into exposure and behavioral activation related to social activities
- Session 7: Problem Solving
    - Problem solving issues around functional limitations, mobility, and other pain-related barriers
- Session 8: Review & Relapse Prevention
    - Review is specific to new content, using skills for CBT-L to address pain flares

CBT-CP: A Cochrane review indicated that CBT-CP reduces pain intensity, disability, mood outcomes, and pain catastrophizing.[33] CBT-CP is a nationally disseminated, evidence-based intervention with the goal of increasing functioning and quality of life through adaptive pain coping skills to support self-efficacy to manage pain.[34-36] This is accomplished through pain psychoeducation, increasing activity level (e.g., walking, pleasant activities), and identifying and challenging pain catastrophizing. This CBT-CP protocol will be reduced from 10 to 8 sessions to match the number of sessions to CBT-L. The sleep hygiene session will be removed, and goal setting will occur in session 1 (rather than a stand-alone session). Both changes are consistent with Brief CBT-CP that was created in the VHA.[37] The manual is included as an **Appendix**.

Therapist training and fidelity. The investigators will provide training on CBT-L/P and CBT-CP. The training will begin with a training session provided, which will involve a review of basic CBT principles, rationale for using CBT-L/P and CBT-CP based on empirical support, and a detailed description of CBT-L/P and CBT-CP with the manual and handouts. Training will include didactics, guided readings as needed, role playing, and supervised training cases as needed until competency is met. We will monitor treatment fidelity by audio recording all CBT-L/P intervention sessions via Teams, Webex, VA Video Connect, or a FIPS-compliant recorder. Once coders are reliable, we will randomly code 30% of these sessions to be coded separately by two independent raters with 20% of these double coded. We will use the fidelity tool during the delivery of the intervention to continue monitoring adherence and competence to deliver the treatment materials. During the treatment delivery, feedback will be given weekly to the therapist during supervision sessions to ensure fidelity to the intervention protocol is maintained.

5.2 Recruitment Methods

Recruitment and retention procedure: Participants will be recruited using Internet social media websites (e.g., Facebook, Reddit) and select print/web portals that have been used successfully in several large studies. Advertisements will include a link to a study landing page with study information and blank entry forms for interested Veterans to enter contact information through VA Qualtrics on Fedramp, a secure, FISMA-compliant server used across government agencies with an authority to operate with the VA. We plan to enroll 48 participants in the protocol overall.

Participants will also be recruited through a data access request using data from the Corporate Data Warehouse (CDW). CDW contains financial, enrollment, demographic, diagnostic, treatment utilization, and other data across Veterans from 1979 to present. All study staff will be trained on accessing these records by Dr. Ashrafioun. Joint Longitudinal Viewer will be used to access medical records to prioritize recruitment of Veterans who are more likely to be eligible.

This pre-screening will help reduce Veteran burden and unnecessary contact of Veterans who would not be eligible. Participants identified through this method will be screened using the same criteria as those recruited through social media websites and select print/web portals as described above. Potential participants will be mailed a personalized letter describing the study and provided with a so that they can contact study staff if they are interested in participating as well as opt out of future contact. Potential participants may be recruited from other studies that are IRB approved following completion of those other studies or if deemed ineligible. Only study staff that are approved on those studies will recruit those participants. Providers may also refer participants to the study by emailing the research staff/team. Providers will be given the approved recruitment letters that are provided to Veterans as well as the approved study landing page for information (content can be found on p. 55 of the approved advertising pdf).

Participants will receive compensation for their participation in the study. The compensation amount will be based on the schedule that follows:

Baseline Assessment	$40
Post-treatment Assessment	$40
30-day Assessment (RCT only)	$40

Therefore, the total compensation for completing all the study components would be $80 for the Aim 1 one-arm trial and $120 for the Aim 2 RCT. Payments will be made via direct deposit or check following each study procedure listed above. Participants who do not complete the entire study for any reason will receive compensation for the components that were completed per the above schedule of payments.

5.3 Informed Consent Procedures

There are two phases where informed consent could be obtained, when completing the screening for eligibility and when enrolling into the study following the screening and if eligibility criteria are met. Verbal consent to participate will be obtained for the screening and baseline appointment. Informed consent will be obtained by study personnel trained in human subjects' protections requirements and how to obtain and document informed consent.

5.4 Inclusion/Exclusion Criteria

Inclusion criteria: Participants will include men and women who:

- Are English-speaking
- Are 18 years of age or older
- Have access to a phone or computer
- Report pain that occurs on at least half the days for six months or more
- Score at least 4 (of 10) on each of the three items on the PEG (**P**ain intensity, and Pain interference in **E**njoying activities and **G**eneral activities)
- Screen positive for loneliness by scoring at least a T-score > 60 on the NIH Toolbox loneliness scale

We will use the Veteran Verification screening for Veterans recruited through social media advertising to help confirm Veteran status.

Exclusion: Veterans will be excluded on the basis of:

- Do not understand informed consent
- Had a recent or have an upcoming surgery

- Have significant unstable or uncontrolled medical conditions, including cancer requiring ongoing oncology treatment
- Active severe substance use disorder

Pregnant women will not be excluded from this study as no invasive medical procedures are being performed and there is no known risk to the mother or the fetus of the proposed interventions. The study will not include prisoners or institutionalized Veterans.

5.5 Study Evaluations

Loneliness: The 20-item Revised UCLA Loneliness Scale will be our primary outcome measure.[38] We will use the 5-item NIH Toolbox Loneliness Scale[39] as our loneliness screening measure. The NIH Toolbox Loneliness Scale is correlated highly (r = .80) with the Revised UCLA Loneliness Scale.[5,39] T-scores >60 indicate loneliness scores 1 standard deviation above the mean and will be used to assess eligibility.[40]

Quality/Quantity of Social Interactions: The Duke Social Support Index (DSSI) assesses several domains of perceived social support, including social network size, social interaction, social satisfaction, and instrumental social support. Research supports the psychometric properties of the DSSI scales.[41-43] *Belongingness and Burdensomeness*: The Interpersonal Needs Questionnaire (INQ-12) assesses thwarted belongingness (i.e., an unmet need to belong) and perceived burdensomeness (i.e., feeling like a burden to one's social support network). Research supports the scale's psychometric properties.[44]

Pain variables: The Brief Pain Inventory[45] will be used to assess pain severity and pain interference. Pain severity consists of 4 items assessing current, average, worst, and least pain experienced. The pain interference subscale comprises 7 items assessing the extent to which pain interferes with various aspects of one's life (e.g., mood, sleep, daily activities).[45] *Pain Catastrophizing:* The Pain Catastrophizing Scale (PCS)[46] is a 13-item measure, with each item rated on a 5-point rating scale (0 = "Not at all" to 4 = "All the time"). The measure is divided into three subscales: magnification, rumination, and helplessness and has strong psychometric properties.[46] *Pain Self-efficacy Questionnaire (PSEQ)*. The PSEQ assesses one's confidence in performing activities while in pain. The PSEQ has demonstrated good construct and convergent validity along with high test-retest reliability.[47] *Tampa Scale for Kinesiophobia (TSK)*: The TSK-11 is an 11-item measure assessing pain-related fear of movement or injury. Research supports the scale's psychometric properties.[48] *Current Opioid Misuse Measure (COMM):* The COMM is a 17-item measure that will be used to assess the frequency of aberrant drug-related behaviors and other behaviors that are prevalent among pain patients who are misusing prescription opioids (e.g., frequent visits to the emergency department). The rating scale on the COMM ranges from 0 ("Never") to 4 ("Very Often"), with higher scores indicating greater risk of misuse of prescription opioids. The COMM has demonstrated strong psychometric support.[49]

Other key descriptive variables: Treatment utilization: We will assess participant past and current substance use, non-pharmacological pain treatment, mental health treatment utilization at baseline and follow-up. We will also assess primary care and specialty medical care visits, both within and outside the VA. This will be done using a modified version of the Treatment

Services Review (TSR).[50] *Quality of life:* The PROMIS Profile-29 will be used to assess the following: anxiety, depression, physical function, fatigue, sleep disturbance, and ability to participate in social roles and activities.[51] The pain interference items were removed because they are redundant with the Brief Pain Inventory. S*uicidal thoughts and behaviors:* For the 5-item Paykel Suicide Scale,[52] respondents will be asked to indicate (yes or no) if they had: (1) felt that life was not worth living, (2) wished, (3) thought about, (4) seriously considered, and/or (5) attempted suicide in the past year (at baseline)/since last visit (for all other assessments). Participants receive a score equal to the greatest magnitude of suicidal ideation or behavior positively endorsed. *Demographics and military background.* At screening, we will assess participants' branch, deployment history, gender, age, educational background, employment, income, race, ethnicity, and marital and cohabitation status.

Exit Interview and Treatment Acceptability. The exit interview will assess overall impressions and impact of treatment, relationship with the therapist, and areas of improvement (See **Appendix**) to inform modifications to improve feasibility and acceptability. A modified Abbreviated Acceptability Rating Profile (AARP) will also assess acceptability.[53]

5.6 Schedule of Assessments

Schedule of Assessments – One Arm Trial			
Measures	**Screening**	**Baseline**	**Post-treatment**
Eligibility Review	X		
NIH Toolbox Loneliness Scale	X		
PEG	X		
Demographics and Military Background		X	
Brief Pain Inventory		X	X
Revised UCLA Loneliness Scale		X	X
Duke Social Support Index (DSSI)		X	X
Treatment Services Review (TSR)		X	X
PROMIS-29 (less pain subscale)		X	X
Interpersonal Needs Questionnaire-12		X	X
Pain Catastrophizing Scale (PCS)		X	X
Tampa Scale of Kinesiophobia		X	X
Pain-related Self-Efficacy Questionnaire (PSEQ)		X	X
Paykel Suicide Scale		X	X
Current Opioid Misuse Measure (COMM)		X	X
Exit Interview/Abbreviated Acceptability Rating Profile (AARP)			X

Schedule of Assessments –Randomized Clinical Trial	

Measures	Screening	Baseline	Post-treatment	1-mo follow-up
Eligibility Review	X			
NIH Toolbox Loneliness Scale	X			
PEG	X			
Demographics and Military Background		X	X	
Brief Pain Inventory		X	X	X
Revised UCLA Loneliness Scale		X	X	X
Duke Social Support Index (DSSI)		X	X	X
Treatment Services Review (TSR)		X	X	X
PROMIS-29 (less pain subscale)		X	X	X
Interpersonal Needs Questionnaire-12		X	X	X
Pain Catastrophizing Scale (PCS)		X	X	X
Tampa Scale of Kinesiophobia		X	X	X
Pain-related Self-Efficacy Questionnaire (PSEQ)		X	X	X
Paykel Suicide Scale		X	X	X
Current Opioid Misuse Measure (COMM)		X	X	X
Exit Interview			X	

5.7 Data Analysis

We will track rate of recruitment per week, and the percentage of participants who complete the protocol, and each follow-up. Participant treatment adherence will be assessed by tracking attendance and homework completion. Session-by-session participant feedback will be used to examine potential reasons for drop-out and non-adherence to inform our small RCT. Therapist adherence scores for the individual sessions and the overall interventions will be assessed as the percentage of the content delivered. Interrater reliability for fidelity will be assessed using intra-class correlation coefficients. We will assess the internal consistency of competence using Cronbach's alpha. Treatment acceptability will be assessed with the modified AARS and exit interview for a richer understanding. For participants who choose to withdraw prior to completing the full protocol, attempts will be made to conduct exit interviews to assess treatment experiences and reasons for early withdrawal. Interviews will be audio-recorded and transcribed. Interview data will be analyzed using matrix analysis,[54-56] a systematic technique for data reduction to thematically organize and analyze data using rows, columns, and cells of a table. This process is time efficient, aligns well with results of in-depth analyses, allows for accurate summarizing of data, and facilitates participant comparisons.[55]Matrices are also an effective way to share findings with interdisciplinary team members for discussion.[54] Following the analyses, these matrices will be reviewed by the investigative team and expert panel in preparation for finalizing the intervention.

Consistent with descriptive analyses for pilot studies,[57] measure completion percentage and means and standard deviations for outcomes will be calculated at each assessment, including change scores and correlations across timepoints. We expect large standard errors

due to small sample size. Distribution of scores will be examined to better evaluate how to analyze these data in future studies (e.g., dichotomizing/ categorizing vs. continuous). Correlations among baseline variables will be calculated to assess the potential for variables to be included as covariates in the larger trial. This may also be useful in identifying potential moderators and mediators for the future larger trial. For data quality and handling of missing data, descriptive statistics will help identify out of range values and outliers. We will examine bias in retention rates at both the univariate and multivariate level of analyses

Data storage, security, and confidentiality

Several procedures for protecting participant confidentiality will be implemented to reduce the risk of revealing participant identity. All informed consent forms will contain identifying information. In order to ensure confidentiality, each consent form will be labeled with a numeric identifier and will be stored in a double-locked file. These will be stored in separate double-locked files from other study materials. As noted in the Data Transport Memorandum, locked courier bags will be used to transport any sensitive study information (e.g., consents) outside VA.

The VA Informatics and Computing Infrastructure (VINCI) will be used for the storage of study data. VINCI is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. VINCI servers for data, applications and virtual sessions are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas. This secure enclave with 105 high-performance servers and 1.5 petabytes of high-speed data storage has multiple layers of security and disaster recovery to prevent data loss.

Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1 (RCS 10-1). Storage and transfer of any Personally Identifiable Information (PII) or Protected Health Information (PHI) must be done in accordance with applicable VA and VHA policies and directives, state and federal regulations, and applicable statutes including the Health Insurance Portability and Accountability ACT (HIPAA). Unless explicitly requested and approved by data stewards, all sensitive patient data must remain on VINCI project servers and only aggregate data without PII / PHI may be transferred from VINCI.

Prior to being uploaded to VINCI for analysis, data will be stored on a secure VA server, which is password protected, and to which only IRB approved VA research personnel have access. Should any identifiable information need to be shared, research teams will utilize a secure, SharePoint site or electronic communication with PKI encryption. Any identifiable paper data will be stored in two separate locked file cabinets (one for informed consents and the other for paper questionnaire data) in the offices of the Center for Excellence for Suicide Prevention at the VA Finger Lakes Healthcare System in Canandaigua, NY. After a participant completes the study, any identifiers will be removed from the paper questionnaire data immediately. Data analysis will occur in the VINCI framework.

5.8 Withdrawal of Subjects

Participants who wish to withdraw may do so at any time without affecting their medical care or participation in any other study. Participants will be informed of any new information during the course of the study which may affect their condition or influence their willingness to continue in this study. Finally, based on decisions made by the Principal Investigator, participants may be taken out of the study because of unanticipated circumstances such as extreme distress. That

is, they may be withdrawn from the study if we judge that participating is not in their best interest.

6.0 Protection of Human Subjects

Risk to Participants

Human Subjects Involvement and Characteristics. The purpose of this study is to assess the feasibility and acceptability of an intervention designed to improve social functioning and pain interference in functioning among Veterans with chronic pain. A total of 48 participants (n = 8 for the Aim 1 one-arm trial and n = 40 for the Aim 2 RCT) will be recruited across the US. According national survey data, 65.5% of Veterans reported experiencing pain in the last 3 months. While Veterans reporting pain tended to be older (60+ years = 56.5%), 12% were comprised of 18-39 year olds, 13.4% were comprised of 40-49 year olds, and 17.9% were comprised of 50-59 year olds. 92.5% were men, while just 7.5% were women, however, women were slightly more likely to report pain in the last 3 months compared to men (70.1% vs. 65.3%). VHA data indicate that medical and psychiatric comorbidity is high among Veterans with musculoskeletal conditions (many of which are associated with chronic pain). We expect that the recruitment pool will be similar to the above estimates; however, we will use recruitment ads to promote recruitment of women and Veterans with minority status to increase representation in our sample.

Source of Materials. Study materials will include self-report questionnaires. The materials will be collected for study purposes only. Information collected will be stored in a locked filing cabinet in a locked office at the study sites that can only be accessed by members of the study team. *All electronic data* will be stored on VA Informatics and Computing Infrastructure (VINCI) project servers. Only approved study team personnel who will be involved in data entry, management and analyses will be granted access to this data. All computers are password protected.

Potential risks.
Psychological distress. Anticipated risks to the participants from assessment procedures and therapy are minimal; however, participants may experience psychological distress, frustration, and/or fatigue. The semi-structured interviews, assessments associated with the intervention, and therapy sessions may encourage participants to recall personal events and life stressors that may evoke distress. Additionally, confidentiality may need to be breached if a participant poses a threat to him or herself or others, including child abuse.

Adequacy of Protection from Risk
Recruitment and Informed Consent.
All research staff conducting recruitment and informed consent will have completed appropriate and up-to-date training in research, research ethics and the proper conduct of research that includes common issues related to recruitment and informed consent.

Participants will be recruited using Internet social media websites and select web portals. Advertisement will nationally target Veterans who are experiencing functional impairment from chronic pain and who may be lonely. Targeted recruitment of women Veterans will also be used for advertisements. All sites will send participants to a study landing page, which serves as a central location for potential participants to follow-up with the study team via phone or completing and submitting an online form.

Participants will also be recruited through a data access request using data from the Corporate Data Warehouse (CDW). CDW contains financial, enrollment, demographic, diagnostic, treatment utilization, and other data across Veterans from 1979 to present. All study staff will be trained on accessing these records by Dr. Ashrafioun. Joint Longitudinal Viewer will be used to access medical records to prioritize recruitment of Veterans who are more likely to be eligible. This pre-screening will help reduce Veteran burden and unnecessary contact of Veterans who would not be eligible. Participants identified through this method will be screened using the same criteria as those recruited through social media websites and select print/web portals as described above. Potential participants will be mailed a personalized letter describing the study and provided with a so that they can contact study staff if they are interested in participating as well as opt out of future contact.

Recruitment and informed consent procedures were designed to ensure patients do not feel like participation is required. Potential participants unable to understand the informed consent process will be excluded from participating. Screening interviews will be completed initially over the telephone (using a script) to assess eligibility criteria. Verbal consent will be obtained at this time to complete the screening. Participants screening positive for exclusion criteria will not be included in the study. For eligible and interested participants, a research coordinator will review the consent form and complete a brief questionnaire to ensure the potential participant understands the study. As with Dr. Stecker's other phone-based interventions, consent will be obtained verbally following the above outlined procedure. The participant will be mailed or emailed a copy for their records.

Participants will receive compensation for their participation in the study. The compensation amount will be based on the schedule that follows:

Baseline Assessment	$40
Post-treatment Assessment	$40
30-day Assessment (RCT only)	$40

Therefore, the total compensation for completing all the study components would be $120. Payments will be made following each study procedure listed above. Participants who do not complete the entire study for any reason, will receive compensation for the components that were completed per the above schedule of payments.

Protection Against Risk.

Psychological distress. The potential risks are negligible. There are no known risks associated with interview procedures. Participants will be informed that they may feel slightly uncomfortable discussing some of their symptoms. Mild discomfort may be likely during the intervention session; however, this is unlikely to have a serious negative impact on the participant's well-being. Participants will be told they can withdraw from the study at any time. Participation or withdrawal from the study will not affect any benefits to which they are otherwise entitled. Special precaution will be taken to safeguard confidentiality. During assessments, if the interviewer is concerned about thoughts and planning of a suicide attempt, the interviewer will ask two follow-up questions: Do you have a desire to kill yourself that you think you might act on and Do you have a plan for killing yourself and intend to carry the plan out? With this information and available suicide assessment measures, the interviewer will evaluate the severity of the participant's suicide risk. If the participant is deemed to be at imminent risk, a safety plan will be initiated. All study staff will receive adequate training in suicidal ideation and

risk assessment, and all work will be supervised by Drs. Ashrafioun or Stecker, who are licensed clinicians.

Some individuals may experience more severe suicidal ideation at one or more of the assessment or intervention sessions given that loneliness and chronic pain are both associated with suicide. Therefore, we include here the proposed safety procedures that we have used in other studies with similar populations.

All assessors and interventionists will have a specific protocol to follow regarding emergency care and will have the clinical back-up of Drs. Ashrafioun and Stecker. This study will use safety procedures that have been previously approved by the IRB in several of our protocols. All research staff will be thoroughly trained on these procedures. These include written procedures for handling emergencies, a written procedure for conducting a full suicide risk assessment whenever suicidality is endorsed (note that for this study the Columbia Suicide Severity Rating Scale), procedures for participants endorsing a suicidal plan or intent (including staying with a patient until they are connected with a mental health provider or 911 help), and a written warm-handoff guideline to connect Veterans to the National Veterans/Military Crisis Line (VCL).

Besides responses on study assessment instruments, participants may also allude to suicide or make other provocative statements, irrespective of the scale rating, and in these instances research staff may also decide to transfer the participant to the VCL.

For example, a participant may score in the severe depression range on the PHQ-9 depression scale and, together with other information obtained during the call, the research assistant may perceive acute risk and decide to transfer the participant to the VCL.

In any of the above instances, the research staff member will read (or paraphrase) the following statement to the participant at the end of the call:

> *I am concerned about your safety and so at this time I am going to transfer you to speak with one of our mental health clinicians at the Veterans/Military Crisis Line. There will be a moment of silence as I connect you. If for some reason we get disconnected please dial 1-800-273-8255 and press #1 to reach the Lifeline. I will stay on the line with you until the transfer is complete. I am now going to transfer you. Please stay on the line.*

The researcher will briefly summarize the participant's situation to orient the VCL responder to the nature of the call (the participant will hear a moment of silence at this time, and then the participant will be transferred to the VCL.

If the participant hangs up or becomes disconnected, the researcher will call the VCL immediately, and the VCL staff will take necessary actions as appropriate according to the VCL safety protocol and/or direct the researcher what actions to take. These actions may include initiating a "rescue" that involves calling 911 at the participant's local jurisdiction and having emergency personnel come to the participant's home to ensure their safety. The VCL staff performs rescues every day, and all rescues are done in collaboration with a supervisor.
We have ongoing collaborations with the VCL and have substantial experience working with responders and supervisors. Our approach to participant safety will be applied to all participants including control participants and is guided by ongoing clinical and research experience in suicide prevention, including our Center Director's affiliation with the VCL.

We will collaborate closely with the VCL during the study start-up phase to review these safety protocol steps. The VCL, which was established in 2007 at the Canandaigua VAMC, can be reached anytime by calling 1-800-273-8255. The VCL has grown to be one of the largest in the world, with a full-time staff of more than 600 full-time responders. VCL responders are paid professional staff and nearly all have a Master's degree in a relevant field (e.g., mental health counseling), distinguishing the VCL from others in the U.S. that are staffed primarily with volunteers.

VCL resources will be available as back-up at all times during study sessions. VCL responders are arguably the foremost experts in managing acute suicidal crises via telephone. They have in place protocols for locating suicidal individuals, identifying the closest police and emergency medical services, and monitoring and documenting "rescues." Moreover, VCL responders have the ability to look up call histories based on callers' phone numbers, a capability that since implemented has greatly aided the ability of responders to rapidly assess callers' needs.

All participants will be provided the VCL phone number at the end of each baseline assessment and at each follow-up assessment and encouraged to call the number should they become suicidal, simply wish to talk with someone, or would like assistance in obtaining a referral for mental health treatment. In situations in which potential suicide risk is identified during a phone call, we plan to use two levels of response: 1) researcher transfers the individual to the VCL (used in acute crises requiring emergency intervention or "rescue"); 2) researcher offers the participant a transfer to the VCL, but does not perform the transfer if he/she does not wish to be transferred (used in non-emergency situations).

Breach of Confidentiality. Statistical electronic data files will be kept VINCI project servers maintained by VINCI OI&T personnel and only summarized data without protected health information (PHI) will be downloaded from VINCI to local storage media. Research staff will use an audited VINCI download utility to move summarized data for reports, presentations and publications from VINCI servers to local storage media. The VINCI download utility provides an audit path including a copy of the downloaded material. The data extraction tool will be adapted for use with software directly available on the VINCI platform (e.g. Microsoft Word and Excel) and study data will be stored and maintained on VINCI. All study team personnel with access to sensitive patient data will stay current on their VA approved information security training and VA approved privacy policy training.

Adverse Events (AE). AEs may include, but are not limited to: worsened physical or mental health, or inadvertent disclosure of confidential research information. Serious Adverse Events (SAE) may include: death, hospitalization due to worsening psychiatric symptoms or suicidal ideation, or all life threatening or disabling/incapacitating events among research participants. Per IRB regulations, SAEs, any event resulting in a deviation from the study protocol (e.g., emergency hospitalization to address suicidal behaviors) or death will be reported to the PI within 24 hours and to the IRB in 48 hours. This will be completed in order to assess significance and determine an appropriate response. AEs that involve temporary distress will be noted by interviewers and provided to the IRB in an annual report.

Confidentiality of Records: Numerous protections are in place to reduce the likelihood of loss of confidentiality. All research data will be kept in locked filing cabinets in secure areas, absent of identifying information, and coded by research number only. Files containing consent forms and other items with identifying information will also be kept in locked filing cabinets, but these will be separate from cabinets containing data from this study. All electronic files will be maintained on a secure study folder behind the VA firewall. Only approved study team

personnel will be granted access to this data. All identifiable information will be stored in a separate folder behind the firewall from the de-identified study ID and data.

Potential Benefits of Research to Participants and Others. There may be direct and/or indirect benefits of study participation. Participants are receiving an intervention that addresses a transdiagnostic factor that may reduce pain-related interference in activities. This intervention can be used for both participants who are not engaged in treatment and for participants who are engaged in treatment, it may augment current services. Dissemination of the findings from the study will contribute to the extant literature, and may contribute to reducing loneliness and pain.

Importance of Knowledge to be Gained. Understanding how to effectively address loneliness among Veterans with chronic pain is a critical approach to curb significantly impairing chronic pain. Loneliness is associated with increased suicide risk, worse pain outcomes, and depression among individuals with chronic pain. Addressing loneliness has the potential to reduce functional impairment from chronic pain. The proposed study tests the 8-session CBT-L that is delivered by phone targeting cognitive biases, and avoidance of social interactions and enjoyable activities. We expect that this intervention will reduce loneliness, increase the quality and quantity of social interactions, and reduce functional impairment from chronic pain. It will lay the foundation for understanding best practices of addressing loneliness and pain. Knowledge gleaned from this study will help inform future implementation and dissemination efforts, which can be used across numerous settings.

Data Safety & Monitoring Plan

Data Safety. To ensure safety of participants in the study proposed and validity and integrity of data collected, the PI (Ashrafioun) will oversee all data and safety monitoring functions and the research team will be advised that he will be the primary contact overseeing these activities. The investigators will meet regularly to monitor study progress and discuss the implementation of monitoring procedures. The PI will also meet regularly with the research coordinator and staff to review monitoring procedures and ensure all efforts are being taken to minimize risks to participants. As indicated below, the PI will track all negative outcomes and incidents as well as conduct interim data analysis every 12 months after the study has started. The study design will be significantly modified (and even screening stopped) if the study is creating potential harm to our participants.

The PI and Dr. Stecker will regularly oversee all aspects of the study, including participant recruitment, informed consent, data collection, management, and analysis, as well as regularly assess the risk/benefit ratio associated with participation in the study. All research staff will participate in an intensive training to help them understand the importance of reducing the risk for participants and learning how to recognize and report any AE or SAE. SAEs may include: death, hospitalization due to worsening psychiatric symptoms or suicidal ideation, or all life threatening or disabling/incapacitating events among research participants. AEs may include, but are not limited to: physical injuries, worsened physical or mental health, or inadvertent disclosure of confidential research information.

If an SAE occurs, the PI will immediately contact the IRB, followed by a written report in 24 hours. He will make a decision whether there is sufficient evidence to suspend data collection, allow for further IRB review, modify the protocol, or make other changes to reduce potential risk to participants. The study will resume based on agreement of the PI and IRB chair. In the event that an AE that is not an SAE is reported to the PI, the PI will discuss the event with the IRB chair. Immediate evaluation will occur to determine if any extra steps can be taken to minimize

the likelihood of that type of AE occurring again. If changes can be made, a report/amendment will be written and submitted to the IRB.

As part of a standard practice, the PI will supervise the implementation of one audit regularly per year of the materials collected and produced as part of the study to ensure proper confidentiality and compliance with ethical principles, including informed consents, questionnaire data, and to make sure that the research staff are following established protocols. The PI will provide an annual summary report of all AEs to the IRB as part of the annual review. If no adverse events have occurred, the report will state, “No adverse events affecting human participants have occurred during this project year.”

Data Monitoring. To ensure adequate participant recruitment and enrollment, each week, the PI will discuss the current number of participants contacted, screened, and enrolled from each site and compare those numbers to the expected based on our preliminary data. If after the first 4 months, it appears we are not reaching our expected number of participants, the PI will discuss potential barriers/obstacles and solutions. Discussions regarding recruitment and enrollment will continue at each meeting with study staff to ensure proper implementation of the study.

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