Video Teleconference (VTC) Emotional Awareness and Expression Therapy (vEAET) for Older Veterans with Chronic Musculoskeletal Pain: An Initial, Uncontrolled Pilot Study

PI: Brandon C. Yarns, MD, MS

NCT Number: Not Yet Available

Study Protocol and Statistical Analysis Plan:

Protocol revised per clinicaltrials.gov cover page requirements (v1.2): 09.09.2020
Local IRB approval granted: 07.21.2020
Protocol v1.1 submitted to the IRB: 07.17.2020

1. Specific Aims

The purpose of the proposed project is to obtain acceptability and feasibility pilot data and select methods and measures for a randomized clinical trial (RCT) that will be part of an upcoming Merit Review Award application on the video teleconference (VTC) delivery of a novel group psychotherapy for chronic pain, Emotional Awareness and Expression Therapy (EAET). The research team has studied in-person EAET for older Veterans with chronic musculoskeletal pain in 2 prior IRB-approved studies at VA Greater Los Angeles (GLA). However, in-person EAET is currently infeasible for all older Veterans at GLA due to COVID-19 related social distancing requirements. Beyond the pandemic, in-person EAET is infeasible for Veterans who are unable to come into the VA for treatment, such as Veterans living in rural parts of GLA or Veterans without access to transportation. Some VTC psychotherapies (e.g., behavioral activation, problem-solving therapy) are as effective as in-person treatment for some conditions (e.g., depression) in older adults. Yet a trial of individual emotion-focused psychotherapy (EFP), similar to EAET, for adults with chronic pain found that VTC EFP was inferior to in-person EFP, which may be due to the detailed, moment-to-moment monitoring of emotions in EFP that could be hindered by VTC audiovisual limitations. The potential for VTC-delivered EAET (vEAET) to improve scalability of this promising treatment is substantial, but vEAET must first be carefully adapted and evaluated EAET is acceptable, feasible, or effective when delivered over VTC.

For this pilot, we propose to consent up to 24 Veterans age 60-95 years with chronic musculoskeletal pain with the goal of having 18 Veterans initiate vEAET treatment (i.e., planning for at least 25% dropout, consistent with our prior studies). Modest funds will be used from the PI's Career Development Award to provide a tablet for each Veteran. Each Veteran will receive one 90-minute individual session of vEAET plus eight 90-minute weekly group sessions of vEAET, all delivered over VTC to Veterans' homes. The study will plan to include 3 vEAET groups, each with 6 Veterans. We will use VA Video Connect (VVC) as the primary VTC platform, with Zoom Version 5.0 (Zoom Video Communication, San Jose, CA) as the back-up platform. Assessments will include satisfaction ratings, pain ratings, and psychosocial functioning, and will be performed at baseline, posttreatment, and 2-month follow-up. We will perform all assessments remotely using OutcomeMD (Los Angeles, CA), a HIPAA-compliant and VA-approved web-based platform. The goal is to perform the entire study remotely without any in-person visits. The Specific Aims are:

1. Acceptability and Feasibility. In 18 Veterans age 60-95 years with chronic musculoskeletal pain, assess recruitment, treatment adherence, treatment credibility, and patient satisfaction to vEAET.

2. Limited-Efficacy Testing and Estimated Effect Size. Assess the effects of vEAET on pain severity, pain interference, psychosocial functioning, depression, anxiety, and social connectedness from baseline to posttreatment and 2-month follow-up and calculate estimated effect sizes for a subsequent RCT.

3. Select Measures for Mediation/Moderation of Treatment Response. Veterans will complete validated measures on pain attitudes, cognitive/behavioral coping, and technological literacy to determine the feasibility of using these measures for future assessment of mediation/moderation in a subsequent RCT.

2. Background/Significance

Chronic pain is one of the most common and costly conditions treated at VA. Rates of chronic pain peak during late middle-age and older adulthood, reaching rates as high as 80% in older Veterans (1, 2). Given the recent "opioid crisis," DoD and VA have prioritized non-pharmacologic treatments as first line for chronic pain, and evaluation of non-pharmacologic treatments for chronic pain is a VA ORD priority area (3).

One promising non-pharmacologic treatment for Veterans with chronic pain is EAET, which emphasizes emotional processing and improving interpersonal functioning for the rehabilitation of chronic pain (4). EAET has shown medium-to-large effect sizes for pain reduction in controlled and uncontrolled trials, including some superiority to CBT for adult non-Veterans with fibromyalgia (4, 5). In a clinical trial at GLA, we found that older Veterans (mean age=73.5 years) with chronic musculoskeletal pain who completed 1 individual session and 8 group sessions of in-person EAET compared to Veterans who underwent the same number of sessions of in-

person CBT had significantly lower pain severity at posttreatment and 3-month follow-up with a large effect size difference and marginally lower pain interference posttreatment (p=0.051) (6).

Yet older Veterans with chronic pain, a vulnerable population, are unable to access in-person group therapy such as EAET due to COVID-19 related social distancing. Primary care providers have viewed telemedicine as a credible option to treat older adults with chronic pain; although technology-related barriers for older adults were identified, and innovative solutions were suggested, such as pre-visit training on the device (7). VA has implemented CBT over VTC for chronic pain nationally, which resulted in medium effect size improvements for 203 patients (mean age=51.9 years) on pain severity, activities of daily living, and negative affect, and high patient satisfaction, results consistent with those found in in-person CBT (8). An RCT also found that 8 sessions of a VTC delivered form of CBT noninferior to in-person CBT for adult Veterans with chronic pain (8). In addition, two large RCTs have found that two simple, individual VTC psychotherapy modalities, behavioral activation and problem-solving therapy, were as effective as their in-person alternatives for older adults, including older Veterans, with depression (9, 10). Finally, two RCTs have investigated VTC delivery of an individual emotion-focused psychotherapy (EFP) similar to EAET for adult non-Veterans chronic pain, in which VTC was superior to treatment as usual and rated as credible and satisfactory (11, 12). However, the latter study (12) found VTC EFP inferior to in-person EFP for chronic pain, which may be due to the detailed moment-to-moment assessment of patients' emotions required in EFP, or, alternatively, may suggest that VTC psychotherapy for older adults with chronic pain may be less effective than VTC psychotherapy for other conditions. Indeed, no study to date has evaluated any psychotherapy over VTC—including neither group psychotherapy nor EFP—for older adults with chronic pain. Therefore, the acceptability, feasibility, and potential efficacy of vEAET for older adults with chronic pain must be carefully tested. In addition, obtaining pilot data on vEAET will allow us to produce a successful Merit Review application.

3. Methods

Study Design Overview. The proposed study is an uncontrolled pilot in which 18 Veterans age 60-95 years will undergo online Emotional Awareness and Expression Therapy delivered over video teleconference (vEAET). The aims are to evaluate the acceptability and feasibility of vEAET, to perform limited efficacy testing and evaluate effect sizes, and to select mediator/moderator measures for a subsequent RCT that will be part of a Merit Review application. Each Veteran will receive one 90-minute individual session of vEAET plus eight 90-minute weekly group sessions of vEAET, all delivered over VTC. The study will include 3 vEAET groups, each with 6 Veterans. We will use VVC as the primary VTC platform, with Zoom (San Jose, CA) as the back-up platform. For convenience in this pilot, the PI will administer vEAET sessions, with the possible addition of another therapist later, in which case the IRB will be contacted. Assessments will include satisfaction ratings, pain ratings, and psychosocial functioning, and will be performed at baseline, after the initial individual session, posttreatment, and 2-month follow-up. We will perform all assessments remotely using OutcomeMD (Los Angeles, CA), a secure, HIPAA-compliant, and VA-approved web-based platform. The goal is to perform the entire study remotely without any in-person visits.

Sample, Recruitment. We will recruit up to 24 Veterans age 60-95 years from two of the PI's open studies (Yarns 2017-070668 and 2019-020112), which are both clinical trials of in-person psychotherapy for chronic pain, through our clinical sites, and using the VISN 22 Data Warehouse. For patients recruited from the open studies, we will only recruit patients who gave their permission to be contacted about future studies on the consent form. Only participants in these studies who did not previously undergo in-person EAET will be eligible (i.e., we will only recruit patients who completed CBT but not EAET or were randomly assigned to EAET but who dropped out prior to receiving any EAET sessions). Eligible participants will receive a letter/flyer via U.S. mail. If there is no contact established after 2 weeks, no more than 2 telephone calls will be made to invite them to participate in the current study. If there is no response after 2 calls, attempts to contact will cease. Second, Veterans will be recruited from outpatient sites at the West Los Angeles VA Medical Center (WLA), including Geriatric Psychiatry, Neuropsychiatry, GRECC, Neurobehavior, Chronic Pain, Interventional Pain, Women's, PCMHI, and Primary Care Clinics. Before clinic, a medical chart review is performed to determine whether potential participants meet basic inclusion/exclusion criteria. Clinicians will ask identified patients whether they consent to be contacted by the research team and will document if patients reply in the affirmative with a note in CPRS and copy a member of the research team as an additional signer. Third, we will

utilize information from the VISN 22 Data Warehouse to identify patients age 60-95 years with diagnoses of chronic pain. Using an IRB-approved waiver of consent, the research coordinator (RC) will screen the electronic medical records of identified patients for potential study eligibility. We will mail prospective patients a recruitment letter and flyer with our contact information via U.S. mail. Those interested will establish contact with the RC by phone, who will complete additional eligibility screening. If potential subjects do not contact research staff by phone within 2 weeks, we will make no more than 2 telephone calls to invite them to participate in the study. If there is no response after 2 calls, attempts to contact will cease. Those found to be eligible after telephone screening will be invited to be primary study participants. If found ineligible, they will be thanked for their time.

Inclusion Criteria. Eligible Veterans are age 60-95 years old and have had at least 3 months of musculoskeletal pain, including the following conditions most likely to benefit from psychotherapy based on previous research (6, 13): low back, neck, leg, or pelvic pain; temporomandibular joint disorders; fibromyalgia; tension headaches; or any combination of these disorders.

Exclusion Criteria. We exclude the following conditions:

- Musculoskeletal conditions likely to respond surgical or pharmacologic treatment (13): hip or knee osteoarthritis, leg pain greater than back pain (to exclude radiculopathy), electromyography-confirmed "tunnel" syndrome (e.g., carpal tunnel syndrome), gout, neuralgias, migraine, and cluster headaches;
- Non-musculoskeletal pain conditions: autoimmune disease that typically generates pain (e.g., rheumatoid arthritis), cancer pain, sickle cell disease, burn pain, infection associated with pain, and cauda equina syndrome;
- The following conditions or circumstances: severe psychiatric disorder such as schizophrenia or bipolar I disorder not controlled with medications, active suicide or violence risk, active severe alcohol or substance use disorder, substantial cognitive impairment based on chart review, previously completed EAET, currently enrolled in another psychological treatment for chronic pain, currently in pain-related litigation or applying for pain-related compensation or compensation increase (e.g., VA service connection for chronic pain), unable to fluently read or converse in English, no internet access.

Medications, Other Treatments. Consistent with other trials of psychosocial interventions for chronic pain (5, 6), participants will not be excluded due to using any medications at any dose, or for pursuing non-pharmacologic treatments for chronic pain other than psychotherapy (e.g., trigger point injections), or for participating in psychotherapy for another condition (e.g., depression). However, current medications and dosages and other treatments are recorded at assessment points for monitoring and possible post-hoc analyses.

Consent, Screening. Screening will include telephone review of a checklist with the inclusion/exclusion criteria. If the potential participant meets screening criteria, he/she is invited to enroll as a primary research participant. Those who fail to meet the inclusion/exclusion requirements are thanked for their time. After a Veteran has expressed interest in the study and has been found to be eligible, the RC mails the Veteran IRB-approved consent and HIPAA forms via secure U.S. mail. Once the Veteran receives the forms, the RC discusses the details of the study, including study procedures, risks, and benefits, with the Veteran by phone. There is an opportunity to ask questions, to have information clarified, and for potential participants to discuss the study with other family members. The Veteran signs the consent and HIPAA forms and returns them to the RC via secure U.S. mail (in a self-addressed, stamped envelope provided to the Veteran). As the need arises, decision-making capacity is assessed by a member of the research team who is a psychiatrist or licensed psychologist via phone using the UCLA Capacity to Consent Form. All prior identifying information obtained during screening is then destroyed. Each participant is mailed a hardcopy of the original signed consent/HIPAA forms. A study folder for each participant is created with an alphanumeric code that does not include portions of the participant's social security number. These folders contain consent and HIPAA forms with corresponding labeling by alphanumeric code. The decoding algorithm is stored in a password protected encrypted electronic file. Hardcopy study folders are stored in a locked filing cabinet in a locked office in our laboratory space (Bldg. 158, Rms. 154-69).

VTC Equipment, Participant Payments. Consistent with other studies of VTC psychotherapy for older adults (9, 10), we will furnish all participants with equipment to complete all VTC sessions and self-report assessments in

their homes. Following receipt of completed consent/HIPAA forms, the RC will send each participant a tablet computer via secure U.S. mail purchased using funds from the PI's VA Career Development Award (CDA). The RC will then provide telephone consultation with participants to instruct them on how to open and complete the self-report assessments and join VTC sessions. The RC will record the amount of time needed to train each participant, which will be reported as a feasibility outcome. Participants will be allowed to keep these tablets following their participation as compensation for their time and inconvenience of completing the training and baseline assessments (value: approximately $100). In addition, participants will be compensated $25 for their time upon completion of the posttreatment and 2-month follow-up questionnaires ($50 total for each participant).

Sites. All research activities take place at the West Los Angeles VA Medical Center (WLA). Veterans participate remotely from their homes

Data Sources and Instruments. Self-report data are collected using a secure, HIPAA-compliant, and VA-approved web-based platform called OutcomeMD (Los Angeles, CA). Self-report data are collected at 4 time points: baseline, immediately after the individual session (treatment credibility only), posttreatment, and 2-month follow-up. The RC enters the OutcomeMD provider portal, selects the appropriate assessments, and sends a link to the email address created for the Veteran by the study, based on the Veteran's study-assigned alphanumeric code. This email address will be set up for the Veteran as part of the configuration of their tablet and mailed to them with it. Veterans click on the link, which opens directly to the assessments in their computer/smartphone web browser; no login or additional information is required from the Veteran. The Veteran's responses to assessments are sent electronically to the OutcomeMD provider portal, which are immediately extracted into an Excel spreadsheet and labelled by the RC with the Veteran's alphanumeric code. In addition, a brief telephone interview will be conducted by a research team member (T.A.Z.) at baseline and posttreatment using VA-approved software (Audacity) directly onto our encrypted VA research server, and the number of words patients use to describe their feelings will be coded using a procedure described in (14). Descriptive measures collected at baseline include demographics (age, sex, race/ethnicity, marital status, education) and clinical characteristics (medical comorbidities, medications, psychiatric diagnoses, substance use). All self-report study variables and their associated measurement instrument are shown in **Table 1**.

Table 1: Self-Report Study Assessments				Base-line	Post-treat.	2-mo. f/u	Expected Direction of Change
	Variable	**Measurement Instrument**					
Acceptability	Patient Satisfaction	Satisfaction with Therapy and Therapist Scale—Revised (15)			√		
	Treatment Credibility	Credibility/Expectancy Questionnaire (16)		*			
Potential Efficacy	Pain Severity	Mean of 4 Brief Pain Inventory (BPI) Items (17):	Current Pain	√	√	√	↓
			Average Pain				
			Worst Pain – 7 days				
			Least Pain – 7 days				
	Pain Interference	PROMIS-Pain Interference CAT (18, 19)		√	√	√	↓
	Psychosocial and Physical Function	PROMIS-Global Health (20)		√	√	√	↑
	Social Connectedness	Social Connectedness Scale—Revised (21)		√	√	√	↑
	Depression	PROMIS-Depression CAT (22)		√	√	√	↓
	Anxiety	PROMIS-Anxiety CAT (22)		√	√	√	↓
	Global Improvement	Patient Global Impression of Change (PGIC) (23)			√	√	↑
Potential Mediators	Beliefs about Pain	Survey of Pain Attitudes (SOPA) (24)		√	√	√	↓

	Cognitive and Behavioral Coping	Coping Skills Questionnaire (CSQ) (25)	√	√	√	↑
	Feeling Words	Feeling Word Telephone Interview	√	√		↑
	Self-Conscious Affect	Test of Self-Conscious Affect-3—Short Version (TOSCA-3)	√	√	√	↓
	Emotion Differentiation	Positive and Negative Affect Scale (PANAS)	√	√	√	↑
	Pain Catastrophizing	Pain Catastrophizing Scale (PCS)	√	√	√	↓
	Discomfort with Anger	Anger Discomfort Scale	√	√	√	↓
Potential Moderators	Age	Self-report of age in years	√			
	Digital Literacy	Functional Assessment of Currently Employed Technology Scale (FACETS) (26)	√			

*The Credibility/Expectancy Questionnaire will be completed immediately following the individual session.

Intervention: Video Teleconference Emotional Awareness and Exposure Therapy (vEAET). All participants receive a single, initial 90-minute individual session followed by eight 90-minute sessions in small groups of 6 Veterans over VTC. The conceptual model of EAET is based on 1) neurobiological research showing structural and functional relationships between emotional brain circuits (e.g., anxiety) and brain circuits dealing with pain; 2) experiential and psychodynamic theories and particularly the relationship between life stress, emotional coping, and symptoms (pain); 3) epidemiological evidence relating trauma/life stress to pain; and 4) research relating alexithymia, emotional expression, and emotional awareness to pain. We will use the individual session protocol developed by the PI (6) and the group EAET manual originally developed by Lumley and Schubiner (27) and adapted for older Veterans with chronic musculoskeletal pain by the PI (6). All sessions include handouts for in-session writing exercises and homework, which will be mailed to participants prior to the first session. The sessions include:

- Individual Session. Therapist introduces the therapy model, which links pain to interpersonal life stress, avoidance of difficult emotions, and brain changes. The patient provides a history of their pain, focusing on how pain has been affected by stress and emotions. A therapeutic alliance is developed around changing stressful interpersonal relationships and emotions to alleviate pain.
- Group Session 1: Rationale, Therapy Model, Identifying Stress-Symptom Connections. Therapist provides further psychoeducation on the therapy model and the key task of therapy: attenuating pain through directly addressing interpersonal stress and experiencing previously avoided emotions. Patients provide examples of how stress and emotions affect their pain. Home exercises throughout therapy include reading and completing worksheet on avoidance, stress, and disclosure of emotions.
- Group Session 2: Triangle Model, Experiencing Anger and Closeness. Therapist presents the Triangle Model, which represents: 1) healthy, adaptive emotions; 2) defenses to avoid experiencing and expressing those emotions; and 3) anxiety and other inhibiting symptoms including pain. In-session experiential exercises begin, starting with how anger and emotions related to closeness with others (e.g., love, longing) are experienced.
- Group Session 3: Conflicted Emotions in Relationships; Experiencing, Expressing, and Releasing (EER) Emotions 1. Therapist describes how conflicted emotions (e.g., love and anger), anxiety about emotions, and avoidance of emotions occur frequently in close relationships. The key intervention (EER) begins: patients recall a recent stressful event in a relationship and experience and release all difficult emotions (e.g., anger, guilt) in the safe context of the group while pain level is monitored.
- Group Session 4: Reversing Self-Blame and Guilt, EER 2. Therapist distinguishes healthy guilt, when one has done wrong, from unhealthy self-blame, which contributes to symptoms. In-session exercises focus on reversing self-blame with healthy assertion toward others and forgiveness/compassion toward oneself. EER continues.
- Group Session 5: Forgiving Others or Letting Go, EER 3. Therapist provides psychoeducation on experiences of being violated, hurt, or neglected, and patients are encouraged to release emotions from these experiences. EER continues.

- Group Session 6: Shame, Secrets, and Private Experiences; EER 4. Shame is defined (always a maladaptive sense of bad, defective, or unlovable self) and differentiated from healthy guilt. In-session exercises focus on intimacy and sharing secrets of which patients have been ashamed. EER continues.
- Group Session 7: Healthy Communication in Relationships. The two types of healthy communication (assertion/agency and connection/vulnerability) are discussed. In-session exercises focus on practicing healthy communication in current relationships. Healthy in vivo communication is distinguished from the intense emotional expression practiced in EER.
- Group Session 8: Review and Planning. Therapist and patients review all exercises and progress made. Patients describe optimal emotional/interpersonal functioning, which serves as a goal for their continued work. Patients develop a written plan for continued exercises to meet their goal.

Interventionist. Dr. Yarns will serve as the study interventionist for the first group in this pilot and subsequent groups as needed. Additional qualified interventions may be added for subsequent groups, and the IRB will be contacted in this case.

VTC Platform. VA Video Connect (VVC) will be the primary VTC platform used. VVC is a web-based on mobile app-based service for Veterans to meet with VA healthcare providers through live secure video on any computer, tablet, or mobile device with an internet connection (28). VVC has the capability to administer group treatments and is currently in widespread use at VA. We will also have a back-up VTC platform in case the VVC platform is temporarily down or Veterans are unable to connect. Zoom 5.0 (Zoom Video Communications, San Jose, CA) will be the back-up VTC platform. Whereas earlier versions of Zoom had security issues, Zoom 5.0 is a secure, encrypted, HIPAA-compliant VTC service that is currently available for use at VA in the clinical care of Veterans.

Fidelity Monitoring. All vEAET therapy sessions will be video recorded for the purposes of fidelity monitoring. In this pilot, an RC will complete a standardized checklist (attached) on a randomly-selected 25% of sessions to ensure that the sessions covered targeted topics. This is performed for the purposes of quality assurance. Participants will consent to the production of video recording at the time of informed consent by completing HIPAA authorization. Videos are encrypted, labeled with an alphanumeric code, and produced using VA-approved software directly onto our encrypted VA research server protected by 128-bit SSL, the secure socket layer technology used for sensitive transactions on the web (pathway R:\RES_Geripsych_Research). The system is accessible only via the VA intranet and employs a hierarchical system of password protected logins, allowing differential access to project team members as appropriate to their roles. The PI and his team have extensive experience conducting studies that have required creating data systems such as this for encrypted electronic files.

Analysis Plan. Prior to performing the primary analyses, descriptive statistics and graphical summaries are obtained for all baseline measures to check for missing data, outliers, and the need for transformations or non-parametric methods, and to obtain characteristics of the sample. We will perform descriptive statistics (e.g., means, standard deviations, frequencies) to evaluate acceptability (satisfaction, credibility) and feasibility variables (attendance, time spent training on VTC equipment). To evaluate within-treatment effects on outcomes, we will use paired-samples t-tests comparing baseline to posttreatment and baseline to follow-up scores on all efficacy outcomes. Within-treatment effect sizes will be calculated using the formula: d = (post [or follow-up] M – baseline M) / SD of change scores. To determine the frequency of individual cases having improvement in pain, we use the standard metric of 30% improvement, as well as the moderately stringent criterion of 50% improvement, and the very stringent criterion of 70% improvement. If some missing values are present due to attrition, we use a conservative estimation approach by assuming no change from the previous assessment and replacing missing follow-up data with the last available point (i.e., last observation carried forward).

4. Safety

Risks. Clinical interview, psychotherapy interventions, and questionnaires: no major risks. Minor risks include inconvenience, frustration with questions, sadness or distress with discussing emotional experiences, and potential embarrassment if the confidentiality of research records is breached. Regarding psychotherapy

specifically, participants may feel discomfort disclosing personal information to the therapist and other group members. Participants are also at risk for nonresponse or limited response to treatment, but are always free to end participation in the study and pursue alternate treatment if they so choose. Risks are generally similar to the risk inherent in receiving treatment as usually provided in person and in clinical care.

Suicide Safety Plan. We do not expect any study participants to develop suicidal ideation in this treatment study for chronic pain. However, it is known that chronic pain patients have twice the rate of suicide of those without chronic pain. Therefore, we have a suicide safety plan in place. The PI is a clinician in geriatric psychiatry, and assessments will be completed periodically to monitor for depression. If researchers feel that the participant is at risk for suicide and/or a threat to others while undergoing clinical interview, completion of assessments, therapy sessions, or other study procedures, he/she will be evaluated by the PI and directed to dial 911 or report to the nearest emergency department. VVC requires information on the Veterans' closest hospital to be recorded at each visit. At other times during the study, Veterans will have the PI's direct telephone number (424-279-8439) to call in the event of worsening symptoms and will also be instructed to dial 911 or report to the nearest emergency department in the event of a psychiatric emergency, such as suicidal or violent ideation. If a Veteran is noted to have significant depression but is not suicidal, the research team will discuss the benefits of treatment and provide contact information for the GLA Geriatric Psychiatry Outpatient Program.

Potential Benefits. The study will be of direct relevance and benefit to older Veterans who suffer from chronic pain. All study participants will receive a psychological intervention, vEAET, which may be helpful for pain and related symptoms, such as depression and anxiety. Results from the study will inform future research on psychological interventions for chronic pain over VTC, which we anticipate will ultimately be helpful to improve access to this treatment for Veterans who are impacted by COVID-19 related social distancing or who cannot or prefer not to come into VA for care.

Risk/Benefit Ratio. The risks of this study are small. We will be gaining valuable information to help improve our understanding of the potential use of vEAET for older Veterans with chronic pain and help inform future research aimed at using alternate psychological treatment strategies for older Veterans with chronic pain.

Alternatives to Participation. The patient may receive ongoing medical care in their respective clinics, including in primary care, pain clinic, etc. for pain whether or not s/he participates in the study. This includes medications and interventional pain approaches (e.g. injections, ketamine). The VA also offers a chronic pain rehabilitation program, cognitive behavior therapy for chronic pain, and physical and occupational therapy for chronic pain. Mindfulness classes, acupuncture, and other complementary/integrated medicine approaches are also offered. The patient may elect to not participate, and this will not adversely affect any ongoing care at the VA.

5. List of Anticipated Research Products

1. Scientific abstract and manuscript reporting on the acceptability, feasibility, and initial efficacy testing of vEAET for older Veterans with chronic musculoskeletal pain.

2. The main "product" will be a strong VA Merit Review application that will include an RCT comparing vEAET with an alternative in this population. These pilot data will be used to address potential limitations related to the lack of prior experience with the VTC and online assessment platforms. These data will also help select measures and estimate effect sizes for subsequent power analyses for the RCT. If the Merit is funded, study start-up can be accelerated due to our experience with the materials and methods.

6. Project Timeline

We plan to complete this pilot over a 12-month period. We anticipate consenting 24 and enrolling 18 Veterans. The IRB application will be submitted in June 2020. The first group is anticipated to begin in September 2020. The groups should be completed by the end of February 2021. We have allowed 3 months at the end of the study to carry out data cleaning and analysis and to begin abstract, manuscript, and grant writing. Please see

the timeline in **Table 2**. Unless participants give permission to bank their data for future research, it will be destroyed 6 years from the end of the fiscal year after completion of the research project.

Table 2. Project Timeline

Task Month	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
IRB application & approval	X	X										
Contact potential participants		X	X	X	X							
Enrollment/baseline assessments (n=12)			X	X	X	X						
vEAET				X	X	X	X	X	X			
Posttreatment assessments					X	X	X	X	X			
2-month follow-up assessments							X	X	X	X		
Interim and final data analyses							X	X	X	X		
Abstract and manuscript preparation										X	X	X
Prepare and submit Merit Review										X	X	X

7. References

1. Kerns RD, Otis J, Rosenberg R, Reid MC. Veterans' reports of pain and associations with ratings of health, health-risk behaviors, affective distress, and use of the healthcare system. J Rehabil Res Dev. 2003;40(5):371-79.
2. Beckham JC, Crawford AL, Feldman ME, Kirby AC, Hertzberg MA, Davidson J, et al. Chronic posttraumatic stress disorder and chronic pain in Vietnam combat veterans. J Psychosom Res. 1997;43(4):379-89.
3. Group TOTfCPW. VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Washington, DC: VA/DoD; 2017 February 2017.
4. Lumley MA, Schubiner H. Emotional Awareness and Expression Therapy for Chronic Pain: Rationale, Principles and Techniques, Evidence, and Critical Review. Curr Rheumatol Rep. 2019;21(7):30.
5. Lumley MA, Schubiner H, Lockhart NA, Kidwell KM, Harte SE, Clauw DJ, et al. Emotional awareness and expression therapy, cognitive behavioral therapy, and education for fibromyalgia: a cluster-randomized controlled trial. Pain. 2017;158(12):2354-63.
6. Yarns BC, Lumley MA, Cassidy JT, Steers WN, Osato S, Schubiner H, et al. Emotional Awareness and Expression Therapy (EAET) Achieves Greater Pain Reduction than Cognitive Behavioral Therapy (CBT) in Older Adults with Chronic Musculoskeletal Pain: A Preliminary Randomized Comparison Trial. Pain Med. 2020;e-published ahead of Print.
7. Levine M, Richardson JE, Granieri E, Reid MC. Novel telemedicine technologies in geriatric chronic non-cancer pain: primary care providers' perspectives. Pain Med. 2014;15(2):206-13.
8. Herbert MS, Afari N, Liu L, Heppner P, Rutledge T, Williams K, et al. Telehealth Versus In-Person Acceptance and Commitment Therapy for Chronic Pain: A Randomized Noninferiority Trial. J Pain. 2017;18(2):200-11.
9. Egede LE, Acierno R, Knapp RG, Lejuez C, Hernandez-Tejada M, Payne EH, et al. Psychotherapy for depression in older veterans via telemedicine: a randomised, open-label, non-inferiority trial. Lancet Psychiatry. 2015;2(8):693-701.

10. Choi NG, Hegel MT, Marti CN, Marinucci ML, Sirrianni L, Bruce ML. Telehealth problem-solving therapy for depressed low-income homebound older adults. The American Journal of Geriatric Psychiatry. 2014;22(3):263-71.
11. Chavooshi B, Mohammadkhani P, Dolatshahi B. A randomized double-blind controlled trial comparing Davanloo intensive short-term dynamic psychotherapy as internet-delivered vs treatment as usual for medically unexplained pain: a 6-month pilot study. Psychosomatics. 2016;57(3):292-300.
12. Chavooshi B, Mohammadkhani P, Dolatshahee B. Telemedicine vs. in-person delivery of intensive short-term dynamic psychotherapy for patients with medically unexplained pain: A 12-month randomized, controlled trial. J Telemed Telecare. 2017;23(1):133-41.
13. Clauw DJ. Diagnosing and treating chronic musculoskeletal pain based on the underlying mechanism (s). Best Pract Res Clin Rheumatol. 2015;29(1):6-19.
14. Yarns BC, Wells KB, Fan D, Mtume N, Bromley E. The Physical and the Emotional: Case Report, Mixed-Methods Development, and Discussion. Psychodyn Psychiatry. 2018;46(4):553-78.
15. Oei TP, Green AL. The Satisfaction With Therapy and Therapist Scale--Revised (STTS-R) for group psychotherapy: Psychometric properties and confirmatory factor analysis. Professional Psychology: Research and Practice. 2008;39(4):435-42.
16. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. J Behav Ther Exp Psychiatry. 2000;31(2):73-86.
17. Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. J Pain. 2004;5(2):133-7.
18. Askew RL, Kim J, Chung H, Cook KF, Johnson KL, Amtmann D. Development of a crosswalk for pain interference measured by the BPI and PROMIS pain interference short form. Qual Life Res. 2013;22(10):2769-76.
19. Amtmann D, Cook KF, Jensen MP, Chen W-H, Choi S, Revicki D, et al. Development of a PROMIS item bank to measure pain interference. Pain. 2010;150(1):173-82.
20. Lapin B, Davin S, Stilphen M, Benzel E, Katzan IL. Validation of PROMIS CATs and PROMIS Global Health in an Interdisciplinary Pain Program for Patients With Chronic Low Back Pain. Spine. 2020;45(4):E227-E35.
21. Lee RM, Robbins SB. Measuring belongingness: The social connectedness and the social assurance scales. J Counseling Psychol. 1995;42(2):232.
22. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the Patient-Reported Outcomes Measurement Information System (PROMIS(R)): depression, anxiety, and anger. Assessment. 2011;18(3):263-83.
23. Arnold LM, Lu Y, Crofford LJ, Wohlreich M, Detke MJ, Iyengar S, et al. A double-blind, multicenter trial comparing duloxetine with placebo in the treatment of fibromyalgia patients with or without major depressive disorder. Arthritis Rheum. 2004;50(9):2974-84.
24. Jensen MP, Turner JA, Romano JM. Pain belief assessment: A comparison of the short and long versions of the surgery of pain attitudes. The Journal of Pain. 2000;1(2):138-50.
25. Riddle DL, Jensen MP. Construct and criterion-based validity of brief pain coping scales in persons with chronic knee osteoarthritis pain. Pain Med. 2013;14(2):265-75.
26. Lepkowsky CM, Arndt S. Research Article Functional Assessment of Currently Employed Technology Scale (FACETS): Reliability and Validity. International Journal of Medical Science and Clinical Invention. 2018;5(9):4064-68.
27. Lumley MA, Schubiner H. Emotional Exposure Therapy for Stress Reduction: A Group-Based Treatment Manual for Patients with Fibromyalgia and Related Chronic Pain Disorders (Version 2). Detroit, Michigan: Wayne State University; 2012.
28. VA Video Connect [Available from: mobile.va.gov/app/va-video-connect.