Initial Testing of Whole Health STEPS (Structured Tiered Engagement with Peer Support)

National Clinical Trial (NCT) Identified Number: NCT04390451

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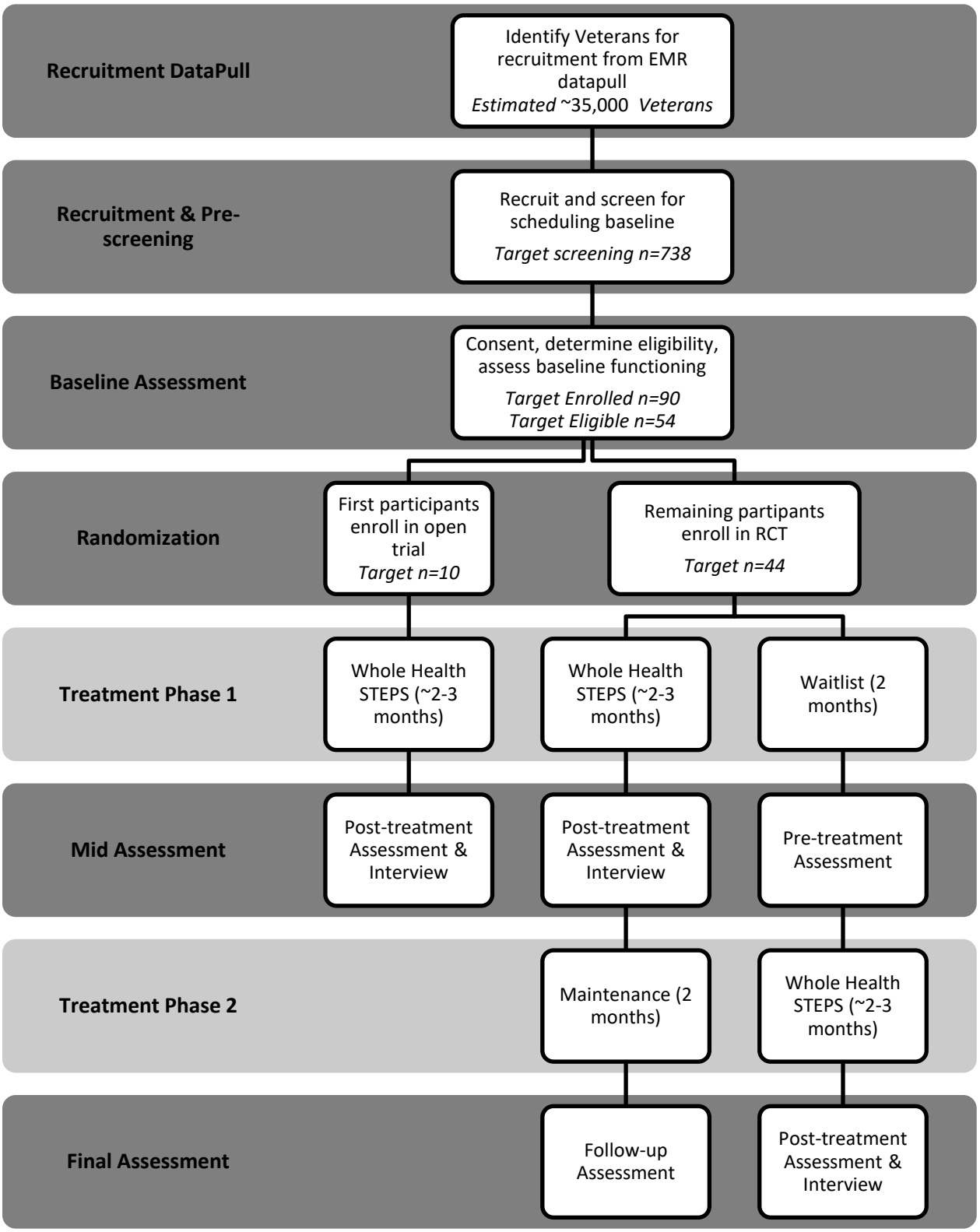
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Initial Testing of Whole Health STEPS (Structured Tiered Engagement with Peer Support)
Grant Number:	1 IK2 RX003390-01A1
Study Description:	This two-phase pilot trial (open trial followed by pilot RCT) is designed to evaluate the feasibility and acceptability of Whole Health STEPS.
Study Population:	The target population is primary care Veterans with mental health symptoms who are not engaged in mental health care.
Description of Intervention:	Whole Health STEPS (Structured Tiered Engagement with Peer Support) is a peer-delivered wellness service designed for delivery in VA primary care settings.

1.2 SCHEMA


Recruitment DataPull
Identify Veterans for recruitment from EMR datapull
Estimated ~35,000 Veterans
Recruitment & Pre-screening
Recruit and screen for scheduling baseline
Target screening n=738
Baseline Assessment
Consent, determine eligibility, assess baseline functioning
Target Enrolled n=90
Target Eligible n=54
Randomization
First participants enroll in open trial
Target n=10
Remaining partipants enroll in RCT
Target n=44
Treatment Phase 1
Whole Health STEPS (~2-3 months)
Whole Health STEPS (~2-3 months)
Waitlist (2 months)
Mid Assessment
Post-treatment Assessment & Interview
Post-treatment Assessment & Interview
Pre-treatment Assessment
Treatment Phase 2
Maintenance (2 months)
Whole Health STEPS (~2-3 months)
Final Assessment
Follow-up Assessment
Post-treatment Assessment & Interview

2 INTRODUCTION

2.1 STUDY RATIONALE

Functional impairment, limitation in social and occupational roles (Üstün & Kennedy, 2009), is a significant problem for Veterans. Across diagnostic categories, mental health symptoms are associated with functional impairment and difficulty with role-related task (Kazis et al., 1998; Löwe et al., 2008; Spitzer et al., 2006). Despite the availability of services, many Veterans with mental health symptoms do not engage in mental health treatment (Elbogen et al., 2013; Seal et al., 2010). ***Whole Health STEPS (Structured Tiered Engagement with Peer Support) is an innovative approach to engaging this population through combining two novel modalities to engage with Veterans, peer support and Whole Health, tailored for delivery in Primary Care Mental Health Integration (PCMHI) a platform designed to increase access to mental healthcare.***

This two phase pilot trial is designed to address two key objectives (1) evaluate the feasibility and acceptability of Whole Health STEPS and (2) evaluate the preliminary impact of Whole Health STEPS on patient outcomes.

- Phase 1 addresses objective 1 and will be an open trial (Eligible n=10) to test the feasibility of peer delivery in primary care and acceptability to Veterans to inform further manual adjustments. Feasibility of research procedures will also be evaluated to inform adjustments to the research protocol.
- Phase 2 addresses objective 2 and will be a pilot RCT with a waitlist control (Eligible n=44) to evaluate impact on functional impairment and feasibility for subsequent grant applications.

2.2 BACKGROUND

Peers within VA are Veterans in recovery from mental illness with specialized training to support other Veterans with mental health concerns *(Chinman et al., 2013)*. Within the context of their job duties, peers perform a number of functions including sharing their mental health recovery story, advocating for Veterans, acting as role models, providing crisis support, acting as liaisons with staff, providing outreach, supporting treatment, teaching coping skills, supporting patient engagement for patients with mental health concerns, and wellness coaching *(Chinman et al., 2013; Swarbrick et al., 2016)*. Benefits from peer services include functional outcomes such as quality of life, socialization, recovery/hope, fatigue/sleep, daily functioning, and healthcare engagement *(Chinman et al., 2014; Davidson et al., 2006; Druss et al., 2010; Lorig et al., 2014)*.

Whole Health is a patient-centered model of care within VA *(Krejci et al., 2014)* which incorporates a range of services with a range of intensities appropriate for peer-delivery. Early research within the VA on Whole health interventions suggests high acceptability and Veteran improvements on a broad range of outcomes including psychological well-being, mental health symptoms, physical health, ability to engage in valued activities, and wellness domains *(Denneson et al., 2019; Hull et al., 2019; Mori et al., 2019)*.

PCMHI is a platform of care which significantly increases access and utilization of mental health services for primary care Veterans, but some Veterans still do not engage in care due to low mental health problem recognition and negative beliefs about psychotherapy *(Johnson & Possemato, 2021; Kehle et al., 2011; Possemato et al., 2018; Wray et al., 2012)*. Peer support and Whole Health are well positioned

to address those barriers and be adapted for delivery in PCMHI using a stepped care model. Stepped care interventions are designed to offer the least intensive intervention that is likely to provide benefit and involve systematic monitoring of progress to increase the level of care as needed to "self-correct" *(Bower & Gilbody, 2005)*. Preliminary evidence from a prior trial of Peer-Delivered Whole Health Coaching *(Johnson et al., 2021)* suggested positive results from a peer-delivered Whole Health approach and informed the stepped care design including the addition of lower intensity interventions as early steps and the frequency and duration of the intervention.

3 STUDY DESIGN

3.1 OVERALL DESIGN

This study consists of a two phased clinical trial.

Phase 1 is an open trial establishing preliminary feasibility and acceptability of Whole Health STEPS and informing adjustments to the clinical manual. Participants will be followed for the duration of their participation in Whole Health STEPS, a period of approximately 2-3 months. Following phase 1 enrollment, the investigators will review the data, make adjustments to the Whole Health STEPS manual and research protocol as necessary, and proceed with enrollment in Phase 2.

Phase 2 is a 2-arm single-site pilot randomized clinical trial with a waitlist control evaluating Whole Health STEPS impact on patient outcomes and feasibility. Random assignment will be made by research staff following eligibility determination using a stratified permuted block design based on baseline functional impairment (mild-moderate functional impairment IPF≤50 vs. severe-extreme functional impairment IPF≥51). Participants will be followed for a period of approximately 4-5 months, 2-3 months will be participation in Whole Health STEPS and 2 months will be either be waitlist or follow-up depending on randomization outcome.

- Hypothesis 2a. Whole Health STEPS will demonstrate an effect size (d) > 0.3 on psychosocial functioning.
- Hypothesis 2b. Whole Health STEPS will demonstrate clinical feasibility including positive results on process outcomes, retention, fidelity, and appropriateness on stepped-care decision points.

3.2 STUDY INTERVENTION DESCRIPTION: WHOLE HEALTH STEPS

Whole Health STEPS is a stepped care package incorporating a range of Whole Health peer services into one structured protocol designed to be delivered by a peer in primary care. The whole package is designed to take place over approximately 2-3 months with regular contact with the peer to evaluate the need to increase/decrease the intensity of peer support. Levels of support include supported self-management in which the Veteran completes a self-directed Whole Health tool (i.e., the Personal Health Inventory) and gets regular calls from a peer to check-in about progress, brief telephone support in which the peer asks additional questions to support Veterans' progress (e.g., inquiry about personal meaning, focus, goals), and full length peer sessions (approximately 30-60 minutes) focused on Whole Health. All peer sessions at all levels will use a semi-structured interview tool to inquire about Veterans' goals and goal progress and other mental health, physical health, and social needs. The peer will facilitate referrals and connections with community resources as appropriate for Veterans' individual needs throughout Whole Health STEPS.

The proposed levels of support are all existing Whole Health services tailored for a peer scope of work. The innovative aspect of Whole Health STEPS is packaging these services together in a stepped care model. These are all variations of existing services and there are no known risks to peer services or Whole Health services.

Peer contact including sessions and other contacts (e.g., reminders, brief check-ins, contact attempts) will be documented in the medical record. Peer sessions will occur either in person and/or remotely over the phone or via VA Video Connect depending on current safety guidelines for in person appointments and Veteran preference. Peer sessions will be audio-recorded using VA approved audio-recording software to ensure the intervention is being delivered correctly and understand how Whole Health STEPS is being delivered. VA approved audio-recording software will also be used at a treatment feedback interview so that Veteran responses can be analyzed.

3.3 CONTROL DESCRIPTION: WAITLIST

Veterans randomized to the waitlist control condition will receive Whole Health STEPS after a 2 month wait. During the waitlist period, Veterans will not be prohibited from pursuing any treatment or services they deem appropriate, and healthcare utilization will be tracked through EMR record reviews. Veterans will be provided with information about available emergency and urgent mental health services, resources for social needs (e.g., homelessness), and other important resources to ensure that they are aware of how to engage support as needed.

Waitlist control was selected as the best option for the RCT to evaluate this service package because compared to designs with control groups where only one group receives Whole Health STEPS, it allows a more powerful test of Whole Health STEPS and it provides more feedback data to establish acceptability of the lower intensity interventions which are central to stepped care intervention design.

3.4 FIDELITY & PEER STAFF QUALIFICATIONS

Peer staff may include Syracuse VA peer support specialists/apprentices, Syracuse VA or CIH staff employed in other roles who have appropriate peer qualifications, and/or peer support specialists/apprentices from other VA sites with whom we have active research or clinical partnerships (e.g., Palo Alto, Pittsburgh, Houston). Peers will have received training in peer support through a training program approved by the PI (e.g., the VA or New York State Peer Certification program) and will receive additional training in Whole Health STEPS procedures including training in Whole. Peer training in Whole Health STEPS will include training techniques such as reading materials (e.g., reviewing the manual) and structured practice (e.g., role plays). Peers will also receive ongoing supervision from the PI or another qualified peer supervisor to review ongoing cases and provide additional follow-up training as needed.

Intervention fidelity will be evaluated through a fidelity checklist developed specifically for Whole Health STEPS.

3.5 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Participant adherence to Whole Health STEPS will be tracked through peer documentation of appointment attendance and research staff documentation of retention (i.e., intervention and research withdrawal and/or lost to follow-up). Intervention retention will be evaluated through the percentage of Veterans who complete Whole Health STEPS. Completion is defined as either (1) continued engagement

with the peer specialist throughout the Whole Health STEPS phase as indicated by continuing to respond affirmatively to peer outreach efforts AND/OR (2) planned termination of Whole Health STEPS because the Veteran has made successful progress.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

To be eligible to participate in this study, an individual must meet all of the following criteria:

Inclusion Criteria	Operational Definition
1. Veteran status	Designated as a Veteran in the EMR
2. Age 18 or older	Age 18 or older in the EMR as of the date of enrollment
3. Enrolled in primary care at the Syracuse VA Medical Center or affiliated Community-Based Outpatient Clinic	Primary care clinic and/or Primary care provider in EMR are affiliated with Syracuse VAMC or CBOC
4. Have at least mild functional impairment	Inventory of Psychosocial Functioning (IPF ≥ 11)
5. Screen positive on at least one primary care mental health screener	PHQ-9 ≥ 10, PCL-5 ≥ 31 AND a qualifying event on the LEC, GAD-7 ≥ 8, and/or AUDIT ≥ 8 for men/≥7 for women

4.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

Exclusion Criteria	Operational Definition
1. Actively engaged with an equivalent or higher level of care with the exception of medication management for mental health concerns	Pending or planned future appointments in: • Whole Health Coaching/Peer Support or other individual coaching/support for health, wellness, or lifestyle changes • PCMHI • Outpatient psychotherapy • Peer support
2. Preference for direct referral to mental healthcare	Veteran answers affirmatively to the question "Would you prefer a referral for mental health services rather than participate in this trial?"
3. Recent changes to psychotropic medications	Change in medication type or dose within the last 2 months to a psychotropic medication or a medication prescribed for mental/behavioral health concerns
4. Severe impairment preventing engagement with a peer, warranting direct referral to a licensed independent provider for monitoring	• High risk based on the P4 screener, and/or • Significant cognitive impairment (BOMC > 10), and/or

	and follow-up, and/or affecting ability to complete research tasks.	• Need for accommodations that would invalidate research measures, and/or • Inability to sustain attention/concentration to complete questionnaires, interviews, and/or peer sessions, and/or • Other significant concerns about impairment.
5.	**Inability to independently communicate in verbal and written English**	Demonstrates inability to understand and respond to research interviews and self-report assessments during the baseline in English, without assistance from a translator or interpreter.

5 RECRUITMENT PLAN

To recruit this sample, we intend to use direct marketing and/or referrals from the primary care team. Direct marketing could include a number of different strategies including posting paper flyers/brochures at VA and community locations (e.g., the Vet Center, ClearPath for Veterans, etc.), posting electronic flyers on electronic platforms (e.g., the VA television screens, VA facebook site), and tabling at the VA Medical Center and community events. Primary care team referrals will be facilitated by informational flyers and brochures, personal communication, and/or presentations at staff meetings. We will also conduct targeted chart reviews and electronic medical record datapulls to help providers identify potentially eligible Veterans and facilitate referrals. For recruitment purposes, the following criteria will be used to identify Veterans from medical records using a case finding procedure or the VA Informatics and Computing Infrastructure (VINCI):

- Veteran status
- Age 18 or older
- Enrolled in primary care at the Syracuse VA or an affiliated clinic based on primary care services at one of the aforementioned locations
- Positive behavioral health screen (i.e., PHQ-9, PHQ-2, PC-PTSD-5, PCL-5, GAD-7, AUDIT, or AUD-C) or relevant mental health diagnosis (i.e., depression, anxiety, PTSD, hazardous alcohol use) on the same day as a recent primary care encounter
- No recent (i.e., last month)[1] or pending peer support, Whole Health Coaching, PCMHI, or psychotherapy appointments.
- No recent (i.e., past two months) changes in dose or type of psychotropic medications
- No high risk suicide flags in the last year or positive suicide screens (i.e., C-SSRS, PHQ-9 item #9) within the last month
- Diagnosis of dementia within the last year

Contact information and identifying information (i.e., name, address, phone number, SSN) will be accessed to allow research staff to verify EMR information and contact potential participants.

[1] Although recent appointments are not part of the exclusion criteria, Veterans with recent appointments are not included in the electronic medical records recruitment pool to reduce recruitment of Veterans who may be pending scheduling their next appointment with an established provider. If Veterans are referred from other sources who have recent appointments of these types, they will be eligible as long as they meet the inclusion/exclusion criteria including no pending appointments.

Demographic information (including race, ethnicity, gender/sex) will also be accessed to allow staff to recruit a diverse population and increase recruitment efforts to Veterans from under-represented groups as needed.

For initial recruitment, Veterans identified through medical records will first be sent a recruitment packet (including a personalized invitation letter, study brochure, and informed consent information) then research staff will make multiple attempts to reach Veterans by the phone to conduct a phone screen. Veterans who are referred directly from a provider (e.g., warm handoff) or who contact the study through direct marketing (e.g., called the phone number on a flyer) will be given the option to complete the phone screen immediately and will be mailed information as soon as practical after initial contact. For all participants, an initial screening will be conducted to determine appropriateness of a baseline interview. Format of the screening (in person or telephone) will be determined based on Veteran preference and relevant safety-guidelines for in person meetings.

As appropriate, we will share names of Veterans we determine to be ineligible prior to contact with other studies approved to recruit using the same datapull procedures with overlapping eligibility criteria (e.g., if a participant schedules an appointment which would make them ineligible for our study after the datapull before recruitment, but that participant would otherwise be eligible for another study approved to access the name through the same means) we will share that information.

See 1.2 Schema for the anticipated number of Veterans to be screened for the target enrollment.

6 ASSESSMENT PLAN

Assessments will be conducted with Veterans in person, over the phone, or electronically using Qualtrics or REDCap (Research Electronic Data Capture) depending on format of the assessment, safety guidelines for in person meetings, and Veteran preference. Electronic data collection will be the primary data collection strategy but as a contingency plan if electronic administration is not feasible, staff will make every effort to collect the data in an alternate format (paper or oral format) to reduce data loss. If paper format is used, it will be returned in person or via pre-paid envelope. Research staff will call, text using a VA iPhone and/or send an SMS text via Qualtrics or REDCap, and/or send e-mails via a no-reply, Qualtrics or REDCap generated email address to remind participants to complete assessments as needed. See Data Security Plan for Qualtrics and REDCap security information. Email and text reminders will follow current VA guidance on information security procedures for these communication methods. If oral format is used, it will be through phone, VA approved video-conferencing format, or in person. As a safety precaution, when conducting assessments virtually, research staff will also confirm a phone number for call back, a physical address for where the Veteran is at that moment, an emergency contact person/phone number in case the Veteran has a medical or mental health emergency while on the phone, and two identifiers to confirm the Veteran's identity.

Electronic medical records data collection will be facilitated by research staff with recruitment activities occurring monthly and outcome data collection occurring at the end of the trial. Upon initial recruitment screening, baseline interviews will be scheduled to review consent and HIPAA information and to determine eligibility. If the Veteran chooses to participate in the study and appropriately answers comprehension questions, research staff will document verbal consent on the approved verbal informed consent script. This modification will reduce burden on participants by eliminating the requirement to travel for a baseline assessment to administer written consent and increase the feasibility of the research trial by broadening the population who will be able to participate.

After obtaining verbal consent, research staff will administer the following assessments at the specified timepoints:

Construct/ Function	Assessment	Recruitment Admin Data	Baseline Part 1	Baseline Part 2	Each Session or Post-Session	Mid Assessment	Final Assessment	Post-Treatment*	Post-Study Admin Data
Sample Description, Recruitment, & Screening	EMR Patient Identifiers and Contact Information	X							
	Self-Report Contact Information		X						
	EMR Demographics	X							
	EMR Mental Health Screeners & Relevant Diagnoses	X							
	EMR Veteran Status	X							
	EMR Primary Care Team Information								
	EMR Medications	X							
	EMR Problem List	X							
	BOMC (for cognition/ orientation)		X						
	P4 Screener (for suicidality)		X						
	Preference for direct referral to behavioral health		X						
	Demographics Questionnaire			X					
Psychosocial Functioning (Primary Patient Outcome)	**IPF (psychosocial functioning)**		X			X	X		
Behavioral Health Symptoms	**PHQ-9 (depression)**		X			X	X		
	GAD-7 (anxiety)		X			X	X		
	LEC (PTSD)		X						
	Criterion A Assessment (PTSD)		X						
	PCL-5 (PTSD)		X			X	X		
	AUDIT (alcohol use)		X			X	X		
Other Peer Services Outcomes	**EMR VA Healthcare and Social Services Appointments**	X							X
	Self-Report non-VA Healthcare and Social Services Utilization		X			X	X		
	RAS-SF (recovery)			X		X	X		

	WAI (therapeutic relationship)							X	
Other Whole Health Outcomes	MILM (meaning in life)			X		X	X		
	QOLI (quality of life)			X		X	X		
	ACORN (resources)			X		X	X		
	WHGAT (Whole Health Goal Attainment)				X				
Whole Health STEPS Feasibility	Intervention retention								X
	Fidelity Checklist				X				X
	Peer Post-session feedback forms (also falls under acceptability)				X				
	Supervisor Post-session feedback forms (design/manual usability)				X				
	UE-ATR (safety)								
Whole Health STEPS Acceptability	*Veteran post-session feedback forms*				X				
	Veteran post-treatment feedback interview							X	
	CSQ (satisfaction)							X	
Research Feasibility	Recruitment and eligibility rates								
	Data Collection & Procedural Problems								
	Research retention								X

Notes. Assessments in bold are included in eligibility determination. Assessments in italics are for the open trial phase only. The post-treatment assessments are added to either the mid or final assessment as appropriate in the RCT phase. If a participant ends peer support services earlier than expected before the mid or final assessments are due (e.g., due to withdrawal from intervention but not research, because their goals were met with fewer sessions), the post-treatment will be administered at the participant's earliest convenience separately from the mid or final assessments.

6.1 PLAN FOR ORDERLY TERMINATION OF PARTICIPATION

When participants are discontinued from the project by investigator decision, research staff will communicate with the participants to inform participants of the discontinuation, the reason for discontinuation, and offer opportunities for participants to express concerns or ask questions.

When participants are discontinued from the project for any reason (by participant choice or investigator decision), the peer and research staff will do their best to ensure that participants' ongoing needs are met and facilitate referrals as appropriate.

6.2 PARTICIPANT PAYMENT

Participants will be compensated at a rate of approximately $20 per hour for research activities (i.e., interviews and self-report assessments). This compensation rate is the rate used for similar behavioral health clinical trials at the Syracuse VA and does not appear to lead to undue influence or coercion.

Compensation will occur through established VA payment procedures approved for research activities (e.g., direct deposit or via a VA debit card). Research staff will collect the minimum required identifiable information to properly process their payments (e.g., if research staff need bank account information to complete a direct deposit form, they will collect the necessary information for the form). Veterans will not be compensated for intervention appointments (i.e., Whole Health STEPS appointments with peers). The compensation for each of the study activities is detailed below.

Open Trial Study Activity	Estimated Burden	Compensation
Baseline Part 1 Consent & Eligibility Determination	~ 1 hour	$20
Baseline Part 2 Remaining Assessments	~ 1 hour	$20
Post Session Rating Forms (approximately 6 over the study)*	~ ¼ hour each *6 total = ~1.5 hours	$5 each *6 total = $30
Mid and Post Treatment Assessment	~1½ hour	$30
Post Treatment Interview	~ ½ hour	$10

* To reduce administrative burden with processing multiple payment vouchers for small amounts, the post-session rating forms will be paid in a lump sum at the end of the study along with the post-treatment interview payment unless participants request a different payment schedule.

RCT Study Activity	Estimated Burden	Compensation
Baseline Part 1 Consent & Eligibility Determination	~ 1 hour	$20
Baseline Part 2 Remaining Assessments	~ 1 hour	$20
Mid Assessment	~ 1 hour	$20
Final Assessment	~ 1 hour	$20
Post Treatment Assessment (added to either Mid or Final Assessment depending on randomization, or administered ASAP after a participant ends peer support services)	~ ½ hour	$10
Post Treatment Interview	~ ½ hour	$10

6.3 SAFETY MONITORING PLAN

Following enrollment, participants will be monitored for safety by the peer, clinical staff and research staff. Research staff will review data for safety concerns on an ongoing basis throughout the study. Specifically, when research staff note AEs or SAEs in routine chart reviews or these are reported by participants, staff and/or the peer will document the finding and alert the PI and/or appropriate clinical back-up to ensure that participants have appropriate clinical services and appropriate reporting procedures are initiated.

Suicidality will also be assessed at baseline, mid, and final assessments. Suicidality assessment will consist of the P4 and item 9 of the PHQ-9 at baseline. At follow-up assessments, item 9 of the PHQ-9 will be checked by research study staff immediately after receipt of questionnaires. Positive endorsements of PHQ-9 item 9 will be followed up directly with the Veteran to review original P4 risk assessment, inquire about changes, and re-administer the P4 risk assessment as needed. All Veterans scoring in the

higher risk category on the P4 will be referred to appropriate clinical services (e.g., on call study clinician and/or appropriate VA mental health resources, such as the Emergency Room, available VA mental health provider, Veterans Crisis Line, and/or the Syracuse VA Suicide Prevention Team) and the PI will be notified.

In addition, Veterans will be monitored for safety concerns by the peer during intervention sessions. Peers are trained to recognize potential safety concerns and crises and ensure that the Veteran receives appropriate clinical support (e.g., on call study clinician and/or appropriate VA mental health resources, such as the Emergency Room, available VA mental health provider, Veterans Crisis Line, and/or the Syracuse VA Suicide Prevention Team). The PI will be conducting ongoing supervision of peer support providers and will check-in about potential safety concerns during supervision.

All AEs and SAEs will be reported via established procedures.

7 RESEARCH STUDY DOCUMENTATION PLAN

CPRS documentation will include documentation of research study initiation, research study completion, and relevant clinical tasks. Routine research study activities (e.g., completing self-report assessments) which are expected during the course of the study but do not inform the Veteran's healthcare will be described in the research study initiation note but not documented separately. Peer services will be documented in clinically appropriate progress notes in a manner consistent with usual clinical practice and peers' role as either clinical or research staff. Additional documentation will be entered into CPRS as needed and appropriate to ensure Veteran continuity of care (e.g., referrals for services, information regarding suicide risk, etc.).

8 RISK AND BENEFITS

The potential benefits of the project outweigh the minimal risks.

8.1 RISKS

There is minimal risk from participation in any of the research activities. The procedures are non-invasive and will not cause physical harm to participants. There are no known risks associated with peer services or the Whole Health model; both are part of standard care offered through the VA. There is minimal psychological risk (i.e., embarrassment, discomfort) to participants when asked to share sensitive information about themselves (e.g., suicidal thoughts, mental health symptoms) with research staff or the peer. No deception is involved in this study.

8.2 MINIMIZING RISKS

Participants will be assessed for suicide risk according to an established protocol and directly referred for additional services (e.g., Veterans' Crisis Line, VA Emergency Room, VA mental health provider, Suicide Prevention Team) as appropriate if they are at high risk. Research assistants will be trained to provide grounding/relaxation activities as appropriate to participants who experience mild psychological discomfort (e.g., distress, frustration, anxiety) as a result of any study activities. Further, any Veteran can be connected with an on-call clinician or mental health provider at any point in the study at their request or if they report mental health symptoms which are concerning to the peer or research staff. Also, facilitating engagement with services, including mental health treatment as needed, is part of the

Whole Health STEPS approach. 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 information including voice recordings, informed consent, payment status, and enrollment information will be stored separately and in accordance with the data security and privacy procedures. Data security and privacy procedures are designed to minimize this risk.

8.3 BENEFITS

The study has multiple potential direct and indirect benefits to participants. One potential direct benefit is that interviews, telephone screenings, and assessment sessions may provide the opportunity for participants to thoughtfully reflect on their current situation and which may increase insight and prompt change (e.g., behavior change or seeking additional treatment). Additionally, all Veterans will receive Whole Health STEPS which may be beneficial given past research on peer support and Whole Health services. 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.

9 DATA SECURITY PLAN

The PI will oversee data and safety monitoring to ensure safety of participants and integrity of data collected. All research staff and the peer will have training appropriate to their roles in data management and security.

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

Coded self-report survey data will be collected using Qualtrics or REDCap, web-based data collection tool. Paper/Pen and oral administration (documented in Qualtrics, REDCap, or Paper/Pen) will be used as contingency plans. Participants will be invited to supply an email address during the baseline interview which will be used to generate a reminder email from Qualtrics or REDCap containing a link to complete follow-up assessments. This email will come from a no-reply, Qualtrics or REDCap generated email address. Participants can choose not to supply an email address. Participants who prefer to receive a text message link of Qualtrics or REDCap surveys will be texted via the phone number that is stored in the Access log. In instances where Qualtrics or REDCap are used, participants will complete online surveys via Qualtrics or REDCap, but VA research staff will download and store all data in one database which will be built and will reside on a VA secured network drive. Qualtrics is hosted in a FedRAMP authorized environment and is compliant with VA security policy (See Qualtrics Security Statement, *https://www.qualtrics.com/security-statement/*). REDCap is hosted on the VA Enterprise Cloud (VAEC) and was developed specifically around HIPAA-Security guidelines.

All data from this study will be stored in locked filing cabinets and password-protected secure computer networks at the Syracuse VA. Only approved research staff and relevant oversight committees will have access to the data. All data will be kept strictly confidential and secure per VA policies, American Psychological Association (APA) ethical standards, and human subjects research policies. Identifiable data will be stored separate from de-identified data in locked filing cabinets and password protected computer files on a VA secured network drive.

Study records will be retained in accordance with current VA policies (VHA Records Control Schedule). Identifiers will be maintained through the duration of the research study and then destroyed consistent with VA policy.

10 DATA SHARING PLAN

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

- Publications from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication.
- This trial is registered at ClinicalTrials.gov and results from this trial will be submitted to ClinicalTrials.gov.
- Final datasets underlying all publications resulting from the proposed research will be shared outside of VA under the following conditions.
    - A de-identified, anonymized dataset will be created and shared. It will be made available upon written request to allow for re-analysis and validation of results. All identifiable information and identifiers (e.g., ID numbers) will be removed from the dataset prior to sharing. Any data involving identifiable information(e.g., appointment dates) will be included as summary data (e.g., appointment counts) only. Sharing will take place under a written agreement prohibiting the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset.

11 DATA ANALYSIS PLAN

Qualitative feedback (e.g., interview responses and open-ended items) will be analyzed using a rapid qualitative analysis approach (Hamilton, 2013). Quantitative analyses for descriptive aims (e.g., fidelity, feasibility) will be analyzed using descriptive statistics (e.g., central tendency and spread statistics such as counts, means, ranges, and standard deviations). Quantitative analyses for patient outcomes will be analyzed using statistical modeling to establish effect size which will be evaluated in comparison with the a priori effect size of d=.3.

12 REFERENCES

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