Project Description

Date: 04/07/2022 Revision of Original Protocol to Adjust for Covid Pandemic

Project Title: Feasibility and Acceptability of The Equus Effect: A Small Randomized Controlled Pilot Study of an Equine-facilitated Therapy

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Purpose

We propose to pilot test an innovative equine-facilitated therapy called The Equus Effect (TEE) as a complement to Veterans' existing VA mental health services to improve social functioning. TEE aims to improve Veterans' social functioning by developing their emotion regulation and interpersonal skills through therapeutic interactions with horses. In line with recommendations for pilot investigations, we will conduct a randomized pilot study to 1) evaluate the feasibility of study procedures, assessments, and outcomes, 2) demonstrate experimental and control interventions can be delivered with fidelity, and 3) examine the acceptability of the interventions. To accomplish these goals, we will enroll a transdiagnostic cohort of 40 Veterans involved in VA mental health services with social dysfunction and emotion dysregulation. We will randomize participants to receive either 1) TEE or 2) attention control (AC), both group interventions. Each week, the 4-session TEE will include 1) mindfulness activities, 2) emotion regulation and interpersonal skills education, 3) experiential activities with horses incorporating opportunities to develop emotion regulation and interpersonal skills, and 4) between-session application of lessons learned from the equine activities. AC will have similar elements without equine features. Intervention outcomes will be measured at 4- and 16-weeks post randomization. Specifically, using mixed quantitative-qualitative methods, we aim to:
Aim 1: Determine the feasibility of recruitment, randomization, retention, assessment procedures, and implementation of TEE and AC. *Hypothesis*: Rates of recruitment will be ≥ 8 participants per month, and Veterans randomized to TEE will attend intervention sessions, remain in the study, and experience clinically significant changes in social functioning and emotion dysregulation at rates equal to or superior to AC.
Aim 2: Demonstrate TEE and AC can be delivered with fidelity. *Hypothesis*: Facilitators will deliver each intervention consistently and as intended across sessions.
Aim 3: Establish acceptability of TEE and AC by assessing intervention credibility and satisfaction and the usefulness of TEE as a complementary mental health intervention using mixed quantitative-qualitative methods. *Hypothesis*: Veterans will find TEE and AC credible and satisfying and Veterans and their mental health clinicians will qualitatively report the therapeutic benefits of TEE as a complementary and integrative health (CIH) intervention for mental health treatment.

This small pilot project takes a bold step forward in proposing to investigate EFT with scientific integrity and has the potential to lend initial credibility to the therapeutic claims of this increasingly popular CIH. Should data indicate that TEE and methods to study its effects are feasible and acceptable, it will set the stage for a RR&D IIR proposal to test the efficacy of TEE in a multi-site randomized controlled trial.

Background

In 2016 the VA Office of Patient Centered Care and Cultural Transformation (OPCC&CT) launched the Whole Health initiative to change VA's healthcare system from a traditional medical model focused on treating specific conditions to a more holistic personalized, proactive, patient-driven approach.[1] With Whole Health, Veterans develop healthcare plans that center on achieving meaningful life goals and improving functioning, consistent with a psychosocial rehabilitation emphasis on recovery-oriented outcomes related to functioning in the community.[2] A key component of Whole Health is the use of complementary and integrative health (CIH) approaches with traditional services. Currently, one facility in each of 18 VISNs are designated as VA Whole Health flagship sites, and many more VA facilities within each of these VISNs are implementing elements of the Whole Health system and expanding CIH options for Veterans.[1]

One class of CIH is animal-facilitated therapy, such as the use of support dogs[3] or interacting with horses.[4,5] Among animals, horses confer unique therapeutic benefits. As prey animals, they are extremely sensitive to the environment and have developed an ability to assess the emotional states, behaviors, and intentions of their herds, other animals, and predators,[6,7] mirror body language,[8] and immediately respond to

subtle nonverbal cues.[9] Through domestication, horses have transferred these skills to relationships with people and can sense a person's emotions even when the person lacks emotional self-awareness.[6,7] Like a mirror, they give immediate feedback about a person's emotional state and nonverbal behavioral cues (e.g., pinning their ears back or walking away from someone who is angry or abrupt; moving tensely and putting their head up high when someone is anxious; relaxing with ears forward and approaching a person who is calm).[9-11] To gain a horse's cooperation, a person must regulate emotional distress and present in a calm, patient, attentive, and confident manner. As such, interactions with horses provide opportunities for people to reflect on and change behaviors that impede effective interpersonal connection, collaboration, and control and to apply these equine-facilitated experiences in their relationships with other people.[12]

Equine-facilitated therapy (EFT) leverages these unique therapeutic benefits by having people interact with horses using unmounted activities (no riding), allowing horses to act naturally without the control of riders.[13] Typically, a horse specialist and a mental health provider work together with participants. The horse specialist focuses on the participant's physical safety and explains the horse's behaviors, and the mental health provider focuses on the participant's experience, behaviors, and emotional reactions. Most programs have participants: 1) practice mindfulness activities (e.g., deep breathing, body scanning) to increase nonjudgmental self-awareness of thoughts, emotions, and sensations, as well as to prepare for horse interactions; 2) learn didactically about horses and their therapeutic value; 3) participate in equine activities (e.g., handling, grooming, leading) to understand their internal experiences and explore and address mental health and interpersonal issues; and 4) debrief experiences and identify opportunities for application between sessions.[4,5,14] EFT is increasingly available at the VA, with approximately 30 VA facilities currently partnering with EFT programs for Veterans.[15] VA-partnered EFT availability is likely to grow in that the 2018 Military Construction and Veterans Affairs Appropriations Act included an amendment to expand funding by 5 million dollars for EFT within the VA.[16]

EFT at the VA has been used to address a variety of diagnostic issues commonly experienced by Veterans, including PTSD, depression, anxiety, substance use and eating disorders, and relationship problems.[5,17] Wide application of EFT may be due to its focus on the management of emotion dysregulation, a transdiagnostic phenomenon underpinning impaired functioning associated with many mental health conditions.[18] In addition, EFT may be recommended when patients respond poorly to traditional mental health treatments; the complementary value of EFT is that the salient emotion-based learning with horses may catalyze progress on issues concurrently addressed in traditional mental health services.[14] Finally, preliminary reports of EFT suggest it may help people reduce anger and aggressive behavior,[12,19] improve mood,[20] and reduce depression[21,22] and PTSD symptoms,[22,23] further supporting its transdiagnostic appeal. None of these reports focus on social functioning as a main outcome, a surprising absence given that high quality social functioning depends on effective regulation of one's emotions,[24] a presumed key mechanism targeted by EFT.

Research about EFT is in its infancy, despite increasing utilization of it in the VA. Few peer-reviewed studies about EFT exist, and those that do are generally of poor methodological quality.[4,5,17] Quantitative research has been limited by the lack of operationalized EFT interventions, independent fidelity assessment, or use of psychometrically established assessments, control conditions, randomization, or post-intervention follow-ups. In addition, qualitative research has not focused on discerning patients' perceptions about effective and ineffective EFT components or how EFT works to improve functioning and well-being. Furthermore, clinicians' perceptions of benefits catalyzed by EFT within traditional mental health services have not been studied, a clear limitation given the presumed complementary value of EFT. Moreover, almost all the research on EFT has focused on school-age children and adolescents, not adults. Given VAs increasing embrace of EFT, carefully conducted research that aims to systematically develop and study EFT for Veterans is sorely needed to ensure that it works.

Significance

The proposed pilot study will advance knowledge in rehabilitation research by studying the feasibility and acceptability of conducting a randomized controlled trial of an EFT, called The Equus Effect (TEE), currently available to Veterans at VA Connecticut Healthcare System (VACHS). TEE is a 4-session intervention that incorporates mindfulness strategies, emotion regulation and interpersonal skill development, and experiential equine activities to improve social functioning for a mixed diagnostic group of Veterans. Data from the pilot study will inform development of a RR&D IIR proposal testing the efficacy of TEE in a multi-site randomized controlled trial. The proposed research aligns with the RR&D SPiRE Program Priority Areas for studying

promising non-pharmacological activity-based interventions to maximize functional recovery,[25] OPCC&CT promotion of CIH within the Whole Health initiative,[1] and the VA 2018-2024 Strategic Plan to ensure Veterans receive integrated care and support that emphasizes their well-being and independence.[26]

Research Plan

1. Study design and overview. We will test the feasibility and acceptability of a randomized controlled trial design to study TEE to improve social functioning. We will enroll a transdiagnostic cohort of 40 Veterans with social dysfunction and emotion dysregulation who are receiving VA mental health services and randomize them to either weekly TEE or attention control (AC) sessions over 4 weeks. Social functioning will serve as the primary outcome; emotion dysregulation will serve as the secondary outcome. Following best practice recommendations for pilot investigations,[27,28] we will use mixed quantitative and qualitative methods. Feasibility will examine performance of study procedures, assessment measures, and outcomes (Aim 1) and fidelity of TEE and AC (Aim 2). Acceptability will involve assessing TEE and AC credibility and satisfaction, as well as conducting key informant interviews with Veterans assigned to TEE and their clinicians (n = 20) to examine perceptions of the acceptability and usefulness of TEE and the ways in which it complements standard mental health care (Aim 3). Intervention outcomes will be measured at baseline and 4- and 16-weeks post-randomization.

2. Study timeline. Year 1 will include start-up tasks and initiating the pilot trial. Year 2 will involve completing the pilot trial, cleaning and analyzing data, and preparing manuscripts and the RR&D IIR RCT proposal to test TEE efficacy (see Table 1).

Table 1. Study Timeline.

	Year 1				Year 2			
Activities	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
IRB	X	X						
Hire and train RA	X	X						
Develop AC	X	X						
Develop TEE and AC fidelity measure		X	X					
Recruit participants/provide TEE & AC		X	X	X				
Complete assessments		X	X	X	X			
Enter and clean data		X	X	X	X	X		
Analyze data					X	X		
Present findings						X	X	
Prepare manuscript and RR&D IIR RCT							X	X

3. Setting. All research procedures will be conducted at VA Connecticut West Haven and Newington campuses. TEE and AC will be delivered off-site at the TEE location in Sharon, CT.

4. Participant eligibility criteria. Inclusion criteria for Veterans are: 1) seeing a VACHS mental health clinician at least three times in the past 3 months with intent to remain in treatment during study enrollment; 2) age 18 and over; 3) social dysfunction (score $\geq$ 2.5 on the Social Adjustment Scale–Self-Report or $\geq$ 1.5 on the Inventory of Interpersonal Problems–32); 4) emotion dysregulation (score $\geq$ 95 on Difficulties in Emotion Regulation Scale); and 5) consent to all study procedures, including audio recording of group intervention sessions. Exclusion criteria are: 1) psychotic disorder as self-reported by the Veteran and verified in the electronic health record or as determined by the Mini-International Neuropsychiatric Interview; 2) acute suicidality, 3) inability to read English or communicate in spoken English; 4) anticipated unavailability to the study during the next 16 weeks; 5) participation in any EFT in the past 24 weeks; and 6) unavailability of a landline or cellular telephone. Clinicians are eligible for study participation if 1) they have seen one of the Veteran participants assigned to TEE at least three times in the past 3 months at the participant's baseline assessment, and 2) this Veteran received at least one TEE session and one psychotherapy/counseling session with the clinician prior to the key informant interview.

Justification. Veterans must report a moderate level of impaired social functioning (primary outcome) for study interventions to demonstrate clinically significant changes in this area; proposed cut-offs exclude Veterans who report few or no problems with social functioning. We also included a cut-off of at least moderate emotion dysregulation (secondary outcome) given how TEE and most EFTs purport to lessen emotion

dysregulation as a key mechanism to improve social functioning. Veterans must receive consistent mental health treatment from a clinician to enable qualitative examination of EFT's complementary therapeutic value. Phone contact is necessary to coordinate transportation to Sharon, CT and arrange study assessments.

5. Randomization. Eligible Veterans will be recruited to form one TEE and one AC group every four weeks. We will use permuted block randomization (1:1 ratio), with variable block size, to maintain balanced assignment to conditions given potential differences in monthly recruitment. The project coordinator will conduct randomization.

6. Recruitment and feasibility. Recruitment will begin at the end of Q2 in Year 1. In FY2018, VACHS served over 58,687 unique Veterans in Connecticut and southern New England, with 14,687 enrolled in mental health services. Most Veterans are seen at our West Haven and Newington campuses. The West Haven campus has five outpatient mental health clinics, three intensive outpatient treatment programs, two residential psychosocial rehabilitation treatment programs, and the psychosocial rehabilitation Errera Community Care Center. The Newington campus has two outpatient programs and two intensive outpatient treatment programs. We will recruit 8-12 Veterans per 4-week cycle to form a large enough cohort each month for block randomizing a sufficient number of Veterans to either TEE or AC. Hence, recruiting 40 Veterans should take about 4 months; we have planned seven months in our timeline in case recruitment is slower than expected. Recruiting 40 Veterans should be quite feasible given the large number of Veterans in VACHS mental health services, the broad transdiagnostic eligibility criteria, and record of Veteran engagement in TEE thus far (> 200 in the past 4 years).

Direct-to-participant and clinician recruitment will occur via flyers, visits to clinic rounds, and email to clinicians at VA Connecticut sites, including Vet Centers in Connecticut. The study also will be presented to Veterans during community meetings at Errera Community Care Center programs located in West Haven and Newington. In addition, clinicians and peer specialists will be provided with study cards that they can hand to Veterans if they feel the Veterans might be appropriate for study participation. If Veteran participants have more than one mental health clinician, they will be asked to identify which clinician they see as primarily providing them mental health psychotherapy/counseling, and the research assistant will invite that person to participate in the study. The decision of Veterans' clinicians to enroll in the study will not affect potential Veteran participants' study eligibility, particularly because their clinicians will be approached for study participation after Veterans have already enrolled. The PI, project coordinator, and Co-Is will have monthly meetings to review the number of individuals assessed for eligibility and those who were found ineligible (with reasons), declined to participate (with reasons), randomized, started, completed, withdrew, and completed assessments at each timepoint. Quarterly/semi-annual reports of these numbers will be provided to the Data Safety Monitoring Board (DSMB).

7. Screening. We will seek waivers of written informed consent and HIPAA authorization for an initial phone screening. The research assistant (RA) will offer Veterans information about the study and invite interested parties to complete a brief phone screening on quickly obtained eligibility criteria (e.g., if they have received EFT in the past 6 months). Individuals who remain eligible will next attend an in-person meeting in which to learn more about the study in detail, including completing an additional screening to further determine inclusion and exclusion criteria (e.g., completion of psychiatric interview, social functioning, and emotion dysregulation assessments). If the potential participant is agreeable, the RA will invite individuals to provide written informed consent and then will complete the screening to determine eligibility. Only individuals who meet eligibility criteria will be invited to continue in the study and participate in the baseline assessment.

Given the vacillating COVID-19 pandemic conditions and Veteran preferences, the entire screening process can occur remotely, via phone or a VA-approved video conference platform, rather than in-person. If conducted in-person, participants will be required to wear a 2-ply face mask when in the room with research staff, and if they do not have one, one will be provided for them. Likewise, research staff will utilize masks and social distancing during study visits and will sanitize the office between each in-person visit and at the end of the day.

If conducted remotely, the consent form will be handled in one of two ways. Preferably, research staff will use an e-consent approach with VA DocuSign. In advance of the next scheduled phone or video conference following the brief phone screening, research staff will send a DocuSign envelope (email containing links to the informed consent and HIPAA authorization documents). The email will contain a reminder for the recipient to not sign the document prior to the scheduled contact time to review it and have questions answered. During the remote visit, research staff will review the documents in the same manner as doing so in person. If the

potential participant agrees to participate in the continued screening and study, if found eligible, research staff will guide them to fill in the fields in the e-consent form (e.g., Last, First, Middle Initial name fields) and to electronically sign it and click "FINISH" to finalize the document. While still on the phone/video conference platform with the participant, research staff will receive an email notification to log into DocuSign, verify that all fields are completed accurately, and sign as a witness. The participant will be shown how to download a copy of the informed consent to their computer for their record or will be mailed a hard copy, if preferred.
If VA DocuSign is infeasible to use with potential participants, the consent form will be mailed to subjects after participating in the phone screening to determine initial eligibility. Upon receipt of the consent form, another remote encounter will occur with the potential participant to review it, and have it signed and returned to the research team, if the Veteran remains interested. Once received, a member of the research team will meet remotely again with the participant to complete the screening, determine eligibility, and, if found eligible, have the participant finish the remaining baseline assessments. Remote sessions will not be recorded.

8. Intervention conditions. Veterans will receive either TEE or AC, both closed group programs in which all members begin the group intervention at the same time. TEE and AC each will consist of four 4-hour weekly sessions over 4-weeks, with 4-6 Veterans attending per 4-week cycle. Activities in both conditions contain a mixture of indoor and outdoor activities; group facilitators and participants will wear 2-ply face masks indoors or outdoors as dictated by prevailing VACHS guidelines. Masks will be provided to participants who do not have them. Jane Strong and David Sonatore, LCSW will conduct TEE sessions. They are Experiential Learning with Horses Instructors who trained at the Epona Equestrian Services Program in Tucson, AZ – an internationally acclaimed equine educational program that trains people in EFT. They have worked together for the past decade developing and delivering TEE to Veterans. Peer specialists from VACHS or staff from the facility in Sharon, CT not delivering TEE will conduct AC sessions. They have experience facilitating general support groups and will be trained by Dr. Martino to deliver the control intervention.

TEE. Each session includes: 1) mindfulness-based activities; 2) didactics about emotion regulation and interpersonal skills; and 3) experiential learning activities with horses that provide opportunities to practice emotion regulation and interpersonal skills. At the end of each session, Veterans debrief about what they learned and identify how they might apply this knowledge to manage their mental health concerns and function better socially. Ms. Strong and Mr. Sonatore have prepared a manual detailing the program's major components and content and will co-facilitate its delivery to participants in this pilot study.

AC. AC will exclude equine-related activities or discussions but maintain mindfulness-based activities, emotion regulation and interpersonal skills didactics, and experiential learning activities with between-session application. During the first five months of the study, Drs. Martino, Harpaz-Rotem, and Decker will develop and manualize AC to parallel the focus, content, and activities of TEE. Instead of experiential equine activities, AC will rely on team-building activities (e.g., scavenger hunt), which aim to enhance social relations by involving participants in collaborative tasks and providing opportunities for emotion regulation and interpersonal skills practice.[29] Group leaders will practice the finalized curriculum with the research team in month 5 and then co-facilitate it for Veterans randomized to this condition.

TEE will occur at the horse stables and pastures/ring where the program occurs in Sharon, CT. AC will occur at a cottage on the same property, but not in the stables and pastures/ring. Table 2 compares TEE and AC sessions. All TEE and AC sessions will be audio recorded, except for the experiential equine activities because of excessive logistical challenges.

Veterans will have the choice to be transported by van to and from the intervention location by the Peer Specialists from VACHS or the Disabled American Veterans Department of Connecticut. If they choose to use van transportation provided for this study, they will first be screened by the driver for symptoms that could be consistent with COVID-19 infection. Participants will only be permitted to enter the vehicle if they pass symptom screening. During the drive, they will always wear 2-ply masks, which will be provided to those who do not have one. They will not be allowed to eat or drink while in the vehicle, and weather permitting, windows will be slightly open to allow for air circulation. COVID-19 risk mitigation procedures for travel will be adjusted according to prevailing VACHS guidelines.

Rationale for AC. For most Veterans, interacting with horses will be an unusual experience, and driving to the countryside and spending four hours in a bucolic setting may confer therapeutic benefits (e.g., stress reduction). Replicating TEE without horse-specific components will be essential to determine therapeutic gains specific to equine interactions. We elected not to include interactions with another large, familiar animal (e.g., a cow) as a more stringent test of "the equus effect" because of its impracticality, uncommonness as a

social/recreational activity, and the possibility that other animals could elicit different responses from different people (e.g., fear/hesitation vs. attraction/approach), making interpretation of potential condition differences difficult.

Table 2. TEE vs. AC.

		Content/Activities	
Session	**Focus**	**TEE**	**AC (manual to be developed)**
1	Mindfulness	Joint fluidity/body scan in horse barn	Joint fluidity/body scan in cottage
	Emotion regulation & interpersonal skills	Fear and vulnerability/video, discussion w/ parallels to horses	Fear and vulnerability; video, discussion; no horse parallels
	Experiential learning activity	Setting healthy boundaries/ grooming, leading, yielding, backing up with horse	Team building activity requiring disclosure and boundary management
2	Mindfulness	Joint fluidity/body scan in horse barn	Joint fluidity/body scan in cottage
	Emotion regulation & interpersonal skills	Anger/Frustration/Agitation; video, discussion w/ parallels to horses	Anger/Frustration/Agitation; video, discussion; no horse parallels
	Experiential learning activity	Collaboration/ grooming, obstacle course with horse	Team building activity requiring collaboration
3	Mindfulness	Joint fluidity/body scan in horse barn	Joint fluidity/body scan in cottage
	Emotion regulation & interpersonal skills	Sadness and Grief; video, discussion w/ parallels to horses	Sadness and Grief; video, discussion; no horse parallels
	Experiential learning activity	Collaboration/ grooming, walk through labyrinth or trail with horse	Team building activity requiring collaboration
4	Mindfulness	Joint fluidity/body scan in horse barn	Joint fluidity/body scan in cottage
	Emotion regulation & interpersonal skills	Review of emotional states; video, discussion w/ parallels to horses	Review of emotional states; video, discussion; no horse parallels
	Experiential learning activity	Collaboration/ grooming, hooking up with horse in round pen	Team building activity requiring communication in pairs

9. Assessments. Assessments will occur at screening, baseline, 4- and 16-weeks post-randomization. Dr. Martino will train the RA (blind to condition) to administer assessments. Assessments will be conducted either in-person or remotely, depending on COVID-19 pandemic conditions and the participants' preference. As with the screening process, if conducted in-person, research staff and participants will be required to wear a 2-ply face mask during study visits and social distance. If the participants do not have a mask, one will be provided for them. Research staff will sanitize the office between each in-person visit and at the end of the day. If conducted remotely, research staff will use either phone or a VA-approved video conference platform. Assessment sessions, regardless of mode of delivery, will not be recorded. The RA will schedule assessment sessions. Veterans will be instructed to not tell the RA their intervention assignments.

Sample description. Demographics will be assessed with the 15-item Phen-X adult Demographic protocol. Military demographics and experiences will be assessed with the 11-item Phen-X Military Service Demographics measure. The Mini-International Neuropsychiatric Interview[30] will assess psychiatric diagnoses.

Outcomes. The primary outcome will be social functioning as measured by the Social Adjustment Scale–Self Report (SAS-SR)[31] and Inventory of Interpersonal Problems-32 (IIP-32).[32] We chose the SAS-SR because it details social functioning in a range of role areas (e.g., work, social and leisure, family), contains skip-outs for nonapplicable items, and has been widely used in clinical trials and outcome research with participants with mixed psychiatric diagnostic characteristics.[33] The overall SAS-SR score is 1 (no impairment), to 5 (highest impairment). We chose IIP-32 because it taps people's interpersonal difficulties across role areas (e.g., hard to be assertive, too aggressive) and is reliable and valid when used with diagnostically mixed groups of psychiatric outpatients.[32] The IIP-32 total score is 0 (no difficulties), to 4 (extreme difficulties). Both aspects of social functioning may be affected by TEE. Our secondary outcome is emotion dysregulation as measured by the Difficulties in Emotion Regulation Scale (DERS).[34] DERS scores range from 36-180, with higher scores indicating more dysregulation. A total score of $\geq$105 falls between nonclinical mean scores (M=77.99-80.66)[34] and the mean of adults with extreme interpersonal and emotional dysregulation (M=128.03).[35]

Other outcomes will include mindfulness (Five Facet Mindfulness Questionnaire),[36] psychiatric symptoms (Phen-X Cross-Cutting Symptom measure that assesses 13 psychiatric domains, including depression, anger, mania, anxiety, somatic symptoms, suicidal ideation, psychosis, sleep problems, memory, repetitive thoughts and behaviors, dissociation, personality functioning, and substance use),[37] PTSD symptoms (PCL-5),[38] coping skills (DBT Ways of Coping Checklist),[39] and the Brief Pain Inventory (BPI).[40] If a participant reports current suicidal ideation, the research assistant will contact the PI, Dr. Martino, or one of the co-investigators who will conduct a thorough assessment and, as warranted, either contact/escort the Vet to see their clinician and/or escort the Veteran to the psychiatry ER at VACHS. If this event were to occur during remote assessment session, whoever is doing the assessment will contact the PI who will do a more detailed imminent risk assessment over the phone. If the PI believes there is risk and is concerned for the study participant's safety, 911 will be called for a welfare check.

Intervention Fidelity. Fidelity assessment will follow methods from the Yale Adherence and Competence System (YACS), a reliable and valid system for assessing fidelity of psychosocial treatments.[41] YACS is a general rating system for evaluating the adherence (how often) and competence (how well) of therapists delivering psychosocial treatments. Items are developed to capture components of a treatment that are unique and essential (e.g., psychoeducation about unique therapeutic features of horses, experiential equine-activities), essential but not unique (e.g., teaching emotion regulation or interpersonal skills), and antithetical to an approach (e.g., direct confrontation). Independent raters trained in the system rate items along 7-point Likert scales (adherence = 1 [did not occur], to 7 [extensively]; competence = 1 [very poor], to 7 [outstanding]) to determine the fidelity of intervention delivery. YACS also includes therapist checklists completed after each session to indicate intervention elements conducted. Dr. Martino co-authored the last edition of the YACS,[42] trained many research groups in it as Education Director of the Yale Psychotherapy Development Center, and has modified and used it to assess the different psychotherapies in several studies. Drs. Martino, Harpaz-Rotem, and Decker will develop a TEE/AC fidelity measure based on the YACS during months 4-9 of the study. Dr. Martino will train two to three independent raters to use the measure to reliably rate all recorded TEE and AC sessions. We will use therapist checklists completed by TEE and AC group facilitators each week to document adherence to prescribed experiential activities.

Intervention credibility and satisfaction. The credibility of and satisfaction with TEE and AC will be assessed with adaptations of the Credibility and Expectancy of Improvement Scale[43] and the Client Satisfaction Questionnaire,[44] respectively.

Key informant interviews. Key informant individual 20/30-minute interviews will take place post-intervention to assess Veteran and clinician perceptions of the acceptability, usefulness, and satisfaction of TEE. Drs. Martino, Portnoy, and Fenton, and Ms. Strong and Mr. Sonatore will develop the Veteran and clinician interview guides to ensure questions and probes ascertain main topics. These interviews will be audio recorded using either Microsoft TEAMS (from a VA desktop or laptop) or a VA-approved audio recorder. Microsoft TEAMS is a HIPAA-compliant, VA approved platform for video conferencing and has transcription generating capacity. We will also gather some demographic and professional characteristics of clinician participants (i.e., age, sex, race/ethnicity, profession/discipline, professional status (e.g., staff, trainee), Veteran status, months treating Veteran, years providing clinical services, and major focus of mental health service provided to Veteran) to characterize the sample.

10. Data management. Quantitative assessment measure responses will be entered into VA REDCap to provide secure automated export procedures for data to be downloaded to Excel and common statistical packages (e.g., SAS) for data analysis. REDCap catches unclear characters, out-of-range variable and logical inconsistencies. The research assistant will check files monthly so that errors can be readily corrected.

11. Data analysis.

Quantitative. To assess feasibility (Aim 1), we will use CONSORT reporting standards to diagram the number of Veterans screened, found eligible and ineligible (with reasons), consented, attended sessions, completed TEE and AC interventions, and retained through follow-up. We also will track rates of unanticipated study-related adverse events in both conditions and participants' rate of completion of all outcome measures. Means, standard deviations, and median scores will be calculated for outcome assessments. The proportions of participants with clinically significant change in outcomes from baseline to 4- and 16-weeks post-randomization will be calculated using each measure's test-retest reliability and clinical cutoffs from the literature, or change of two standard deviations from the baseline mean when clinical cut-offs are not available.[45] To assess intervention fidelity (Aim 2), we will determine the proportion of sessions that contain all

prescribed program elements and reach YACS-based proficiency and examine intervention discrimination. For acceptability (Aim 3), we will examine means, standard deviations, and median scores calculated for intervention credibility and satisfaction measures.

Qualitative. To further assess acceptability (Aim 3), we will conduct, audio record, and transcribe verbatim key informant interviews assessing the acceptability, usefulness, and satisfaction of TEE and TEE's effect on the Veterans' use of traditional mental health services from the perspective of Veterans and their clinicians. We will use an established rapid content analysis approach commonly utilized VA-funded research.[46] Analysis will occur throughout data collection, allowing for quick and accurate reduction of qualitative data and production of results useful for evaluating ongoing interventions.[46] As transcripts become available, they will be reviewed and summarized by two members of the research team (Drs. Portnoy and Fenton). Discrepancies in the summary pairs will be discussed and resolved through consensus. We will then transfer the summaries into matrices and use matrix analysis methods to identify key themes related to the acceptability, usefulness and satisfaction of TEE.[47] Matrices systematically note the similarities, differences, and trends in responses across interviews, thereby expediting synthesis and summary of findings. We will identify themes that are evident across multiple exit interviews. These cross-cutting themes will become the framework for our final analysis, for which we will use a hybrid deductive and inductive analytic approach[48] in which the established themes will be evaluated against the data and new themes will be incorporated into the evolving coding scheme.[49]

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