

Project Title: Improving Anxiety Treatment Engagement and Effectiveness in Primary Care-Mental Health Integration: Multi-site Hybrid I RCT of a Brief Veteran-Centered Anxiety Intervention

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Background

Anxiety is prevalent but undertreated in VHA primary care. Anxiety disorders and subthreshold symptoms¹⁶ affect many Veterans³⁸⁻⁴⁰ with a 15-20% prevalence in primary care.¹ The negative impact includes functional impairment,² decreased quality of life,⁴¹ and increased healthcare utilization.^{38,42} Anxiety also increases risk for suicidal ideation and attempts,⁴³ 40% of VHA primary care patients with anxiety symptoms were at increased suicide risk.⁴⁴ Yet anxiety remains under-treated in primary care. Only half of primary care patients with anxiety disorders receive minimally adequate treatment.^{9,17} Within VHA, only 15-44% of Veterans with a new anxiety diagnosis had ≥ 1 session of behavioral treatment in the subsequent 12 months.⁴⁵ When anxiety treatment is provided, it is usually pharmacological,^{9,17} despite most patients preferring behavioral treatment.^{18,19} Anxiety treatment is a major gap in VHA, as no protocols in the Evidence-Based Psychotherapy initiative focus on non-trauma anxiety.¹⁵

PCMHI provides an opportunity to address VHA's anxiety treatment gap. VHA's Primary Care-Mental Health Integration (PCMHI) initiative²⁰ aims to improve the treatment of mild-to-moderate severity mental health conditions in primary care by embedding behavioral health providers (BHPs; e.g., psychologists, social workers) in primary care to assist PACTs. BHPs provide consultation, assessment, and brief intervention for mental and behavioral health concerns. PCMHI is integral to reducing VHA's anxiety treatment gap because most patients with anxiety who seek treatment do so in primary care.⁴⁶ Anxiety is the second most common reason for referral to PCMHI.¹¹ Offering treatment in PCMHI expands options beyond pharmacotherapy,¹⁷ improves patient-centeredness, and decreases stigma.

Brief behavioral anxiety interventions that are evidence-based and feasible for PCMHI are needed. Although a number of empirically-supported anxiety treatments have been developed for specialty mental health,⁴⁷ they are not readily translated to the PCMHI setting.²¹ Our systematic review of behavioral interventions for anxiety found that most primary care-based interventions have limited implementation potential given incompatibility with recommendations for effective PCMHI practice management (i.e., episodes of care should not exceed six, 30-minute sessions).^{21,26,48} The format of most extant interventions is not feasible for PCMHI due to the high frequency (weekly vs. every 2-4 weeks), intensity (12-20 vs. 1-6 sessions), and duration (50 vs. 30 minutes).²¹ Most interventions are disorder specific (GAD or panic disorder), which is problematic within PCMHI as comprehensive diagnostic assessment is not feasible, and many patients do not meet criteria for any one disorder, have unspecified anxiety,⁴⁵ or exhibit subthreshold symptoms¹⁶ or symptoms of multiple disorders.² In contrast to specialty care, the goal in PCMHI is to reach a large segment of the population, which necessitates lower-intensity care aimed at reducing symptoms and improving functioning.²⁶ Finally, many treatments do not account for high likelihood of comorbid depression (50-60%),² which should not be ignored given that comorbid anxiety and depression cause more functional impairment and worse treatment outcomes than either alone.⁴⁹

Although several promising anxiety interventions designed for primary care have been tested in VHA, long-term implementation potential is limited. For example, Stanley et al.'s intervention targets only generalized anxiety disorder (GAD) and includes up to 10 sessions.^{8,24} Cully et al.'s intervention was tailored specifically for patients with heart failure and/or chronic obstructive pulmonary disease.²⁵ Coordinated Anxiety Learning and Management (CALM)¹⁰ is a complex collaborative care management intervention and may raise concerns regarding cost and feasibility due to requiring annual computer program licenses, anxiety clinical specialists, psychiatric prescribers for pharmacotherapy, and up to 12, 60-minute sessions. Thus, there is an urgent need for brief behavioral interventions that are suitable to address the range of anxiety presentations (i.e., threshold and subthreshold anxiety spanning GAD, panic, social anxiety, phobias, unspecified anxiety, adjustment-related anxiety) typical among primary care patients and are truly feasible for delivery in VHA PCMHI.^{21,50}

With little to no guidance for how to deliver brief behavioral anxiety treatment, BHPs are left to idiosyncratically adapt protocols from specialty care.⁵¹ Research suggests BHPs frequently pull from cognitive-behavioral therapy (CBT).⁵² Our pilot work showed that BHPs were much more likely to deliver psycho-education (95%), relaxation training (64%), and supportive therapy (61%) than other evidence-based anxiety intervention techniques, such as exposure (21%). Further, BHPs report using a high number of techniques ($M=5.8$, $SD=2.1$) within a single session, all at low intensity (range: 2-9 minutes).¹² These usual care practices raise concerns about the appropriateness and potency of intervention that patients with anxiety are receiving.⁵³

We have developed a brief PCMHI anxiety intervention to address this critical gap in VHA care. Over the past five years culminating in the PI's HSR&D Career Development Award-2 (CDA2 #15-262), we have developed an anxiety intervention, Veterans Anxiety Skills Training (VAST), that is: (1) evidence-based (drawing from

CBT),⁴⁷ (2) transdiagnostic (able to accommodate the wide range of anxiety presentations seen in primary care),⁵⁴ (3) feasible for PCMHI (≤6, 30-minute sessions)⁴⁸, and (4) Veteran-centered (tailored to Veterans based on their treatment preferences and needs; see Preliminary Work section). VAST is a modular, CBT-skills based anxiety intervention designed specifically for VHA PCMHI (see Table 1 for details).

Table 1. Description of Key VAST Characteristics

Key Characteristic	Description
Evidence-based	- Grounded in the empirical evidence base for anxiety treatment - Emphasizes self-management coping skills from CBT, selected based on combination of clinical expertise and patient preference
Transdiagnostic	- Applicable to a range of anxiety presentations (e.g., worry, panic) - Applicable to a range of severity (subthreshold, mild, moderate) - Able to address comorbid depression symptoms
Feasible for PCMHI	- Sessions ≤30 minutes with maximum of ≤6 sessions - Material / skills can be quickly explained / demonstrated - Format and content informed by PCMHI provider barriers
Veteran-centered	- Format and content guided by Veterans' treatment preferences - Tailored to Veterans (content, terminology, graphics, & materials specifically designed to appeal to Veterans' needs and interests) - Personalized to patient (modules selected collaboratively based on specific anxiety presentation and treatment preferences)

Evidence-Based: VAST embodies evidence-based practice⁵⁵ through integration of empirically-supported CBT techniques, flexibility that allows tailoring to individual patients based on clinical expertise, and incorporation of patient preferences. VAST content was adapted from extant primary care anxiety treatment protocols to fit VHA PCMHI practice.^{8,10,24,25} Following recommendations for effective PCMHI practice,²⁶ VAST emphasizes coping skills to empower patients in self-management, specifically CBT intervention techniques (see Table 2) with demonstrated efficacy⁴⁷ in reducing anxiety: psychoeducation,⁵⁶ cognitive restructuring,⁴⁷ exposure,⁴⁷ relaxation training,⁵⁷ and mindfulness meditation.⁵⁸

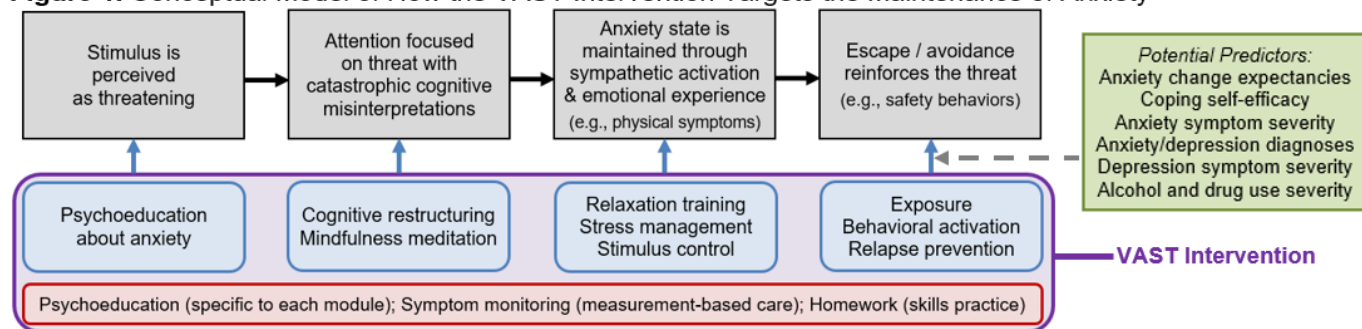
Table 2. Summary of VAST Modules

Name	Essence of Module	Rationale for Module Inclusion
Initial Session	Psychoeducation on anxiety, CBT model, and the VAST intervention	Psychoeducation normalizes, increases understanding, and provides treatment rationale
Face Your Fears	Identify avoidance behaviors and plan at-home exposures	Exposure is the most effective intervention for anxiety; Addresses behavioral symptoms
Identify Anxious Thinking	Identify strategies for challenging automatic thoughts and distortions	Cognitive therapy is effective for reducing anxiety; Addresses cognitive symptoms
Relax Your Body	Experiential demonstrations of relaxation exercises	Relaxation training is effective for reducing anxiety; Addresses bodily symptoms; Has broad appeal
Live in the Here & Now	Experiential demonstrations of mindfulness meditation exercises	Mindfulness/meditation is effective for reducing anxiety; Has broad appeal
Improve Your Mood	Identify meaningful pleasurable activities consistent with values	High comorbidity of depressive symptoms among those with anxiety
Improve Your Sleep	Identify behavioral changes to improve stimulus control for sleep	High comorbidity of insomnia among those with anxiety; Sleep was Veterans' most preferred focus
Manage Your Stress	Develop action plan for healthy stress management strategies	More approachable framing; Stress management was Veterans' most preferred therapy style
Maintain Your Progress	Develop relapse prevention plan to continue using effective coping skills	Consolidate learning; Relapse prevention (or referral for further treatment as appropriate)

Color code: Red = standard initial and final modules; Green = core skill modules; Blue = optional skill modules.

Measurement-based care (MBC) using self-report of anxiety (Generalized Anxiety Disorder-7; GAD7⁵⁹) and depressive (Patient Health Questionnaire-9; PHQ9⁶⁰) symptoms is employed to monitor progress and inform treatment planning.⁶¹ The theoretical framework underlying VAST is the cognitive-behavioral model.⁶ See Figure 1 for our conceptual model of how VAST components target the process through which anxiety is maintained. CBT, including transdiagnostic CBT,⁶² has strong empirical support for reducing anxiety.^{47,50,63}

Figure 1. Conceptual Model of How the VAST Intervention Targets the Maintenance of Anxiety



Note. Gray boxes show the anxiety process (transdiagnostic model of anxiety maintenance as reviewed by Norton⁷). Blue boxes show the 9 VAST modules. Red box shows cross-cutting features of the VAST intervention that apply across all modules. Green box shows potential baseline predictors of treatment response (dashed gray arrow represents the possible association with treatment response).

We employed a modular design given many advantages.²² Modules are self-contained, meaningful units that are inter-connected but function independently to permit flexibility.²² In VAST, after an initial session focused on assessment and psychoeducation, Veterans choose 1 of 3 core modules (exposure, cognitive coping, relaxation; Table 2) for the first skills module; these 3 are highlighted to ensure that all patients receive at least one intervention with stronger empirical support, while offering options spanning behavioral, cognitive, and physiological symptoms of anxiety. Patients then choose up to 3 additional skill modules (from the remaining core modules or 4 optional modules) followed by a final session, for a total of up to 6 sessions. Studies comparing modular and standard designs of the same CBT interventions for anxiety/depression found better outcomes for modular designs.²⁹ For example, modular CBT yielded faster improvements and better overall outcomes compared to standard CBT and usual care, whereas standard CBT did not differ from usual care.⁶⁴

Transdiagnostic: A transdiagnostic approach to CBT has been proposed by numerous experts for both theoretical (i.e., common symptoms and maintaining processes) and pragmatic (i.e., increased ease of treatment dissemination) reasons.⁵⁴ As a transdiagnostic intervention, VAST is designed to be applicable across the range of anxiety symptom presentations seen in primary care, in terms of diagnosis and severity. We also ensured the intervention is capable of addressing comorbid symptoms of insomnia, depression, and stress through optional modules due to our research finding that 64%, 58%, and 56%, respectively, of PCMHI patients being seen for a presenting complaint of anxiety report these comorbid symptoms.¹²

Feasible for PCMHI: We adapted the scope of the CBT intervention techniques to fit into a brief format (≤ 6 biweekly 30-minute sessions) based on PCMHI guidelines.^{48,50} All skills modules involve behavioral techniques that can be quickly explained/demonstrated. As CBT is the most common (87%) theoretical orientation among VHA PCMHI BHPs,¹¹ CBT skills are easily translated into practice with less training burden. With modular designs, the number of sessions and treatment duration are decreased,²⁹ as only those modules relevant to the patient are delivered. BHPs perceive modular treatment to be more responsive than standard CBT and report higher overall satisfaction compared to standard CBT or usual care.³⁰ Modular designs permit flexibility in clinical decision-making that may increase BHP acceptability of using manualized treatments.³³

Veteran-Centered: VAST has been tailored to the Veteran population and is personalized to individual patients to enhance engagement and satisfaction. The treatment type (individual), format (face-to-face), setting (VHA primary care), and provider type (BHP) were selected based on Veterans' clear preferences for this type, format, setting, and provider in our prior research.²³ We included modules on sleep (stimulus control), stress management (healthy coping strategies), and mood (behavioral activation) due to Veterans' preferences for anxiety treatment that addresses sleep difficulty, takes a stress management approach,²³ and the high comorbidity of depression,² respectively. The sleep and stress modules may be less stigmatizing to the primary care population and serve as a bridge to better engage Veterans in treatment.⁶⁵ The flexibility of a modular design also facilitates Veteran-centered care in that intervention content is tailored to individual patients, consistent with PACT's goal of enhancing personalized care.⁶⁶ Attending to patients' treatment preferences improves engagement,⁶⁶ reduces dropout by half and may even enhance outcomes.²⁸

A Parallel Focus on Implementation of VAST

When developing VAST, we made a strategic decision to emphasize feasibility for PCMHI as well as Veteran-centeredness to enhance implementation into clinical practice. RE-AIM is commonly used as a framework to evaluate intervention implementation potential by assessing *Reach*, *Effectiveness*, *Adoption*, *Implementation*, and *Maintenance*.³⁶ Our pilot data (see Preliminary Work) show high treatment engagement and acceptability

of VAST among Veterans, both of which directly impact *Reach*. Initial results for *Effectiveness* are extremely promising and will be examined in Aim 1. Study therapists rated VAST as highly acceptable, appropriate, and feasible for PCMHI, all elements that impact *Adoption* by BHPs in practice. However, an important factor in *Implementation* and *Maintenance* is BHPs' ability to implement VAST with high levels of fidelity and maintain it, meaning *adhering* to intervention content as defined in the treatment manual (e.g., proportion of essential components delivered) and demonstrating *competence* or quality of delivery (e.g., maintaining rapport).⁶⁷ High treatment fidelity is associated with better outcomes.⁶⁸ Study therapists in our pilot RCT received training and low-intensity implementation support similar to what is typically used in VHA Evidence-Based Psychotherapy roll-outs.¹ Although study therapists achieved high levels of fidelity, they were removed from the competing demands of full-time clinical practice, as all were trainees (psychology interns or fellows), which may reduce the generalizability of fidelity data. We have limited knowledge as to whether our approach to training and low-intensity implementation support will suffice to prepare real-world BHPs working in PCMHI to achieve and maintain high-fidelity delivery.

One common way BHPs reduce fidelity when implementing manualized treatments outside the context of a research study is reducing the content or number of sessions. This may be related to patient preference to not return or not complete treatment for typically unknown reasons; however, it is possible that some patients respond quickly to treatment and feel better such that they do not need the full treatment dose. Our preliminary work (see below) has found that approximately half of Veterans who receive VAST respond to treatment (i.e., demonstrate clinically significant improvements in anxiety severity and functional impairment) in half the standard episode of care (i.e., within 3 sessions). Identifying subgroups of patients likely to experience a treatment response would be informative for improving treatment efficiency and providing evidence to guide BHPs when implementing VAST, so they can present to patients evidence-based projections for treatment response. Several variables have high conceptual relevance to VAST and empirical precedent from prior research.⁶⁹⁻⁷¹ Baseline anxiety and depression severity,⁷⁰ as well as treatment expectancies and coping self-efficacy,^{69,71} predict anxiety treatment response and may thus help to identify subgroups for whom VAST is more likely to be effective. Diagnoses of specific anxiety disorders and comorbid depression, as well as current substance use, may also be relevant.^{69,72} Identifying whether these factors (baseline anxiety and depression severity and diagnoses, alcohol and drug use, anxiety change expectancies, and coping self-efficacy) predict early and overall treatment response would help guide BHPs when implementing VAST in practice.

Significance

This study addresses VHA Veteran care priorities of mental health and suicide prevention, MISSION Act priorities of increasing access to care and improving patient satisfaction, and HSR&D focus areas of quality, effectiveness, and efficiency as well as implementation science methods. Improving anxiety treatment in PCMHI will address a major gap in VHA primary care and mental health care broadly, given the absence of EBPs addressing non-PTSD anxiety.¹⁵ This work will yield a transdiagnostic intervention able to accommodate the wide range of anxiety presentations seen in PCMHI, which will increase efficiency for BHPs in training and clinical care. The hybrid I multi-site RCT design addresses VHA ORD goals to increase Veteran access to high-quality clinical trials and increase real-world impact of research, as our process evaluation will inform future implementation research to accelerate translation³⁴ into practice.

Aims

This hybrid type I multi-site RCT will evaluate the effectiveness of VAST delivered by real-world BHPs compared to PCMHI usual care in reducing anxiety (Aim 1) measured by the Overall Anxiety Severity and Impairment Scale (OASIS).³⁵ Primary care patients with elevated anxiety symptoms at two VA healthcare systems will be randomly assigned to condition. BHPs in PCMHI will be randomly assigned to condition to prevent contamination of usual care; those in the VAST condition will receive standard intervention training, supervision, and consultation. Aims 2 and 3 will help to inform future implementation of VAST in real-world PCMHI practice. Our exploratory Aim 2 is to examine patient-level predictors (e.g., baseline symptom severity) of early and overall treatment response (i.e., clinically significant improvement at 8 and 16 weeks, respectively) within the VAST condition. To guide future implementation efforts, we will conduct a process evaluation using an embedded sequential explanatory mixed methods design (Aim 3) focused on the Implementation and Maintenance domains of RE-AIM.³⁶ Specifically we will examine fidelity of VAST delivery, including the proportion of BHPs who achieve and sustain (a) minimally acceptable and (b) sufficient levels of fidelity³⁷ as well as barriers to and facilitators of high-fidelity intervention delivery. In sum, the specific aims are to:

- 1) Compare patient clinical outcomes for VAST vs. PCMHI usual care between baseline and 16 weeks (post) in a multi-site RCT in which BHPs deliver the intervention in routine care. We will also examine whether treatment gains are more likely to be maintained for VAST vs. PCMHI usual care at 28 weeks (follow-up).
Hypothesis 1: Patient-level clinical outcomes will improve more from baseline to 16 weeks for participants receiving VAST compared to PCMHI usual care.
- 2) For participants assigned to receive VAST, explore patient-level predictors of (a) early (8 weeks) and (b) overall (16 weeks) treatment response (defined as a clinically significant decrease in OASIS total score).
- 3) Conduct a mixed-methods process evaluation of VAST implementation to examine rates of, barriers to, and facilitators of achieving and sustaining high-fidelity intervention delivery.

Preliminary Work

As described above, our prior research building toward this proposal has included examining Veterans' anxiety treatment preferences²³ as well as BHP practices in PCMHI usual care for anxiety.¹²

Understanding Interventions and Challenges in Behavioral Treatment for Anxiety in PCMHI. We interviewed a national sample of 18 VHA BHPs regarding anxiety treatment in PCMHI. Recommendations for ensuring feasibility of PCMHI anxiety interventions included being able to tailor interventions to the individual patient's presentation and a modular design for flexible delivery.

Refining the Treatment Manual for a Brief Primary Care Anxiety Intervention. We interviewed 5 local BHPs. BHPs rated the number, duration, frequency, and format of VAST sessions as highly feasible ($M_s \geq 4$ out of 5) for PCMHI. Feedback was used to refine the VAST manual to improve feasibility.

We then conducted an open trial with 6 participants to pilot VAST. Treatment engagement was high. Overall, 5 of 6 participants showed clinically significant improvements across the majority of clinical outcomes. In feedback forms completed immediately after each module, participants reported that all 9 modules were helpful in learning to manage their anxiety and they were likely to try the CBT coping skill. Participants indicated high treatment satisfaction and credibility.

Reducing Anxiety and Stress in Primary Care Patients: Pilot RCT of a Brief Intervention. We are currently completing a pilot RCT to evaluate the feasibility and acceptability of VAST as well as its preliminary effectiveness in reducing anxiety compared to PCMHI usual care. Feasibility of research procedures is demonstrated by low study attrition (19%) and high assessment completion rates (96% 4-week, 96% 8-week, 86% 12-week, 75% post/16-week). Feasibility of VAST is evidenced by 92% of participants engaging in treatment (i.e., attending ≥ 1 session), and among those, attending $M=5.4$ (1.3) sessions. Further, VAST study therapists reported high participant comprehension of and engagement with session material, and high rates of homework completion. Study therapists have achieved high fidelity in adherence along with competent delivery. Acceptability of VAST among Veterans is demonstrated by significantly higher scores for therapeutic alliance, treatment credibility, and treatment satisfaction for VAST compared to PCMHI usual care. Acceptability of VAST among study therapists is demonstrated by high ratings for VAST on validated scales⁷⁶ of intervention acceptability, appropriateness, and feasibility for PCMHI. Preliminary results suggest that VAST is outperforming PCMHI usual care, and approximately half of VAST participants showed early treatment response (i.e., clinically significant decrease [≥ 4 points]⁷⁷) from baseline on the OASIS by 8 weeks.

Methods

Settings: This study will be conducted at 2 sites: the VA healthcare systems at Syracuse and Western New York, where long-standing collaborative relationships exist between clinic administrators/staff and our team. The VA Syracuse healthcare system includes the Syracuse VAMC and 8 affiliated community-based outpatient clinics (CBOCs; Auburn, Binghamton, Oswego, Potsdam, Rome, Tompkins County, Watertown, Watertown 2). The VA Western New York includes the Buffalo VAMC, the Batavia VAMC, and 9 affiliated CBOCs (Buffalo, Dunkirk, Jamestown, Lockport, Niagara Falls, Olean, Packard, Springville, West Seneca). We anticipate that approximately 1/2 of participants (~90) will come from the Syracuse system and 1/2 from the Western New York system. We have received an exception to the single IRB provision from VA ORD. We received (on 3/24/2021) separate IRB approval from the Western New York VA Health Care System IRB to cover research activities conducted with Veterans at VA Western New York.

Participants: Eligibility criteria are as follows:

Inclusion criteria:

- 1) Veteran,
- 2) Age ≥ 18 years,
- 3) Seen in the Syracuse or Western New York VAMCs or CBOCs primary care clinic in the past 12 months,
- 4) Screen positive for current (past 2 weeks) clinically significant anxiety symptoms (≥ 8 on GAD7)¹

Exclusion criteria:

- 1) Inability to communicate in English (as assessed by study staff);
- 2) Hearing impairment that precludes completion of telephone eligibility screening (as assessed by study staff);
- 3) Cognitive impairment that precludes informed consent, defined as any of the following:
 - (a) not able to comprehend the study description or eligibility screening as assessed by study staff,
 - (b) diagnosis of dementia or severe cognitive impairment per self-report, primary care provider, or Problem List, or
 - (c) screen positive for cognitive impairment (≥ 3 errors on screener);
- 4) Diagnosis of Obsessive-Compulsive Disorder (OCD) or serious mental illness (SMI, i.e., psychotic disorders, bipolar disorder) in Problem List;
- 5) Encounter diagnosis of PTSD within the past 2 years or screen positive for PTSD (≥ 4 for men or ≥ 5 for women on the Primary Care PTSD Screen for DSM-5 [PC-PTSD-5]⁸⁴);
- 6) Currently in psychotherapy/counseling for anxiety and/or depression, defined as any of the following within the past 30 days:
 - (a) attending ≥ 1 non-intake specialty mental health session,
 - (b) attending ≥ 2 PCMHI sessions, or
 - (c) being hospitalized for mental health treatment;
- 7) Current (past 2 weeks) severe depressive symptoms (≥ 20 on PHQ9);
- 8) At imminent risk of suicide, defined as being in need of intensive treatment (e.g., hospitalization) to ensure safety, based on study staff's suicide risk assessment (verified by the PI);
- 9) Started or had dosage change in psychotropic medication for anxiety or depression in the past 30 days

Rationale: The population of interest is Veteran primary care patients with clinically significant anxiety symptoms, so a cutoff score of ≥ 8 on the GAD7 was selected to follow prior research¹ as it optimizes the balance of sensitivity and specificity. We limited the eligibility criteria as much as possible (e.g., not requiring specific anxiety disorder diagnoses, not excluding those with depression or substance use diagnoses) and do not prohibit (but will track) medication changes during the trial so our results will generalize more broadly. We will exclude Veterans with mental health concerns that suggest treatment needs greater than primary care, such as SMI, cognitive impairment, inpatient hospitalization in last 30 days, severe depressive symptoms, or imminent risk for suicide. PTSD and OCD are no longer considered anxiety disorders, and VAST is not designed to treat trauma or OCD. We will exclude those who are currently in psychotherapy for anxiety and/or depression to eliminate confounding treatment. We will allow patients to be on medication for anxiety and/or depression, provided it was started or the dosage was stabilized at least 30 days prior.⁸ Veterans with a recent medication change will be asked if they want to be re-screened after 30 days stable.

Recruitment: Recruitment will occur using 5 methods we have used in prior studies, including the current pilot RCT: (1) direct referrals from PCPs, other Patient-Aligned Care Team members, PCMHI BHPs, or the specialty mental health clinic, (2) flyers in primary care waiting rooms or VAMC physical or electronic bulletin boards, (3) referrals from other local PCMHI research studies, (4) case finding for patients referred for anxiety from primary care or other specialty medical clinics to the outpatient mental health clinic and (5) case-finding for patients (a) with anxiety in primary care encounter diagnoses in the last month or (b) referred to PCMHI for anxiety. The latter method of case-finding in primary care yields the most participants. Identified Veterans are sent recruitment letters (sent with primary care provider approval) describing the study and alerting them that staff may call in 7-14 days to explain the study. Letters include a telephone number to call to opt out of any future contact if the Veteran prefers not to be called. We have support from primary care and PCMHI leadership to use these recruitment methods. There are several other local behavioral health research studies,

and patients who are ineligible for other studies may be interested in a referral to this study if it seems appropriate.

For case finding recruitment methods, potential participants will be identified via data pull from CPRS. Thus, we are requesting a waiver of HIPAA authorization for recruitment to pull data or conduct chart reviews and case finding. The information will allow us to check whether Veterans meet certain inclusion and exclusion criteria, contact Veterans who may be eligible to tell them about the study, identify the correct patients, attempt to recruit participants with sociodemographic diversity, and ensure Veterans are able to receive compensation if they decide to participate. We will pull data for all living Veterans who meet inclusion criteria 1, 2, and 3 and have an anxiety diagnosis in (a) their Problem List or (b) recent primary care encounter, but do not meet exclusion criteria 3, 4, 5, 6, or 9.

In addition to VISN2 data pull or study staff chart review of the VA electronic medical record, recruitment lists may be obtained through the VA Informatics and Computing Infrastructure (VINCI). VINCI is a VA Health Services Research & Development (HSR&D) resource center that provides a secure, central analytic platform for performing research activities within VA. VINCI includes servers for securely hosting databases from VA data sources including the VA electronic medical record. Recruitment lists are generated through VINCI with an IRB-approved data request to the VA Corporate Data Warehouse, where data are prepared and placed into a secure database for use only by approved members of the study team.

Sample size: Based on power calculations (see below) factoring in an expected attrition rate of 20% (based on the pilot RCT and Dr. Funderburk's RCT of a PCMH depression intervention [HSR&D IIR 14-047]), we will recruit 178 participants (89 per condition). Based on the pilot RCT, 45% of Veterans reached will complete eligibility screening; of those screened, 28% will be eligible, and of those eligible, 85% will enroll in the RCT. Thus, we expect to screen up to 748 Veterans to obtain 178 enrolled participants. Our prior work suggests approximately 85% of participants will be male and 75% will be White consistent with local demographics. We seek to recruit a diverse sample and will oversample females and racial/ethnic minorities as needed if the sample is skewed from local demographics. We anticipate that approximately 1/2 of participants will come from Syracuse and 1/2 from Western New York.

After 2 years of recruitment, due to much better than anticipated retention rates, we re-ran the power calculations, which indicated we would obtain 80% power with only 169 randomized (9 fewer than 178, or 5% of total). With approval, we ended recruitment with 169 randomized out of 177 consented (5 did not complete baseline, 1 found to be ineligible after baseline, 2 unresponsive to attempts to randomize). We later determined that 2 participants (Western New York) should have been deemed ineligible, so the final sample size was 167.

Eligibility screening: Eligibility criteria obtained from data pull will be reviewed first, then screening (15 minutes) will be done by telephone to reduce Veteran burden. (VA Video Connect [VVC] is also possible if Veterans request this format rather than telephone. If Veterans specifically request in-person eligibility screening, we will accommodate their preference if national and local VA policy and public health guidance related to the COVID-19 pandemic permits face-to-face encounters). During this initial screen, the research assistant conducting the screening will briefly describe the study, nature of the screening questions, and limits to confidentiality. We are seeking a waiver of informed consent for the eligibility screening because (a) answering the screening questions is minimal risk being very similar to completing annual VA clinical reminders (e.g., PHQ9) in primary care, (b) although we are not obtaining full verbal consent for screening to keep the time burden lower for Veterans, we will provide sufficient details about the study and screening for Veterans to make an informed decision to participate in the screening, (c) we will obtain informed consent to enroll in the study at the baseline session, and (d) the study could not be feasibly carried out without the brief eligibility screening given the number of patients who must be screened. For Veterans who agree to be screened, we will screen for cognitive impairment and current symptoms of anxiety, depression, and PTSD and assess current mental health treatment (past-month psychotherapy, pharmacotherapy, and inpatient psychiatric hospitalization). For any Veteran who reports suicidal ideation on PHQ-9 item 9, research staff will follow the detailed suicide risk assessment protocol as appropriate to evaluate and ensure safety (assessments will be reviewed with the PI or co-Is [all licensed psychologists] for clinical supervision).

Veterans who are interested and eligible based on the eligibility screening will be scheduled for a baseline assessment. If the baseline assessment is not able to be conducted within 14 days of eligibility screening, we will reconfirm eligibility prior to the baseline by re-screening with the GAD7 and PHQ9 since these symptoms may fluctuate. If the baseline is not able to be conducted within 30 days of eligibility screening, we will

reconfirm eligibility prior to the baseline by re-administering the GAD7, PHQ9, PC-PTSD-5, and past-month mental health treatment history. At the baseline reminder call, staff will re-confirm eligibility related to recent counseling/psychotherapy for anxiety and/or depression via Veteran self-report and/or chart review.

Baseline assessment: When scheduling the baseline assessment, standard VHA treatment format options (in-person, telephone, VA Video Connect (VVC) will be offered as appropriate (in-person will only be used if national and local VA policy and public health guidance related to the COVID-19 pandemic permits face-to-face encounters). We will use VVC whenever possible. At the beginning of the appointment, we will verify the participant's current location and phone number to ensure if any disruptions occur, we can re-contact the Veteran and provide assistance.

For participants who opt to complete the baseline assessment via telephone or VVC, we will send two copies of the IRB-approved consent/HIPAA authorization form via mail, along with a pre-addressed, pre-stamped envelope for the participant to return their signed form to the research staff at the Syracuse VAMC. The mailed packet will also include copies of the response options for some of the baseline questionnaires as well as an information sheet with relevant phone numbers for VA behavioral health services and crisis resources including the Veterans Crisis Line. The participant will be able to reference these materials during the informed consent process and will be asked to sign the consent/HIPAA authorization form during the telehealth appointment prior to completing any baseline questionnaires. Participants will be asked to return the signed form to us using the self-addressed envelope.

After providing written informed consent by signing the consent form during the baseline session, participants will complete the baseline assessment (90 minutes, \$40 compensation) consisting primarily of self-report measures, mental health treatment history, and a brief structured diagnostic interview (see Table 3 for schedule of measures).

Other assessments: Staff conducting all assessments will be blinded to condition. The 4-, 8-, and 12-week brief assessments (10 minutes, \$10 each) will be conducted by telephone to reduce burden, and the baseline (90 minutes, \$40), 16-week post (90-120 minutes, \$50), and 28-week follow-up (~3 months after post, 30 minutes, \$40) assessments will be offered as in-person once national and local VA policy and public health guidance related to the COVID-19 pandemic permits face-to-face encounters; however, to reduce burden, Veterans will have the option to complete any assessment via telephone or VVC if preferred or necessary. We will offer a modest additional retention incentive of \$40 for completing all 6 assessments, so the maximum total compensation is \$200 during the 7-month study.

To increase retention in assessments, participants may receive reminder calls, texts, and/or letters. Letters are especially helpful for the post and follow-up assessments given the time gap from the prior study contact. Texting will be offered for Veterans' convenience, and they can opt in to that format of contact at baseline if they want. Study staff will not text PHI and will remind Veterans that this method of communication is not secure so they should not text any PHI to us. If we are ever unable to reach someone by telephone, we will send a letter requesting a return call at their convenience if still interested in learning about / continuing with the study.

Veteran participant randomization: Participants will be randomized to either VAST or PCMHI usual care using stratified block random assignment based on

- (1) site (Syracuse vs. Western New York),
- (2) anxiety severity (GAD7 score of <15 vs. ≥15), and
- (3) depression severity (PHQ9 score of <15 vs. 15-19).

GAD7 scores ≥15 indicate severe symptoms,⁵⁹ and PHQ9 scores of 15-19 indicate moderately severe symptoms.⁶⁰

PCMHI usual care condition: Within the PCMHI usual care condition, BHPs can choose to deliver whatever care they deem appropriate. All sessions will be audiotaped. (If the audio recorder should fail, the BHP will be asked to complete the recording form as self-report after the session.) Independent raters will review a random sample of 25% assess the intervention techniques used and dosage (minutes). We used this process successfully in the pilot RCT, demonstrating feasibility.

Intervention condition: Within the VAST condition, BHPs will conduct up to six 30-minute sessions (generally

biweekly, but with flexibility for Veteran scheduling preferences). All sessions will be audiotaped. (If the audio recorder should fail, the BHP will be asked to complete the recording form as self-report after the session.) The treatment manual is grounded in evidence-based practice and is applicable across a range of anxiety symptom presentations (i.e., type [e.g., generalized anxiety, social anxiety, panic symptoms] and severity [subthreshold, mild, moderate]). We adapted intervention techniques from cognitive-behavioral therapy (CBT) that have demonstrated efficacy in treating anxiety,^{47,56,57} as well as behavioral activation for depression and stimulus control for insomnia. All of the included intervention techniques have been used within modules in prior studies of primary care-based anxiety treatment with good results.^{8,10,24,25} The manual emphasizes a psycho-educational approach and teaching self-management skills²⁶ to empower patients using behavioral techniques that can be quickly demonstrated in session and assigned for at-home practice. Consistent with prior research,^{8,10,24,25} we employed a modular approach in the treatment manual to facilitate tailoring the content to individual patients. The choice and order of modules used within the intervention will be a collaborative decision between the therapist and patient based on patient preference in combination with therapist clinical recommendations. Participants will often complete self-report measures of anxiety and depression symptoms (GAD7/PHQ9) as part of measurement-based care.⁶¹ (Participants who endorse >0 on the PHQ-9 item 9 will be assessed further consistent with VA clinical practice guidelines.) BHPs will track GAD7/PHQ9 scores and modules in brief post-session checklists.

Treatment format and documentation: For both conditions, whenever possible study staff will make the initial treatment session scheduling contact for consistency, and standard VHA treatment format options (in-person, telephone, VA Video Connect) will be available. For all participants, study initiation (baseline) and completion (28-week follow-up assessment) notes or dropout/withdrawal notes (as applicable) will be entered into CPRS. Due to the need to maintain blinding of assessment staff through the 28-week follow-up assessment, a progress note will not be entered for the 16-week post assessment, unless the participant demonstrates a worsening in risk level (e.g., suicidality develops/increases), in which case a note will be entered so that the healthcare team is aware for clinical reasons. For all treatment sessions, progress notes will be entered into CPRS consistent with standard PCMHI documentation practices.

Provider recruitment: All BHPs working in PCMHI (e.g., psychologists, clinical social workers) at the Syracuse and Western New York healthcare systems, including full-time, part-time, and trainee (e.g., interns, fellows) will be eligible for recruitment. Recruitment invitations will be offered verbally during PCMHI or primary care staff meetings and/or via email or provider study list. Recruitment invitations will briefly describe the study and invite interested individuals to contact the PI to learn more. PCMHI Team Leads at both sites strongly support the project. To ensure we avoid undue influence with any trainees working in PCMHI, we will emphasize the voluntary nature of participation in the study and that the decision to participate or not has no bearing on success or evaluation in their training programs.

Interested providers will meet with a research assistant to hear more about the study. We will obtain informed consent to participate in the study, including permission to audio record treatment sessions. We are requesting a waiver of written documentation of informed consent to allow for verbal informed consent instead given that participation is minimal risk for providers. We will collect basic demographics and training background (e.g., time in PCMHI) to be able to describe the sample of providers, but as always providers can skip any questions they don't want to answer. Brief measures (administered during protected time) before and after the VAST intervention training will be used to assess whether the training is helpful for providers and to obtain feedback on how to improve the training to inform future implementation. Brief interviews will assess feedback on implementation of the intervention. Treatment session recordings are consistent with standard procedures used in VA Evidence-Based Psychotherapy rollouts that many VA providers complete and will not be shared with anyone outside the research team.

Provider randomization: BHPs will be randomized to providing either VAST or PCMHI usual care to all study participants. We will stratify by site and provider type (full-time vs. part-time or trainee). BHPs who leave during the study will have to be replaced in the same condition to ensure coverage of both conditions across sites, but any new providers will be randomized to condition.

Intervention training, supervision, and fidelity assessment: BHPs randomized to the VAST condition will receive appropriate training and supervision to ensure delivery with acceptable fidelity. Fidelity ratings will be used to monitor fidelity for quality control and for Aim 3. Minimally acceptable and sufficient adherence will be defined

as mean adherence of $\geq 60\%$ and $\geq 76\%$,³⁷ respectively, of essential component delivery across all sessions in an episode of care (i.e., up to 6 sessions) for ≥ 1 participant (or in the training role play). Minimally acceptable and sufficient competence will be defined as “more capable than deficient” and “predominantly capable,” respectively, which correspond to the majority of domains being rated as capable and skilled, respectively.³⁷ Minimally acceptable/sufficient fidelity comprises both adherence and competence that are minimally acceptable/sufficient. Fidelity data will be made available only to VAST supervisors (not administrative supervisors). Failure to reach minimally acceptable fidelity for ≥ 2 participants will trigger an offer of supplemental individual supervision as needed.

BHPs assigned to VAST will receive initial training by the PI using a training plan developed in the pilot RCT, then 1 hour of monthly group supervision (case review) with the PI or co-I Johnson to support intervention fidelity. BHPs will also be invited to optional monthly 1-hour group consultation calls (general VAST implementation). Supplemental individual supervision will be offered as necessary for BHPs failing to reach minimally acceptable fidelity. BHPs must reach the minimally acceptable level of fidelity in a role play to be approved to see participants. All sessions will be audio-recorded. (If audio-recording fails, the BHP will complete the adherence portion of the treatment fidelity measure after the session. Independent raters (trained by the PI) will complete fidelity ratings (with double-rating of 20% of sessions to ensure adequate inter-rater reliability), per the following schedule: (1) all sessions for at least the first 2 participants for each BHP or subsequent participants until achieving minimally acceptable fidelity, (2) random selection of 50% of sessions for the next 4 participants, and (3) for any additional participants beyond the first 6, a random selection of 20% of core modules delivered (Relax Your Body, Face Your Fears, Identify Anxious Thinking - which embody the essence of the intervention and thus have highest utility for assessing fidelity).⁸⁵

Measures: see Table 3 summary of patient measures and administration times

Eligibility screening

Demographic information collected during the screening includes sex, age, race, ethnicity. Additional demographics and lifetime use of mental health treatment will be collected at baseline to describe the sample. All measures of psychological constructs have strong psychometrics in terms of reliability and validity.

Anxiety symptom severity will be measured by the GAD7 self-report questionnaire,⁵⁹ which is widely used in PCMHI for MBC.⁶¹ The total score indicates severity of anxiety symptoms: minimal (0-4), mild (5-9), moderate (10-14), severe (15-21).⁵⁹ The GAD7 ($\alpha = .92$) has demonstrated construct and criterion validity and is a good screening tool for common anxiety conditions.¹

Depressive symptom severity will be measured by the PHQ9 self-report questionnaire ($\alpha = .86$),⁶⁰ which is widely used in VHA⁶¹ and has good construct and criterion validity. The total score indicates severity of depressive symptoms: minimal (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), severe (20-27).

Cognitive impairment will be assessed using a 6-item screener adapted from the Mini Mental Status Examination to provide an unobtrusive brief screening tool for telephone or in-person use in clinical research.⁸⁶ A cutoff score of ≥ 3 errors has high sensitivity and specificity for cognitive impairment and dementia.⁸⁶

Presence of probable PTSD will be assessed using the 6-item Primary Care PTSD Screen for DSM-5 (PC-PTSD-5).⁸⁷ A cutoff score of ≥ 4 for men and ≥ 5 for women is optimally efficient.⁸⁴

Treatment history will be assessed using a brief interview covering mental health treatment in the past 30 days at eligibility screening and lifetime at baseline.

Primary outcome

Anxiety severity and impairment will be measured using the 5-item OASIS,³⁵ which was designed for use across anxiety disorders and subthreshold symptoms. Participants indicate frequency and intensity of anxiety, level of avoidance, and interference with activities and social functioning on a Likert scale from 0 (none) to 4 (extreme/all the time).³⁵ A total score of ≥ 8 indicates clinically significant anxiety.⁸⁸ The OASIS demonstrates reliability ($\alpha = .84$) and validity in primary care patients⁸⁸ and is sensitive to change.⁸⁹

Secondary outcomes

Anxiety and depression symptom severity will be measured with the relevant 7-item subscales of the Depression Anxiety Stress Scale-21 (DASS),⁹⁰ adding a fine-grained assessment of symptom severity to

complement the OASIS. Participants indicate how much each item applies to them over the past week. This measure has good psychometric properties in clinical and non-clinical samples⁹¹ and reliably distinguishes between symptoms of anxiety (panic/worry), stress (tension/agitation), and depression (low mood/anhedonia).

Additional pre-specified outcomes

Overall functioning will be measured using the 3-item Sheehan Disability Scale (SDS), a self-report measure of general impairment.⁹² The SDS comprises 11-point discretized analog scales assessing how much psychiatric symptoms impair work, social, and family life. The SDS has good reliability and is sensitive to change.⁹²

Quality of life will be measured using the 16-item Quality of Life Enjoyment and Satisfaction Questionnaire–Short Form (Q-LES-Q-SF),⁹³ which is reliable ($\alpha=.86$) and valid.

Suicidality will be assessed using the 8-item Columbia-Suicide Severity Rating Scale (CSSRS),⁹⁴ part of the CDE and VHA's current suicide screening measure. The CSSRS has strong predictive validity and is sensitive to change.⁹⁴ We will use the total score as well as the VHA dichotomous suicide screening scoring.

Potential predictors of treatment response

Baseline anxiety and depressive symptom severity will be based on GAD7 and PHQ9 total scores.

Diagnoses (GAD, social anxiety disorder, panic disorder, agoraphobia, specific phobia, major depressive episode) will be assessed with the Mini International Neuropsychiatric Interview (MINI) version 7.0.2 for DSM-5.³ The MINI has good reliability and validity⁴ and its brevity is ideal for PCMHI settings.⁵

Anxiety change expectancies will be assessed with a 20-item Anxiety Change Expectancy Scale, which has good reliability and predictive validity beyond baseline symptomatology.⁹⁵

Coping self-efficacy will be assessed with the 26-item Coping Self-Efficacy Scale,⁹⁶ which assesses perceived self-efficacy in coping with life's challenges.

Alcohol use will be assessed with the 10-item Alcohol Use Disorder Identification Test (AUDIT).¹³

Drug use will be assessed with the 10-item Drug Abuse Screening Test (DAST).¹⁴

Tertiary outcomes, additional predictors, and potential mechanisms

We are including several tertiary treatment outcomes, additional exploratory predictors of treatment response, and potential mechanisms of the treatment effects. These measures will help to inform future research.

Changes in pharmacotherapy (start new medication, stop existing medication, or dosage change) will be assessed at the 4, 8, 12, 16, and 28 week assessments.

Therapeutic alliance will be assessed at post using the 12-item Working Alliance Inventory-Short Form Revised (WAI-SR),¹⁰⁷ which asks patients to rate their experience of the therapist in terms of quality of the relationship bond, agreement on the goals of treatment, and agreement on the tasks of treatment. This measure has good reliability and validity.^{107,108}

Treatment satisfaction will be assessed at post by the Client Satisfaction Questionnaire (CSQ), an 8-item self-report questionnaire with evidence of reliability ($\alpha = .93$) and validity.¹⁰⁹ Each item rating and the total CSQ score will be used to evaluate participants' satisfaction with the treatment they received.

Treatment credibility will be assessed at post using a 4-item adapted version¹¹⁰ of the Expectancy Rating Scale (ERS),¹¹¹ which asks patients to rate how logical this type of anxiety treatment seems, how confident they are that the treatment would eliminate anxiety, how confident they would be in recommending the treatment to a friend with anxiety, and how much improvement they expect to result from it.

Treatment expectancies will be assessed using two single item measures of outcome expectancies, which have been used in prior research.¹⁴⁰ One item is a cognitive measure of expectancies while the other is an affective measure of expectancies.¹⁴¹

Worry will be assessed using the Abbreviated Penn State Worry Questionnaire (PSWQ-A)¹¹⁸ which consists of 8 items evaluating one's ability to control worry and tendency to worry.

Somatic symptoms will be measured using the Somatic Symptom Scale-8 (SSS-8)¹¹⁹ which assesses the presence or absence of somatic symptoms and severity of those symptoms.

Sleep will be measured using the Insomnia Severity Index (ISI),¹¹² which consists of 7 items evaluating perceived insomnia (e.g., severity, satisfaction with sleep pattern, interference with daily functioning) over the past week. The ISI has good evidence of reliability and validity in clinical and community samples.¹¹³ It is

responsive to insomnia treatment¹¹³ and performs well as screening tool for insomnia.¹¹²

Behavioral avoidance will be measured using the Behavioral Avoidance subscale of the Multidimensional Experiential Avoidance Questionnaire (MEAQ),¹¹⁴ which consists of 11 items assessing overt situational avoidance of unpleasant emotions.

Readiness to change will be assessed with a 1-item readiness ruler (adapted¹¹⁵) that asks respondents to indicate how ready they are to make a change to improve their anxiety, that is, how ready they are to try out new skills learned in treatment for anxiety at home, outside of appointments. The scale ranges from 1 (not ready to change) to 10 (already trying to change).

Anxiety sensitivity will be assessed using the Short Scale Anxiety Sensitivity Index (SSASI)¹²⁰. This scale measures fear of anxiety-related physical, cognitive, and social symptoms.

CBT-mindedness will be measured using the Cognitive Behavioral Therapy Suitability Scale¹²¹ which assesses attitudes aligned with CBT.

Pain intensity and interference will be measured using the PEG,¹¹⁶ which is an ultra-brief, 3-item measure. Participants indicate their pain intensity, pain interference with enjoyment of life, and pain interference with general activity in the past week. The PEG has good reliability and validity and is sensitive to change.¹¹⁶ This measure will be included because chronic pain is extremely prevalent in the VHA primary care population and is associated with greater psychological distress,¹¹⁷ and it may impact treatment engagement or effectiveness.

Social support will be measured using the Medical Outcome Study Social Support Survey (MOS-SSS),¹²³ which assess availability of four types of social support (e.g., tangible, emotional-informational).

Loneliness will be measured using the 3-item version of the UCLA Loneliness Scale,¹³⁷ which measures overall loneliness.

Health literacy will be measured using VA's single-item screen that asks how confident the patient is in filling out medical forms by themselves¹²⁴.

Decisional balance for anxiety will be measured using the Decisional Balance Scale¹²² which is a 10-item scale that assesses the pros and cons of facing feared stimuli.

Lack of emotional awareness and Lack of emotional clarity will be measured using the Difficulties in Emotion Regulation Scale (DERS)¹²⁵ awareness and clarity subscales, respectively, which assess the degree to which one is aware of and recognizes the nature of the emotions that they are experiencing, respectively.

Perceived control will be measured using the Anxiety Control Questionnaire (ACQ)¹²⁶ which assesses perceived control over emotional reactions and external threats.

Knowledge about anxiety, relapse prevention, and coping will be assessed using one item each from the Illness Management and Recovery (IMR) measure.¹²⁷

Cognitive restructuring use and behavioral activation use will be assessed using the Cognitive-Behavioral Therapy Skills Questionnaire (CBTSQ)¹²⁸ which measures patients' utilization of CBT skills.

Mindfulness will be measured using the 5-item version of the Mindful Attention and Awareness scale¹²⁹ which assesses the ability of the patient to observe what is taking place in the present.

Perceived stress was measured using the PSS-4¹³⁰ which assesses the degree to which one perceives experiences in their life as stressful.

Social determinants of health will be captured via screening results for food insecurity, homelessness, and interpersonal violence from the participant's VA medical record.

Social needs will be measured using the Addressing Circumstances & Offering Resources for Needs (ACORN) measure.¹³⁹ The screener assesses health-related social needs of Veterans.

Healthcare engagement will be measured by the 8-item short form of the Healthcare Engagement Measure (HEM).¹³⁸ This scale assesses how patients feel about the care that they receive.

Medical complexity will be assessed using the Charlson Comorbidity Index,¹³¹ which uses a weight index to categorize the medical comorbidity of patients. The CCI is based on diagnoses pulled from the individual's VA medical record.

Healthcare utilization will be assessed using self-report items about non-VA appointments (primary care, emergency department, and mental health visits) at baseline (covering 12 months prior to baseline), post (covering 4 months active treatment phase of the study, and follow-up (covering 3 months since post assessment). We will also conduct a data pull to obtain objective data from CPRS on VA appointments (primary care, emergency department, and mental health visits) in the 12 months prior to study enrollment, the 4 months in the active treatment phase of the study, and the 12 months after the post assessment. The following information will be pulled for any VA appointments occurring during the covered periods: date, provider, stop codes (to identify clinic setting), CPT codes (to identify type of appointment), duration, and diagnoses.

Treatment goals will be assessed at baseline and post using open-ended questions regarding what Veterans hope to gain from anxiety treatment.

Table 3. Summary of Patient Measures and Time of Administration

Measure	Construct	Eligibility screening	Baseline	4/8/12-week Interim	16-week Post	28-week Follow-up
Demographics	Demographics	x	x			
Screener	Cognitive impairment	x				
GAD7	Anxiety symptom severity	x	x		x	x
PHQ9	Depressive symptom severity	x	x		x	x
PC-PTSD-5	Probable PTSD (screen)	x				
Treatment history	Psychotherapy & pharmacotherapy	x (last month)	x (lifetime)	x (meds)	x	x
MINI	Anxiety & depression diagnoses		x			
ACE	Anxiety change expectancies		x			
CSE	Coping self-efficacy scale		x		x	x
AUDIT	Alcohol use		x		x	x
DAST	Drug use		x		x	x
OASIS	Anxiety severity & impairment		x	x	x	x
DASS	Anxiety & depression symptoms		x	x	x	x
SDS	General functioning		x		x	x
QLESQSF	Quality of life		x		x	x
CSSRS	Suicidality		x		x	x
WAI-SR	Working alliance				x	
CSQ	Treatment satisfaction				x	
ERS	Treatment credibility				x	
PSWQ-A	Worry		x		x	x
SSS-8	Somatic symptoms		x		x	x
ISI	Insomnia severity		x		x	x
MEAQ-BA	Behavioral avoidance		x		x	x
RTC	Readiness to change anxiety		x			
SSASI	Anxiety sensitivity		x		x	
CBT-SUITS	CBT-mindedness		x			
PEG	Pain intensity and interference		x		x	x
MOS-SSS	Perceived social support		x		x	
Health literacy	One-item screen for health literacy		x			
DBS	Decisional balance for anxiety		x			
DERS-C	Lack of emotional clarity		x		x	
DERS-A	Lack of emotional awareness		x		x	
ACQ	Perceived control		x		x	
IMR item	Knowledge about anxiety		x		x	x
IMR item	Coping		x		x	x
IMR item	Relapse prevention plan		x		x	x
CBT-SQ	Cognitive restructuring use		x		x	x
CBT-SQ	Behavioral activation use		x		x	x
MAAS-5	Mindfulness/present awareness		x		x	
PSS-4	Perceived stress scale		x		x	x
Social determinants	Screening results (from VA EMR)		x			
Complexity	Charlson Comorbidity index (EMR)		x			
HCU	Healthcare utilization		x		x	x
Tx goals	Treatment goals		x		x	
HEM	Healthcare Engagement		x		x	
ACORN	Social needs		x		x	
Expectancies	Treatment Expectancy (cognitive)		x		x	
Expectancies	Treatment Expectancy (affective)		x		x	
UCLA	Loneliness		x		x	

Note: green = eligibility screening, orange = predictors, blue = primary and secondary outcomes, yellow = additional outcomes and predictors as well as exploratory mechanisms

Process evaluation

VAST Treatment fidelity among providers

Treatment fidelity will be measured using the VAST fidelity measure developed and refined in our pilot RCT. Adherence is assessed via dichotomous indicators of whether specific subcomponents were delivered and scoring rules to yield the proportion of essential components delivered. Competence is assessed on a 4-point scale from inadequate to proficient skills.³⁷ Essential components for adherence and domains for competence (e.g., rapport, personalization) were selected based off the theory and goals of our intervention and consideration of the fidelity measurement literature. Each module has a unique adherence measure; all modules use the same competence measure. We have achieved good interrater reliability in our pilot RCT. Across 29 double-rated sessions, kappa = .66 for adherence (substantial agreement⁹⁷) and intraclass correlation coefficient = .63 for competence (moderate agreement⁹⁸).

Aim 3 will use an embedded sequential mixed methods (QUANT → qual) design⁹⁹ for our process evaluation of VAST implementation, focusing on the RE-AIM³⁶ domains of Implementation and Maintenance, specifically fidelity of VAST delivery within real-world VHA PCMHI practice. Fidelity outcomes include the mean adherence and competence across (a) all sessions for the first 2 participants for all BHPs (fidelity after initial training), (b) all sessions after reaching minimally acceptable fidelity (sustainability), (c) the entire study (overall fidelity), the mean number of participants who complete VAST prior to the BHP reaching (d) minimally acceptable fidelity and (e) sufficient fidelity (time required to reach fidelity), and the proportion of BHPs who: (f) achieve and (g) maintain minimally acceptable fidelity, (h) achieve and (i) maintain sufficient fidelity during the study, and digress back to below (j) minimally acceptable and (k) sufficient fidelity after reaching sufficient fidelity. Qualitative data will be used to elaborate on fidelity results. Qualitative data will include notes made by BHPs in post-session checklists, a tracking log kept by study staff of BHP engagement in implementation support activities (e.g., consultation calls), and semi-structured interviews with BHPs assigned to the VAST condition occurring twice: (a) after BHPs have had 2 participants complete VAST and (b) in study years 2-3 (or sooner if the BHP departs their position/PCMHI). Both interviews will assess barriers and facilitators to high-fidelity delivery of VAST and feedback on VAST intervention training and implementation support, but the early interviews will focus on the initial training and the latter interviews will focus sustainability over time. At enrollment we will administer a brief demographic and background questionnaire (e.g., discipline, years in PCMHI setting). Measures administered before and/or after VAST intervention training to assess its adequacy include two subscales of the Evidence-Based Psychotherapy Attitudes Scale,¹³³ the Training Satisfaction Rating Scale,¹³⁴ and brief measures adapted from prior work¹³⁵ of typical practice, knowledge/beliefs about VAST, self-efficacy to deliver VAST, and qualitative feedback regarding how to improve the training to improve future implementation. At each interview, providers will complete 4-item validated measures of VAST feasibility, acceptability, and appropriateness for PCMHI.¹³²

Data Analysis and Statistical Considerations

Power Analysis

Aim 1: Our primary aim of this longitudinal randomized two-arm parallel group clinical trial is to adequately test our primary null hypothesis (Hypothesis 1) of no differences in anxiety severity and impairment measured by the OASIS between VAST and PCMHI usual care across a 16-week treatment period. Multilevel modeling (MLM) using a random coefficients model will be used to test Hypothesis 1 by assessing the group by time fixed effect coefficient. A sample size of 178 (89 per group) will offer at least 80% power to detect a medium effect of .50 in the group by time coefficient with an experiment-wise alpha of .05 (2-tailed).

To estimate sample size, we employed the Hedeker method for multi-level longitudinal designs¹⁰⁰ using preliminary results from our pilot RCT comparing VAST to PCMHI usual care. A significant reduction in OASIS total score was observed within the VAST arm resulting in a large between-group effect (Cohen's d 2.0). Since PCMHI usual care presumably contains elements of VAST, albeit fewer and at lower dosages, the true effect size is likely lower than that observed in our pilot. Also, effect sizes ranging from .37²⁵ to .50²⁴ and .85⁸ have been observed in prior primary care anxiety treatment studies. Therefore, we have conservatively selected a mid-range effect of .5 in-line with prior research while achieving more than adequate power for effects closer to those found in our pilot study. Estimates from our pilot RCT of the random intercept variance ($\tau_0=11.2$), covariance (-.4), slope ($\tau_1=.07$) and residual variance ($\sigma^2=2.9$) were used in conjunction with an anticipated effect size of 0.5 at week 16 to calculate the sample size necessary to adequately test our primary hypothesis. A benefit of the Hedeker method is that it incorporates rates of missing data across time into the sample size

algorithm to ensure adequate power. Our sample size of 178 is adjusted for a steady decreasing attrition/missing data rate (8%, 5%, 4%, 3%) every 4 weeks after baseline. We determined the overall 20% attrition rate using our pilot RCT and co-I Dr. Funderburk's recent RCT of a PCMH intervention conducted at our 2 sites.

To estimate power for our two secondary outcomes of anxiety and depression symptom severity measured by the two respective DASS subscales at the 16-week post-assessment, we lowered the alpha from 5% to 2.5%. A lower alpha was selected in order to not inflate the experiment-wise alpha due to testing two correlated outcomes on the same patient group. Utilizing fixed and random effect estimates from our pilot RCT, our sample size of 178 patients provides at least 80% power to detect effects in the 0.7 range. A lower random effect co-variance between intercept and slopes of OASIS allows for detection of smaller effect sizes than the two specific anxiety and depression symptom severity subscales. Nonetheless, effect sizes calculated from our pilot data were greater than 1.0, for which this clinical trial is more than adequately powered.

Three other secondary measures of tertiary importance are quality of life (QLESQSF), general functioning (SDS), and suicidality (CSSRS). While relevant to the scope of this trial, they are descriptive and exploratory in nature; thus, power is not warranted. Means (SD) and confidence intervals will be calculated for the purpose of describing effects within groups. Hypothesis tests will be undertaken with care given to the reporting of results given that Type I and II error rates are not well defined.

Aim 2 is an exploratory analysis and Aim 3 is primarily a descriptive analysis so power is not warranted.

Data Analysis

The data analytic strategy emanates from the primary aim and is in line with the method used to estimate the sample size necessary to

adequately test the primary

hypothesis. The primary analysis

will be conducted using the intention-to-treat approach; participants who are randomized will be analyzed according to their assigned group regardless of amount of treatment received. The data will be screened for missing cases, outlier scores, and non-normal response distributions. Assumptions underlying statistical models will be assessed by examining standardized residuals, influence diagnostics, and homogeneity of variance (e.g. among groups).

Aim 1: To compare patient clinical outcomes for VAST vs. PCMH usual care between baseline and 16 weeks (post). MLM will be used to test the primary null hypothesis that no differences exist in the rate of change in anxiety severity and functional impairment measured by the OASIS between VAST and PCMH usual care against the two-sided alternative that differences do exist. A composite equation consisting of within- and between-person effects will be used to analyze our data. The within-person (level 1) equation estimates participants' unique intercept (time=0) and outcome trajectory. The between-person (level 2) equation estimates the average initial status at time 0 and rate of change in the primary outcome (OASIS total score). If the alternative hypothesis is confirmed, there would be a significant cross-level interaction between group and time of assessment suggesting a greater rate of improvement across time among participants randomized to the VAST condition (up to 6 sessions) relative to PCMH usual care. Below is the multi-level composite equation that will be utilized to model anxiety as measured by the OASIS. The true outcome score for the i^{th} person at the j^{th} time point is a linear combination of a between-subject main effect for group, a main effect for time, and a cross-level interaction term between group and time allowing for the fixed effect slope estimate to vary between groups.

Random effects include an intercept and slope. Both level-1 and 2 (subject) residuals are assumed to be normally distributed.

$$Anx_{ij} = \underbrace{\gamma_{00} + \gamma_{01}Group_i + \gamma_{10}TS1_{ij} + \gamma_{20}TS2_{ij} + \gamma_{11}Group_i*TS1_{ij} + \gamma_{21}Group_i*TS2_{ij}}_{Fixed} + \underbrace{\mu_{0i} + \mu_{1i}TS1_{ij} + \mu_{2i}TS2_{ij} + \varepsilon_{ij}}_{Random}$$

Our composite equation assumes a linear trajectory across time, based on our hypothesis of maintaining steady improvement in outcomes throughout the active study period. Since individuals frequently react differently over the course of observation, we propose an alternative theory-driven piecewise linear (PWL) model to capture an initial effect from treatment followed by weakened improvement during subsequent weeks. Exploratory graphical methods (group mean, subject-specific outcome trajectory plots) will be used to assess segmented linearity (or lack thereof) across time. The Bayesian Information Criterion (BIC) (L(n)k-2LL) will be used to assess fit among non-nested models. This composite equation differs from our primary models in that it includes 2 time segments (TS1, TS2) as well as cross-level interactions between each time segment and group.

The above models will also be utilized for analyzing anxiety severity and impairment (OASIS) as well as anxiety and depression severity (DASS) at 28-week follow-up. While this study is not necessarily powered to detect differences between treatment groups sustained over 28 weeks of observation due to unknown parameters such as the amount of missing data, information gained will be used and described in the appropriate context. Methods described below pertaining to missing data will be inspected and, if plausible, used in conjunction with MLM to compare rates of improvement between the primary 16-week study period and extended follow-up. If the reliability of estimates during extended follow-up are poor due to a high rate of missing data, simple means and confidence intervals will be calculated and used for descriptive purposes.

Secondary Analysis: Consideration of Potential Confounders

Three potential confounding variables (treatment dose, therapeutic alliance, and medication), will be considered secondarily to our primary analysis. As observed in our pilot study, participants assigned to VAST (vs. usual care) may attend more sessions of treatment. If the number of sessions attended is associated with improved outcomes, this has the potential to inflate the treatment effect in favor of VAST. To guard against an inflated treatment effect, the number of treatment sessions will be entered into our primary model to partition out the effect from treatment dose from the effect of VAST. Thus, a global effect will be reported as well as a “pure” effect from VAST after number of treatment sessions has been removed from the overall effect.

Similar to treatment dose, our pilot study revealed higher therapeutic alliance in the VAST condition (vs. PCMH usual care). The highly collaborative approach built into VAST may contribute to this finding, or it is possible that therapist skills/effectiveness may differ across conditions. Therapeutic alliance will be examined as a proxy for therapist effects because it is relevant regardless of provider condition or theoretical orientation (in contrast to CBT skills, which may not be relevant for usual care providers with other non-CBT theoretical orientations). We plan to separate out this effect from the intervention by adding therapeutic alliance (WAI) to our primary model. The difference between the total intervention effect from our primary analysis and the adjusted time*group coefficient will be calculated and described as the effect due to therapeutic alliance.

Eligibility criteria require a stable history of psychotropic medication use or non-use. However, patients may receive medication management (stop, start, or change dosage) during the 16-week study period. While randomization balances patient characteristics such as medication use between groups, change during the course of the trial could alter the growth of anxiety as well as become a “symptom” or result of treatment. Therefore, we plan to assess medication management by initially forming frequency tables of the number and percent of patients who start a new medication, stop an existing medication, and change medication dosage. Indicator variables will be formed for each type of medication management that occurs in $\geq 10\%$ of the sample. Indicators will be considered as either time-invariant or varying over time, as the effect could instantaneously influence anxiety severity and impairment. Assuming sufficient variability is observed in medication management indicators and estimation of both time invariant and varying effects are reasonable, the condition effect will be adjusted by the stronger of the invariant/varying coefficients and reported as an adjunctive result.

Aim 2: To explore predictors of early (by 8 weeks) and overall (by 16 weeks) VAST treatment response. Treatment response is defined as a clinically significant decrease (from baseline) of ≥ 4 points⁷⁷ in OASIS total score. Separate multivariate logistic regression models will be used to predict treatment response (yes/no) at (a) 8-week follow-up and (b) 16-week post. Predictors, all assessed at baseline, will include: anxiety symptom severity (GAD7), anxiety diagnoses (yes/no for GAD, social anxiety disorder, panic disorder, agoraphobia, and specific phobia; from the MINI), depressive symptom severity (PHQ9), depression diagnosis (yes/no for major depressive episode from MINI), total number of anxiety/depression diagnoses, coping self-efficacy, anxiety change expectancies, and alcohol (AUDIT) and drug use (DAST). GAD7/PHQ9 scores will be used for symptom severity because that is what BHPs would have access to in clinical practice as part of MBC.

Aim 3: To examine rates of, barriers to, and facilitators of achieving and sustaining high-fidelity VAST delivery. Descriptive statistics (proportions or *Ms/SDs*) will be calculated for all quantitative variables generated from fidelity ratings. Qualitative data (e.g., interviews) will be coded using conventional content analysis.¹⁰¹ Rapid analysis methods, which yield results consistent with those of in-depth qualitative analysis,¹⁰² will be used to ensure feasibility with the timeline. Templated summary matrices will be created in Excel to identify themes and visually summarize data. Qualitative data will be used to provide insight into quantitative data.

Handling Missing Data

Multiple Imputation (MI) will be used for managing missing data.¹⁰³ The advantage of MI over other methods is

that it preserves associations with other variables, adds variability during the imputation process, and accounts for variability due to multiple imputes resulting in efficient and unbiased parameter estimates.¹⁰⁴ Valid criticisms of MI pertain to the variables used to fill in the missing values, which may differ among analysts and lead to biased parameter estimates.¹⁰⁵ Accordingly, we'll use recommendations from VanBuuren¹⁰⁶ as well as practical guidelines in our imputation model. Our guideline encompasses inclusion of all items from the respective measure, variables that are correlated with the analysis variable, and variables that predict the missingness.

Data Security and Privacy

All research staff will be trained by the PI in the responsible conduct of research, including privacy, confidentiality, HIPAA and IRB regulations, as well as recruitment procedures, conduct of telephone screening, and data entry, management, and analysis. RAs participate in mandated IRB training as well as internal training on informed consent. Research staff are trained on maintaining confidentiality and the security of the data with supervision by the PI. All study staff are up to date with VA Privacy and Information Security and Rules of Behavior training. Only current, IRB-approved research staff will have access to the data; if study staff leave the research team at any point, their access to data will be terminated. All data will be kept strictly confidential and secure per American Psychological Association (APA) ethical standards and VA and IRB requirements.

For recruitment, potential participants will be identified via data pull from CPRS. Thus, we are requesting a waiver of HIPAA authorization for recruitment to pull data or conduct chart reviews and case finding. The information will allow us to check whether Veterans meet certain inclusion and exclusion criteria and contact Veterans who may be eligible to tell them about the study. We will pull data for all living Veterans who meet inclusion criteria 1, 2, and 3 and have an anxiety diagnosis in (a) their Problem List or (b) recent primary care encounter, but do not meet exclusion criteria 3, 4, 5, 6, or 9.

Research staff conducting eligibility screenings and research assessments will alert the PI to any safety concerns. All research staff are trained by the PI in data collection regarding mental health topics and suicide risk assessment. In addition to the PI, other licensed independent mental health providers will be available as back-up on call clinicians to ensure safety in the event of urgent clinical concerns. The PI will notify the IRB, in writing, immediately, of all serious and unexpected adverse events, regardless of whether or not the event was related to the study. The PI supervises periodic internal audits to ensure data integrity and management in accordance with VA guidelines and IRB regulations.

We are requesting a waiver of consent for the initial telephone eligibility screening. Veterans who are eligible following the phone screen and wish to participate in the study will complete written informed consent and HIPAA authorization at baseline. If completing over telehealth/telephone, copies of the consent and HIPAA authorization forms will be sent to the participant ahead of the scheduled baseline, including pre-stamped, pre-addressed envelope to send signed copies back to Syracuse VA or Buffalo VA where they will be stored separately from any de-identified data in a file cabinet in VA Center for Integrated Healthcare offices at the Syracuse VA or Buffalo VA Medical Center under double-locked conditions to which only IRB-approved research staff will have access.

Provider participation is minimal risk, as all study procedures are consistent with extant procedures the VA uses for psychotherapy rollouts. Thus, we are requesting a waiver of written documentation of informed consent for PCMH providers to allow for verbal informed consent instead to protect their privacy. All PCMH providers will be VA employees. No interventions are being conducted with the providers, rather they will receive training and supervision on delivering the VAST intervention to Veterans or they will be providing usual care to patients. Instead of obtaining written consent, we will complete verbal consent, including a description of the study, all elements of consent, and consent to be audio recorded.

No identifying information will be stored with data. Any paper or electronic data will instead use a random identification number. This random identification number will be linked with the participant name within a password-protected electronic file stored separately from study data on a VA secure server to which only IRB-approved research staff will have access.

Data will be used for research purposes only. All data will be stored securely within the VA; no data will be removed from VA premises. Any paper data will be stored in VA Center for Integrated Healthcare offices at the Syracuse VA Medical Center, Rochester VA Outpatient Clinic, or VA Western New York Healthcare System at Buffalo in file cabinets under double-locked conditions. All electronic data will be stored on the VA secure server in password-protected files. Data obtained through VINCI is stored on secure VA VINCI servers, which has multiple layers of security, until it is downloaded by the study team to store on the local secure server. To ensure the protection of Veteran data, VINCI maintains compliance with the guidelines in VA Handbook 1200.12 and all other applicable VA and VHA policies and regulations. Data will not be transmitted outside VA at all. Identifiable data will not be transmitted within VA, with the possible exception of being uploaded to VINCI or sent via encrypted VA email to IRB-approved staff for data analysis. Coded data will be entered into Microsoft Excel or Access to facilitate data analysis in Excel, SAS, SPSS, and/or Atlas.ti (licenses owned by the Center for Integrated Healthcare and/or accessible through VINCI) which may be used for data cleaning and analysis. Audio recording will be done with VA compliant recorders per ISO guidance.

No biospecimens will be utilized for this study. De-identified data (i.e., quantitative data that includes Likert scaled items without any names, dates, ages) may be sent electronically via encrypted email to IRB-approved staff for analysis if necessary. After data analysis is complete, results from group or aggregate data may be reported in research publications or at scientific conferences; however, no identifiable data will be included. All data will be maintained as defined in the VHA Records Control Schedule and destroyed at the appropriate time in accordance with these regulations and IRB guidelines, consulting with the Privacy Office as needed.

This study will use the VA Health Services Research and Development (HSR&D) Data Safety Monitoring Board as required by VA ORD for a funded multi-site clinical trial. Annual reports will be submitted to the DSMB, including adverse events, serious adverse events, and progress with recruitment and retention. Only de-identified summary data will be shared with the DSMB for the purposes of study oversight and data safety.

A description of this study will be available on www.clinicaltrials.gov as required by federal law. The ClinicalTrials.gov ID number is NCT04829240.

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