PEER-DELIVERED WHOLE HEALTH COACHING TO IMPROVE RECOVERY IN VETERANS WITH PTSD

National Clinical Trial (NCT) Identified Number: NCT03364192

Principal Investigator: Emily M. Johnson, Ph.D.

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STATEMENT OF COMPLIANCE

All investigators and clinical trial site staff responsible for the conduct, management, and oversight of this clinical trial completed Human Subjects Protection and ICH GCP Training.

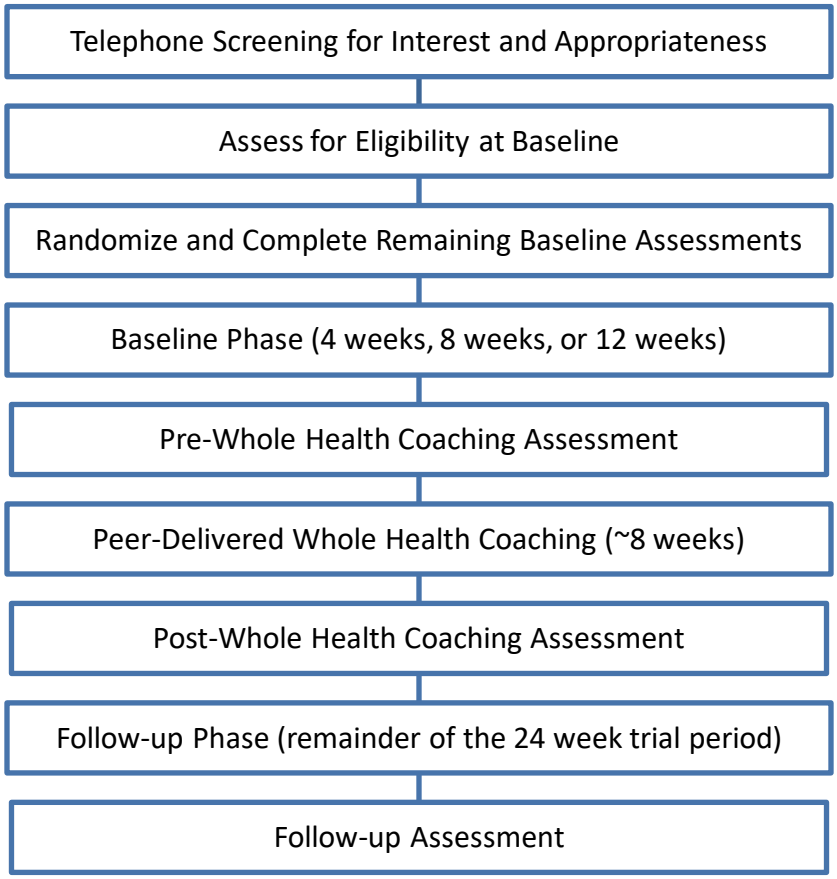
The protocol, informed consent form(s), recruitment materials, and all participant materials were submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form was obtained before any participant was enrolled. All amendments to the protocol were reviewed and approved by the IRB before the changes were implemented to the study. In addition, all changes to the consent form were IRB-approved.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Peer-Delivered Whole Health Coaching to Improve Recovery in Veterans with PTSD
Study Description:	This project implemented peer-delivered Whole Health Coaching with Veterans experiencing clinically significant PTSD symptoms but who chose not to engage in specialty mental health. This project utilizes a concurrent/non-concurrent multiple baseline design across subjects to investigate patient outcomes (specifically, goal attainment) before, during, and after Whole Health Coaching.
Objective:	Identify changes in Veterans' health and wellness behaviors after Whole Health Coaching.
Primary Outcome:	Goal Attainment Scaling
Secondary Outcomes:	PTSD Checklist for DSM-5 (PCL-5) Inventory of Psychosocial Functioning (IPF) Client Satisfaction Questionnaire-8 (CSQ-8)
Study Population:	Veterans enrolled in primary care at participating sites with probable PTSD defined as screening positive for a Criterion A event and PCL-5 score 33 or higher.
Description of Sites/Facilities Enrolling Participants:	Syracuse VA Medical Center and Affiliated Community Based Outpatient Clinics
Description of Study Intervention:	Whole Health Coaching is a Veterans Health Administration variation of integrative health coaching. For this study it will be administered by a peer support specialist.
Study Duration:	1 May 2018-31 October 2019
Participant Duration:	24 weeks

1.2 SCHEMA



2 INTRODUCTION

2.1 BACKGROUND & RATIONALE

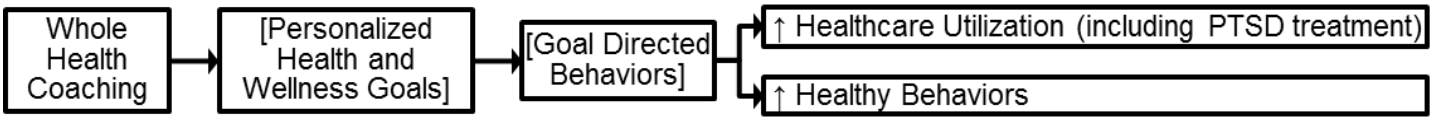
Veterans with PTSD have high rates of unhealthy behaviors and low rates of positive health and wellness behaviors. Veterans and service members with PTSD have high rates of smoking and substance use, worse health, more sick-call appointments, and low rates of preventative health behaviors (i.e., exercise and medical screening).[1] Veterans with PTSD also have higher rates of inpatient hospitalizations.[2,3] Also, despite dissemination of highly effective evidence based psychotherapies for PTSD across VHA,[4] rates of engagement are low; for example, only 11.5% of Veterans entering treatment with a provider trained in Cognitive Processing Therapy or Prolonged Exposure initiated one of these two treatments, and only 7.9% completed the treatment protocol.[5] Three classes of interventions demonstrate positive support for increasing "patients' willingness and ability to take independent actions to manage their health and care": (1) skill development, problem solving, and peer support; (2) social environment changes to facilitate healthy beliefs, social norms, and behaviors; and (3) tailored coaching, which facilitates goal setting at appropriate levels.[6]

Whole Health Coaching seeks to increase health and wellness behaviors through a personalized plan for recovery and values-based goal setting. Whole Health Coaching is a health coaching service designed by the VHA OPCC&CT. Whole Health Coaching differs in approach, focus, and principle from

traditional health coaching through defining success in terms of progress on personalized values-based goals rather than disease-specific outcomes. Sessions move through four phases to help Veterans progress on wellness goals. In phase 1, coaches work with Veterans to develop a personal health mission by exploring values and creating a vision for health. In phase 2, coaches conduct assessment to evaluate current and desired functioning in eight areas of self-care and develop a focus. In phase 3, coaches and Veterans develop a plan including setting goals, developing action steps, exploring barriers, and establishing accountability. In phase 4, coaches review progress and modify goals and action steps as needed. Coaches move through phases at the Veteran's pace and can return to a phase at any point as needed.

Although there is no research directly evaluating the outcomes of Whole Health Coaching, it is based on a style of health coaching called integrative health coaching, which has good research support.[7] Integrative health coaching and Whole Health Coaching incorporate many skills similar to motivational interviewing[7] (e.g., open-ended questions, reflections, scaling questions, exploring attitudes and beliefs around behaviors), behavioral activation (e.g., assessment of life goals and values, activity scheduling),[8] and goal setting. However, it is unique in its whole-person orientation to health rather than a focus on a specific behavioral concern (e.g., depression, weight loss).[7] In principle, focusing on Veteran defined values and goals increases patient engagement and healthy behaviors (Figure 1). Recent reviews indicate that health coaching demonstrates efficacy for improving health behaviors, physical health, and social and mental health functioning.[9,10] Further, evidence suggests that integrative health coaching can improve stress, healthy eating, exercise, and physical and emotional health in a high-risk population with multiple co-morbidities.[11]

Figure 1. Proposed impact of WHC on outcomes



Note that Whole Health Coaching is not a stand-alone treatment for any mental health or medical conditions, rather it is designed to increase patient engagement in treatment and healthy behaviors that are tailored for patient's health needs. Typically, if a Veteran with PTSD is having problems at work and has co-morbid health problems like obesity and diabetes, this Veteran would get a series of problem-specific recommendations for each of these concerns from providers including a primary care provider, mental health providers, vocational rehabilitation specialist, endocrinologist, nutritionist, etc. While any of these providers might set specific goals and tailor treatment recommendations to the Veteran's presenting concerns, recommendations would likely be specific to the individual problem(s) being treated by that provider. In contrast, if this Veteran were to engage in Whole Health Coaching, the emphasis would be on a whole health evaluation; broad, non-problem specific domains of health (e.g., activity level, sleep, spirituality); and generating feasible goals and action steps based on the Veteran's values and ability. The coach can then help the Veteran make healthcare decisions and identify self-management strategies considering provider recommendations. The whole health emphasis is the primary difference, so Veterans are not working with a provider on a specific diagnosis, but rather overall health and wellness. There is a focus on domains and values that are uniquely important to the Veteran (Table 1). For Veterans with PTSD, this ideally includes engagement in evidence-based PTSD treatment as part of the personalized health plan.

Once a focus is selected, Whole Health Coaches help Veterans specify goals, develop action steps to work towards those goals, and evaluate progress. Action steps toward goals might include treatment recommendations or self-care actions from healthcare providers. Coaches also provide support for goal attainment, help Veterans incorporate provider recommendations, and connect Veterans with appropriate services to follow through on action steps. For example, if a goal for a Veteran with PTSD is to reduce hypervigilance or irritability and the Veteran develops action steps towards self-management, then the coach would provide support for the self-management plan. However, if a Veteran with a goal to reduce hypervigilance or irritability develops action steps focused on engaging in formal treatment, then the coach would provide navigation to appropriate services (e.g., PTSD Clinic or anger management) and provide support for maximizing utilization of these services (e.g., developing action steps for attending sessions and completing homework.

Table 1. Sample of Whole Health Coaching Assessment and Goals.

Assessment Domain	Example
Values	Family and Work
Area of Focus	Power of the Mind: Relaxing and Healing
SMART Goal	In the next 3-6 months, I will learn relaxation and mindfulness skills to cope with irritability with my family and co-workers.
Action Steps	In the next week, I will read about VHA treatment options and try a yoga class at the YMCA.

Since Primary Care-Mental Health Integration (PC-MHI) addresses population-level barriers to behavioral healthcare, it is an ideal setting for engaging Veterans with PTSD through Whole Health Coaching. PTSD is prevalent within VHA with 20% of outpatients screening positive for PTSD[12] and 11.5% of primary care patients meeting full diagnostic criteria.[13] PTSD diagnoses are commonly (44% of the time) made in non-mental health settings such as primary care.[14] PTSD in primary care patients is associated with worse mental health functioning, co-morbid mental health concerns, hazardous alcohol use, and elevated risk of suicidality.[12,15-18] VHA's PC-MHI initiative was designed to address population-level barriers to mental healthcare including both access and stigma.[19] Since PC-MHI providers are embedded within primary care clinics, they regularly interact with Veterans who typically do not follow through on mental health referrals. Thus, the PC-MHI setting provides an opportunity to engage with Veterans with PTSD who are not using specialty mental health care.

Peer specialists can provide unique and valuable benefits to Veterans with PTSD. Peer specialists are Veterans with at least one year of personal recovery from a mental health concern whose role as VA employees is to provide support to Veterans.[20] There are 1,100 peers working in VHA nationally, and large medical centers must employ at least 2 peer specialists.[21] Within their role, they work with Veterans both individually and in groups to perform multiple functions including: sharing their recovery story, advocating for Veterans, acting as role models of recovery, providing crisis support, acting as liaisons with clinical staff, providing outreach education, supplementing treatment, providing case management and navigation, and teaching coping skills.[20] Peers in the VHA are already receiving training in and delivering Whole Health Coaching, a movement that mirrors implementation of peer wellness coaching in other state healthcare systems.[22] In fact, a recent review demonstrates support for three types of peer services, two of which are highly relevant to the role of the peer specialist delivering Whole Health Coaching in primary care.[23] Evidence suggests that patients receiving care from peers delivering services as part of a team, such as multidisciplinary PACTs, show improvements in treatment engagement, social functioning, and quality of life.[23] Further, research on peer-delivered structured curricula (e.g., coping, problem solving) demonstrated that peers were effective in this role.[23] Evidence also suggests that mental health peers working with patients on mental health concerns and/or health

issues can improve patient outcomes including quality of life, socialization, hope, recovery, fatigue, sleep, symptoms, daily functioning, patient activation, and use of health services.[23-26]

Veterans with PTSD report that peer services can significantly improve PTSD services through providing social support, normalizing symptoms, instilling hope for recovery, and linking Veterans with additional services.[27] Some specific benefits that Veterans reported about working with a peer compared with a non-peer provider are: increased trust, increased likelihood of following through on recommended treatments, and increased hope for recovery along with decreased stigma.[27] In addition, Veterans indicated that peer services to encourage implementation of provider recommendations and pursuit of life goals would be helpful.[27]

2.2 RISK/BENEFIT ASSESSMENT

Potential Risks

There is minimal risk to Veterans from their participation in any of the research activities. The procedures are non-invasive and will not cause physical harm to participants. There is minimal psychological risk (i.e., embarrassment, discomfort) to participants when asked to share sensitive information about themselves (e.g., regarding trauma and suicidality) with the research staff. Participants will be assessed for suicide risk according to an established protocol. No deception is involved in this study. To minimize risk of breaching confidentiality, all electronic and paper self- report data collected will be identified by a random identification number rather than individually identifiable information. Identifiable voice recordings will be stored separately and in accordance with the data security and privacy procedures below. Identifiable information for informed consent, payment, and enrollment status will be stored separately from study data and will also comply with the data security and privacy procedures.

All research staff will be up to date on all required VA and IRB trainings in the responsible conduct of research including privacy, confidentiality, HIPAA regulations, recruitment procedures, informed consent, and data management.

Additionally, the PI will provide study-specific training in those topics as well as appropriate conduct of the telephone screenings, interviewing skills, collection of self-report data, intervention delivery, and data entry/management, and analysis. The PI will supervise and provide regular internal trainings and audits of aspects of the responsible conduct of research. Only approved research staff will have access to the data. All data will be kept strictly confidential and secure per American Psychological Association (APA) ethical standards and IRB protocol.

Veteran Safety

Multiple procedures will be in place to minimize psychological risk including (1) participants will be reminded that they can choose not to answer any question that they are uncomfortable with, (2) participants will be reminded that they can choose to withdraw from the study at any time, (3) on-call clinicians (licensed independent providers) will be available to speak with Veterans who report distress during any study procedure, and (4) participants will be reminded that they can choose to engage in additional mental health services, including specialty PTSD treatment, at any point in the study. All referral requests will be promptly facilitated by the PI or on-call clinician and urgent requests will be provided with same day access through the facility procedures. This study team has conducted numerous studies using similar methods and there have been very few issues. We do not anticipate any serious or significant risk with these procedures.

A number of procedures will be in place for participants who have more urgent needs including needs for immediate medical or mental health care. If participants should require medical attention, they will

be directed to contact VA medical services, local community hospital, and/or 911 as appropriate. For Veterans who are unable to contact required medical services for themselves, research staff will assist with connecting Veterans with required services. For Veterans who report urgent need of mental health services, they will be evaluated by the on-call clinician and connected with appropriate emergency mental health services as needed. For Veterans deemed at imminent risk of harm to self or others, they will be connected with the on-call clinician who will facilitate emergency services as necessary (e.g., police, Suicide Prevention Team, etc.). The PI and co-Is are licensed clinical psychologists with experience in crisis evaluation and management, and research staff will also have access to a list of on-call clinicians to contact for the study including other licensed psychologists and social workers at the Center. Research staff will have detailed training in these protocols for managing urgent needs including imminent suicidal/homicidal risk. If Veterans enrolled in the study demonstrate non-imminent suicide risk (e.g., ongoing ideation with no plan or intent), additional suicide risk assessments will be conducted by study staff and the intervention provider as needed.

Potential Benefits.

The potential benefits of the proposed project outweigh the minimal risks. Risks are non-invasive and consist primarily of the possibility of mild psychological distress. There are several potential direct benefits for participants. The interviews, telephone screenings, and assessment sessions may provide the opportunity for Veterans to thoughtfully reflect on their current situation which may increase insight and prompt change (e.g., behavior changes or seeking additional treatment). Veterans will also receive monetary compensation for all assessments completed.

Additionally, all participants will receive the peer-delivered Whole Health Coaching intervention, which may increase progress toward health and wellness goals and other improvements in other outcomes (e.g., PTSD symptom reduction, functional outcome improvement, patient activation). Indirect benefits include the opportunity to learn about and participate in clinical research that aims to improve Veteran healthcare. The data and feedback collected in this project will serve to improve services offered for all Veterans. Overall, the risk to benefit ratio seems favorable. The protocol outlines procedures for minimizing risk, and the benefits of evaluating peer-delivered Whole Health Coaching are high. We believe the potential benefit of this research outweighs the limited risk to research participants.

3 STUDY DESIGN

This is a quantitative project with a minor qualitative component. This project will use a multiple-baseline design across participants with non-concurrent replications to measure the impact of Whole Health Coaching on Veterans' progress toward health and wellness goals. In this design, outcomes are monitored over time prior to the onset of an intervention, to establish a baseline, and after the onset of an intervention to evaluate changes in outcomes for each participant.[32] In addition, the start of the intervention is staggered across participants to demonstrate experimental control (i.e., that the intervention and not some other extraneous variable was responsible for any changes that were observed). Data from each participant's intervention phase are compared to that person's baseline phase (within-series comparisons) and to the overlapping portions of other participants' baseline phases who have not yet begun the intervention (between-series comparisons). We plan to recruit so that Veterans start baseline in groups of 2-3 and move through the study concurrently. Participants who start baseline concurrently will be randomized to different baseline lengths to establish temporal precedence of change and control for history effects.[32] The minimum baseline length of 4 weeks (eight possible assessment points) allows for sufficient assessments for the statistical model. Intervention will be introduced when each participant meets a baseline stability criterion defined as at least four data points total, the final two of which fall within the range of the previous data points (i.e., no increasing slope or trend over the final three baseline data points). There will be flexibility to extend baseline by one week if

participants have not met the stability criterion. The maximum possible baseline will be 13 weeks. Following the baseline period, participants will complete ongoing twice weekly assessments throughout the 8 week peer-delivered Whole Health Coaching phase, and 3-12 week post-intervention phase for the remainder of the 24-week study period.

4 STUDY POPULATION

We will enroll 50 participants aiming to have 25 eligible participants and 8-10 study completers.

Study completers are defined as Veterans who complete sufficient research tasks to conduct visual analysis for the multiple baseline design (i.e., at least 4 baseline data points that meet the stability criterion, initiate intervention within 2 weeks of scheduled intervention start date, and complete at least 4 intervention phase assessments) and complete the intervention (i.e., completed the Personal Health Inventory with the peer as the basis of Whole Health Coaching, defined a focus for coaching (Whole Health Coaching Stage II Phase II), set a goal (Whole Health Coaching Stage III Phase I), established an action step (Whole Health Coaching Stage III Phase II), and assessed the action taken (Whole Health Coaching Stage IV Phase I).

4.1 ELIGIBILITY CRITERIA

Criteria	Methods for Determining Eligibility
Inclusion	
Veteran status (Non-Veterans will not be included)	EMR data (either though datapull or chart review)
Enrolled in primary care at the Syracuse VA (and affiliated CBOCs) and seen in primary care within the past year	EMR data (either through datapull or chart review)
Age over 18	EMR data (either through datapull or chart review)
Probable PTSD 1. Criterion A is met 2. Score above the specified cutoff	PCL-5 1. LEC + Criterion A screener positive 2. PCL-5 ≥ 33
Exclusion	
Unable to communicate in spoken and written English	Research staff assessment. Exclude if ANY of the following are present: • Unable to verbally respond to informed consent items • Unable to engage in meaningful coherent back-and-forth dialogue with researcher to the extent that this interferes with research procedures • Unable to read study materials and complete written tasks required for research participation Research staff will bring any concerns to the PI for PI discretion and clinical judgment of communication concerns.
Gross cognitive impairment	Blessed Orientation Memory Concentration (BOMC) > 15.

	All Veterans scoring BOMC above 10 and below 16 will be referred to the PI for PI determination of likely cognitive impairment based on participant's cognitive screening responses, direct evaluation of Veteran, and/or EMR review
Current symptoms of mania/psychosis	EMR data (either through datapull or chart review) and Research staff assessment of inability to engage in the consent or research process. All research staff concerns will be reviewed with the PI for evaluation of likely impairment due to mania/psychosis and PI discretion for enrollment.
At risk for suicide	Measured by the P4 screener, defined as any Veteran with "higher" risk on the P4 Screener or Veterans with "lower" risk on the P4 and evaluated by the PI or another clinician to be clinically unstable or at risk. UNTIL Referral to suicide prevention is complete AND connected with ongoing services from a licensed independent provider who agrees to monitor safety concerns, be a point of contact for the peer support specialist, and determines the Veteran is stable for enrollment. Given subsequent eligibility requirement that the Veteran not be receiving psychotherapy in a non-primary care setting, if a Veteran is to be enrolled in the study with LIP monitoring, the LIP would need to be a primary care staff member, ongoing psychiatrist (for medication management only), or PCMHI provider.
Engaged in psychotherapy in a non- primary care setting in the last 2 months	EMR data (either through datapull or chart review) and self-report
Changes to psychotropic medications for PTSD within the last 2 months	EMR data (either through datapull or chart review) and self-report
Preference for direct referral to specialty mental healthcare	Veteran self-report

4.2 STRATEGIES FOR RECRUITMENT AND RETENTION

Patients who screen positive on the PC-PTSD screen (which is delivered as part of standard practice), who have PTSD chart diagnoses, and/or are deemed clinically appropriate for referral will be referred by their PCPs, PC-MHI providers, or OEF/OIF/OND case managers. To help identify potential referrals, research staff will create a list of these patients monthly and then ask their providers to refer these patients to the study. This list may be developed using the Veterans Affairs (VA) electronic medical record, or via the VA Informatics and Computing Infrastructure (VINCI). VINCI is a VA HSR&D resource center that provides a secure, central analytic platform for performing research activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes servers for securely hosting databases from VA data sources. VINCI servers are physically located at the VA Austin Information Technology Center (AITC), located in Austin, Texas, which has multiple layers of security and disaster recovery to prevent data loss. Only designated members of the study team are granted access to study-specific data through a certified VHA network computer within the VA or approved Virtual

Private Network (VPN) and Remote Desktop application. The recruitment lists are generated through VINCI with an IRB-approved request from individual VistA systems to the VA Corporate Data Warehouse where it is prepared and placed into a secure database for use by the study team.

Once the names are identified from the VA electronic medical record and/or received from VINCI and the primary care provider has signed-off, research staff will send an IRB approved letter that is signed by the P.I. to all referred Veterans with the purpose of introducing the study. Study staff will then contact referred patients by phone or in person to assess their interest in participation and administer an initial screen. Additionally, referral interactions with study staff may occur in person at the Syracuse VAMC or Behavioral Outpatient Center.

We also plan to engage in multiple direct recruitment strategies. Research staff will set up an information table in the common areas at the VAMC. Research study staff will be present at the table and will distribute IRB approved brochures and/or flyers containing information about the study. IRB approved flyers may also be placed around the Syracuse VAMC and other community locations (e.g., the Vet Center), where appropriate. Approved electronic flyers will also be posted electronically at the VA medical center and other electronic venues (e.g., the Syracuse VA facebook page). The IRB approved flyers and brochures include research staff contact information, allowing potential participants to directly contact staff via phone. Interested and potentially eligible patients will be scheduled for a baseline research appointment within their PC clinic where study inclusion will be determined.

5 STUDY INTERVENTION

5.1 STUDY INTERVENTION(S) ADMINISTRATION

5.1.1 STUDY INTERVENTION DESCRIPTION

Whole Health Coaching will be implemented as designed by the VHA OPCC&CT and delivered by a peer specialist who has completed the OPCC&CT Whole Health Coaching training. Whole Health Coaching is explained in detail in the background. Veterans will meet weekly with a peer specialist for 30-50 minutes. The service is designed to accommodate varying patient readiness for change and system barriers, but 8 weeks is a typical length. For this project, the peer support specialist will adjust the time frame and frequency as needed to help Veterans achieve progress on wellness goals. Although typical primary care interventions are briefer, peers in primary care are not bound by the same guidelines typically recommended for PC-MHI providers. Unlike the model for PC-MHI which focuses on facilitating increased access through population-based care (i.e., providing a small amount of services to many patients), the peer support model focuses on improving the patient experience of care. This allows the peers to spend more time with Veterans.

6 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

6.1 INVESTIGATOR DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants may be removed at PI discretion for research integrity (e.g., if participants are not completing study expectations such as engaging with the peer support provider) or safety purposes (e.g., if a participant demonstrates elevated risk and would benefit from removal from the study).

6.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

7 STUDY ASSESSMENTS AND PROCEDURES

7.1 ASSESSMENTS & ASSESSMENT SCHEDULE

Screening Measures. The Blessed Orientation-Memory-Concentration test (BOMC) is a 6-item interview of cognitive impairment that will be administered prior to any other measures. Scores range from 0 (all items correct) to 28 (all items incorrect). This measure has sound psychometric properties.[35] The P4 Screener will be administered by research staff to assess risk for suicide. It assesses the 4 P's: past history, plan, probability, and preventive factors and then classifies respondents as minimal, lower, or higher risk for suicide. The P4 will be re-administered at the follow-up assessments as needed to evaluate risk. The P4 has been validated in several large studies of medical patients enrolled in depression studies and has sound psychometric properties.[36] The PCL-5 will be used to screen for presence of PTSD symptoms. The PCL-5 includes assessment of Criterion A traumatic events. To confirm the absence of non-VA mental healthcare, a short questionnaire titled Non-VA Service Utilization Screen will be administered. Screening for mania, psychosis, non-PC-MHI psychotherapy, and changes to PTSD medications in the past 2 months will be via chart review of VA records and self-report of non-VA services. A Demographics and Military Background questionnaire will be used to assess basic demographic information (e.g. sex, age, education, employment, and income) as well as military background including deployment history (e.g., length, number, and locations), military rank/positions, branch, active/reserve status, and dates of service. This self-report measure is modeled after one used in CIH studies of Veterans with PTSD.

Primary Outcome. The primary outcome directly evaluates the target of Whole Health Coaching: progress toward health and wellness goals. Progress toward health and wellness goals will be measured by Goal Attainment Scaling (GAS), one of the most established applied methods for evaluating individualized progress toward rehabilitation goals.[37-40] GAS has strong psychometrics as an outcome measure in rehabilitation and mental health.[38,40] In rehabilitation, recent reviews show strong inter-rater reliability, convergent validity, and sensitivity as an outcome measure.[38,40] In mental health, fewer studies were reported in the review, but available psychometric data are consistent with rehabilitation findings.[40] Additionally, GAS demonstrated sensitivity to change in a recent peer-delivered coaching intervention.[41] GAS is a measurement technique designed to be adapted to meet the needs of individual patients, settings, and studies; we have adapted a version with specified behavioral anchors[42] to evaluate the domains targeted by Whole Health Coaching. We selected this version to (1) reduce burden in establishing individualized rating criteria and (2) increase transparency, reproducibility, and validity. We also plan to follow other recommended guidelines to further enhance validity, reproducibility, transparency, and rigor.[39]

Secondary Outcomes.
The *Inventory of Psychosocial Functioning (IPF)* consists of 80 items on a 7 point scale measuring functioning in romantic relationships, family relationships, work, friendships and socializing, parenting, education, and self care.[49] The IPF was developed to evaluate functional impairment in Veterans with PTSD and demonstrates good reliability, internal consistency, and convergent validity.[49]

The *PTSD Checklist for DSM-5 (PCL-5)*, a 20-item scale, measures diagnostic criteria of PTSD on a 0-4 scale.50 The PCL-5 demonstrates good reliability and validity.[50]

The 8-item *Client Satisfaction Questionnaire (CSQ)* is designed to measure patient satisfaction with services and demonstrates good reliability.[51]

Table 2. Assessment Schedule	**Administration Time Points**			
Measure	**Baseline Assessment**	**Pre & Follow-up Assessments**	**Post Assessment**	**Twice Weekly Assessments (All Phases)**
Blessed Orientation-Memory-Concentration (BOMC)	X			
P4 Suicide Screener	X			
Non-VA Service Utilization Screen	X			
Demographics & Military Background	X			
PTSD Checklist-5 (PCL-5)	X	X	X	
Inventory of Psychosocial Functioning (IPF)	X	X	X	
Client Satisfaction Questionnaire (CSQ)			X	
Goal Attainment Scaling (GAS)	X			X
***Note.** Additional suicide risk evaluations will be conducted as needed to monitor for suicidality.				

7.2 PAYMENT

Participants will be paid $20 each for completing the one-time baseline (including ineligible participants), pre, and follow-up assessments and $30 for completing the post assessment. For the twice weekly assessments, participants will be reimbursed on a payment schedule similar to one used in a previous study including $5 for each completed assessment with bonuses for high compliance rates.[34] Participants will not be reimbursed for intervention sessions.

8 STATISTICAL ANALYSES

To analyze the primary outcome, GAS, we will use a variation of multi-level modeling (MLM) tailored to analyze single- case experimental design data.[58] The appropriateness of the model will be evaluated and adapted as needed to fit the data including evaluating and implementing covariance structures to accommodate autocorrelation such as an auto- regressive error structure. We will evaluate alternative models to assess model assumptions and robustness of treatment effects. These analyses will be supplemented with visual inspection by graphing participants' outcomes in a multiple- baseline design format throughout the study.[59] Graphs will be aligned across participants in order to establish temporal precedence of symptom change and intervention onset and demonstrate replication across participants within the sample. MLM and visual analysis of the primary outcomes will be supplemented with a non-overlap of all pairs effect size.[60] Other quantitative outcomes will be analyzed through descriptive statistics, and will be used to generate pre-post effect size estimates for Veteran outcomes to establish initial estimates of efficacy for power estimates.

9 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

9.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

9.1.1 INFORMED CONSENT PROCESS

At the one-time in-person baseline assessment, Veterans will be provided with comprehensive oral and written information about the study procedures, anticipated risks and benefits, and rights as a research participant (including the right to refuse participation or withdraw from the study at any time). Veterans

will be informed that participation (or lack of participation) in the research study will not affect their eligibility for care at the VA. Veterans will be asked to provide written informed consent and will be offered a copy of their signed informed consent document for their records. Limits of confidentiality and importance of Veterans' safety will be outlined.

9.1.2 DATA AND SAFETY MONITORING PLAN

The PI along with co-Is Drs. Possemato and Maisto, will oversee data and safety monitoring to ensure the safety of participants and integrity of data collected. The study is non-invasive and involves interviews, self-report questionnaires, and attendance at intervention sessions. The interventionist is a certified peer support specialist with previous experience implementing research protocols at the Syracuse VAMC and training in crisis management. The PI, a licensed clinical psychologist, will be on-call and a back-up list of on-call clinicians will be available for the interventionist and other research staff working on the project.

Coded self-report survey data will be collected via paper and pen or using PsychData, an online data collection tool. No identifiable information will be entered into PsychData. Some data will temporarily be stored on the PsychData system but all data entered by participants will be downloaded by research staff to secure VA systems regularly. See PsychData Security Statement in Appendix 2. In instances where PsychData is used participants will complete online surveys via PsychData, but VA research staff will download and store all data in secure VA drives. Only coded data will be entered.

Identifiable data will be stored in locked filing cabinets and password protected computer files.

All protocol deviations, adverse events, serious adverse events, and other problems will be identified and reported to the IRB and other appropriate individuals/offices as stipulated by VA regulations. All study records and files will undergo periodic internal audits to ensure protocol compliance, as well as additional audits per VA policy. All paper and electronic data will be stored according to the methods described above, which are compliant with data security VA policies.

Recruitment, intervention, and assessment procedures will be monitored by the PI on a weekly basis to ensure we are meeting our goals and complying with all policies. In addition, the PI supervises periodic internal audits of data safety and security of all ongoing projects to ensure data integrity and management in accordance with VA guidelines.

We plan to send fully anonymous data from the anonymous online survey to a statistical consultant via Safe Access File Exchange (SAFE) for the consultant to analyze the data off the VA network using his own equipment. No sensitive data or identifiable records will be sent, all survey responses are fully anonymous. All original copies of the data will remain on secure VA drives.

10 REFERENCES

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