A Hybrid Effectiveness-Implementation Trial of a Wellness Self-Management Program (Living Well)
Central IRB Protocol
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Background and Purpose

Overview

Veterans with serious mental illnesses (SMI) are at elevated risk for co-occurring medical conditions resulting in increased risk of disability, high health care spending, reduced quality of life and early mortality. Physical wellness is increasingly recognized as a key component of the VA's commitment to developing recovery-oriented treatment, promoting attention to interventions that promote and improve patient self-management of chronic medical conditions. The Chronic Disease Self-Management Program (CDSMP), a peer-facilitated group intervention that emphasizes training in disease self-management strategies, action planning, feedback and problem-solving, has been shown across multiple studies to improve health related attitudes and behaviors, health status and efficient utilization of medical services among adults with a range of chronic medical conditions. A recent adaptation of this program for SMI consumers found improved patient activation and health related quality of life, with effect sizes similar to those seen in CDSMP general population studies. In a separate contemporaneous effort, our team developed and evaluated a modified and enhanced version of the CDSMP called Living Well. Our results included significant improvement in somatic and mental health related attitudinal (self-efficacy, patient activation), behavioral (self-management behaviors) and functional outcomes (general health functioning, physical and emotional well-being) as well reduced emergency room use for medical care.

The VA has been a national leader in creating service delivery models integrating psychiatric and somatic care. To complement and enhance these systems-level initiatives, there remains an urgent need to establish and disseminate effective Veteran-centered self-management interventions, such as Living Well, that show promise for improving functional outcomes and limiting use of expensive emergency room visits for the management of chronic medical conditions. Also, although the VA is becoming a national leader in engaging and training peer specialists to help support mental health recovery and self-management, such efforts have not been extended to medical self-management services for SMI Veterans, thereby limiting the VA's capacity to adequately address the full recovery needs of Veterans. Further, little is known about how to best enhance the uptake, implementation and sustainability of peer programming related to medical illness self-management.

Building on the established efficacy of consumer facilitated medical illness self-management programming used in the general population and two recent adaptations for use with SMI adults in the public health sector (including our own evaluation of an intervention called Living Well), we propose to complete a randomized controlled effectiveness trial of our Living Well intervention and simultaneously conduct a well specified process evaluation to optimize knowledge accrual regarding important factors that may improve future adoption, implementation and sustainability of the Living Well intervention in the VA system of care.

Hypotheses

The purpose of this study is to: 1. Complete an effectiveness trial of Living Well in the VA context, and; 2. Concurrently collect, in the context of a process evaluation, important contextual and cost information that can help speed throughout to public health impact.

For the remainder of this protocol all required descriptions will be presented first for the EFFECTIVENESS TRIAL and second for the PROCESS EVALUATION.

Objectives and hypotheses for the EFFECTIVENESS TRIAL:

Objective: Complete a randomized controlled effectiveness trial comparing Living Well to a general medical illness education and support group among SMI Veterans with co-occurring chronic medical conditions. Those receiving Living Well will demonstrate:

Hypotheses for EFFECTIVENSS TRAIL:

Primary Hypotheses (regarding functional and service-related outcomes)

Hypothesis 1: Improved general, physical, and emotional functioning post intervention.

Hypothesis 2: Lower rates of medical emergency room use for management of a chronic medical condition six months post randomization.

Secondary Hypotheses (regarding more proximal attitudinal and behavioral outcomes)

Hypothesis 3: Improved health-related self-efficacy and patient activation post intervention. Further, such improvements will mediate the effects of the functional and service outcomes specified above.

Hypothesis 4: Improved self-management behaviors post intervention. Further, such improvements will mediate the effects of the functional and service outcomes specified above.

Secondary Hypothesis (regarding retention of intervention effects)

Hypothesis 5: Sustained improvements across functional, attitudinal and behavioral outcomes for three months after completing treatment.

Objective for the PROCESS EVALUATION:

Complete a well specified process evaluation based on the RE-AIM evaluation framework to better understand contextual factors that can improve future adoption, implementation and sustainability of the Living Well intervention in the VA system of care. A cost analysis will also be completed as part of this effort.

Methodology

Research Design

Research Design for EFFECTIVENESS TRIAL:

The research design for the EFFECTIVENESS TRIAL will include a randomized trial (N=250) comparing participants assigned to the Living Well self-management intervention or the medical illness education and support comparison group. Using an intent-to-treat framework, we will collect data from every participant at four time points, at consent, at randomization, post-treatment (3 months from randomization assessment), and again 3 months later (6 months from randomization).Services data regarding use of the ER and other medical services including outpatient appointments with primary and

specialty care medical providers within the VA will be collected at the follow-up assessment (6 months from randomization) as this allows for a more realistic timeframe for assessing effects on service utilization. To inform related analyses we will also collect retrospective service utilization data for a full six months before consent. We will recruit participants from outpatient programs with the VAMHCS (Baltimore and Perry Point) and from the DCVA.

Research Design for PROCESS EVALUATION:

A well-specified process evaluation based on the RE-AIM Framework will be used to guide the PROCESS EVALUATION. The acronym stands for Reach, Effectiveness, Adoption, Implementation, and Maintenance which together determine public health impact. This evaluation will integrate findings from two streams of inquiry: 1) A qualitative study that combines focus groups and in-depth individual interviews conducted both before and after the clinical trial, and; 2) a cost analysis focused on implementation/operating costs and cost consequences.

Setting

Effectiveness Trial participants will be recruited from outpatient programs within the Baltimore and Perry Point VA Maryland Health Care System (VAMHCS) as well as the Washington, DC VA Medical Center.

Recruitment

Potential VA participants will be identified by several methods: (1) CPRS chart review and screening via use of partial HIPAA waiver, (2) VA clinician referrals of participants who meet inclusion criteria and who might be interested in participating, (3) Self referrals by participants who hear about the study and are interested in participating or who have participated in other MIRECC studies and have indicated a willingness to be contacted for studies in the future, (4) Self-referral via IRB approved study flyer (5) Use of the VAMHCS MIRECC Recruitment Database (Protocol # 00042721) to identify participants who meet study eligibility criteria.

Participants will be screened for eligibility via chart review. Study staff will then contact a VA treatment team member to determine if a potentially eligible participant is clinically stable enough to participate in the study and can be contacted for recruitment.

Per VA requirements, initial contact with veterans will be made in person or by letter prior to any telephone contact. Specifically, we will approach individuals before or after their VA appointments.

We will also send out a letter to the participant to see if they are interested in participating in the study. They will be given contact information for the study staff as well as a pre-stamped envelope and postcard to mail back to indicate their interest or lack of interest. A follow-up phone call will be made to ensure the participant received the mailing.

Further, it should be re-iterated that research assistants who will interact with participants are all specially trained to work with persons with serious mental illnesses. Research staff will first consult the participant's treatment team for permission to begin the consent process. This will help avoid approaching people who may be in crisis or may not be able to comprehend the study

procedures, risks, and benefits.

Participants

1) *Effectiveness Trial Participants (Veterans)*:

   Inclusion Criteria: (1) Diagnosis of Schizophrenia/Schizoaffective disorder, bipolar disorder, major depression with psychotic features, psychosis NOS, or PTSD, (2) Age 18-80, (3) chart documented presence of at least one of the following chronic medical conditions: a respiratory condition, diabetes, arthritis, cardiovascular condition, (4) Receiving mental health services at a designated study site, (5) willing and able to provide consent to participate, (6) deemed clinically stable enough to participate in the study by a treatment provider.

   Exclusion Criteria: (1) Serious cognitive impairments due to brain damage or injury, (2) Enrollment in ongoing studies at the MIRECC, A Randomized Control Trial of Ending Self-Stigma for PTSD and Improving Negative Symptoms and Community Engagement in Veterans with Schizophrenia.

2) *Clinicians and Stakeholders in the Process Evaluation Trial:*

   Inclusion Criteria: (1) Employed by the VA as a national stakeholder, clinician or administrator as defined by: Stakeholder: National VA Central Office Staff affiliated with the Health Promotion and Disease Prevention Program, Office of Peer Services within the Psychosocial Rehabilitation and Recovery Services (PSR&R) section of the VA National Office of Mental Health Services, the VA's Office of Patient Centered Care, and the Primary Care-Mental Health Integration Program (PC-MHI). Clinician: local mental health providers and administrators associated with VA mental health treatment programs. (2) Willing and able to provide consent to participate in the Process Evaluation focus groups and/or individual interviews.

   Exclusion Criteria: (1) None.

3) *Peer Facilitators in the Process Evaluation Trial:*

   Inclusion Criteria: (1) Served as a peer facilitator for the Living Well group condition, (2) Willing and able to provide consent to participate in the Process Evaluation interview.

   Exclusion Criteria: (1) None.

Participant Safety Procedures

If the research interviewer hears about or sees that the participant intends to harm themselves or someone else, s/he will tell a doctor or some other authority so that they can get some help, even if it means telling the authorities without the participant's permission. In such a situation, the researchers would only disclose information that would prevent harm to the participant or other people believed to be in danger.

If we hear about or see something that would immediately endanger the participant or others, such as child abuse, we will seek help, to protect the child. If a participant tells us information about child abuse,

physical abuse or sexual abuse we must disclose this information to the appropriate individuals and/or authorities. We must report this information regardless of when the child abuse occurred (whether it is occurring now or happened in the past) or who was the victim of the abuse (whether it was the participant or someone else). Also, the researchers will report certain diseases that can be given to other people.

Study Procedures

1. Procedures Associated with the EFFECTIVENESS TRIAL:

We will complete a randomized trial (N=250) comparing participants assigned to the Living Well self-management intervention or a medical illness education and support comparison group. Using an intent-to-treat framework, we will collect data from every participant time of consent, as well as at times of randomization, post-treatment (3 months from randomization assessment), and again 3 months later (6 months from randomization).

Services data regarding use of the ER and other medical services including outpatient appointments with primary and specialty care medical providers within the VA will be collected at the follow-up assessment (6 months from randomization) as this allows for a more realistic timeframe for assessing effects on service utilization. To inform related analyses we will also collect retrospective service utilization data for a full six months before time of consent.

Procedures defining the consent, randomization, post-treatment and 6 month follow-up Veteran assessments:

All participants will complete assessment interviews at the time of consent, randomization post-intervention (3 month post-randomization), and 3 months post treatment (6 months from randomization). Trained RAs blind to the participant's condition assignment will administer all assessments. In order to ensure that the assessors remain blind, the RA completing the randomization interview (who then informs the participant of their treatment condition) will not complete the post-treatment or 3-month post-treatment follow-up interview with that same participant. However, the post-treatment and 3-month post-treatment follow-up interview may be completed by the same RA. Prior to starting the post-treatment and 3-month post-treatment follow-up, participants will be told not to reveal their study condition (Living Well or medical illness education and support group). If they do, the RA will make a note in the interview materials indicating that the blind was compromised and at what point during the interview this occurred. This RA will still complete the rest of the interview with the participant. If the blind does become compromised, a different RA will conduct the next scheduled assessment. Interviews will take approximately 1 ½ to 2 hours to complete. Please see Detailed Description of Measures section of this protocol for list of assessments and interviews included in the follow-ups.

If study staff is unable to contact enrolled participants by telephone to schedule a randomization, post-intervention, or 3 month post-treatment interview, a letter will be sent to participants to let them know we are attempting to contact them.

Also, we will include CPRS/Chart Summaries of Medical ER Use and Prescribed Medications: CPRS extracted chart data (including admission and discharge codes) will be extracted and used to summarize rates, patterns and reason for visit for the six month interval post randomization. The decision to look at this for a full six months in lieu of immediately post-treatment was made in order to allow for a more realistic timeframe for assessing intervention effects on service utilization. We will also extract details regarding both psychiatric and somatic medications.

Procedures Defining the Delivery of the Experimental and Control Condition Interventions:

Living Well (Experimental Condition):

Living Well will be implemented as a 12 session small-group intervention (4-8 persons). Groups will meet weekly for 75 minutes for three months (12 sessions). The 12 session weekly curriculum will be delivered as a series of 4 three-session modules. Module one provides an overview of the full course and begins with a review of the key concepts of self-management and proceeds with sessions focused on learning the behavioral action planning and problem solving skills that are used across the remaining modules. Since the first module of this intervention contains the fundamental building blocks that will be utilized throughout the intervention, participants who miss any of the first 3 start-up sessions will be offered an opportunity to meet individually with a facilitator to review the missed session content. These review sessions can be completed by the participant either in person or by phone. Remaining modules focus on a variety of wellness topics including health eating, medication management, and communicating with providers. After completing the 12 weekly groups, participants will return to complete once monthly booster group sessions for the next three months. All Living Well group sessions and booster sessions will be video recorded. The Living Well intervention will be led by a trained interventionist and co-facilitated by a peer provider using the manualized curriculum developed in our previous research. The pairing of a trained peer and professional affords maximal flexibility and will help support uptake of the intervention. This study is based on the intent-to-treat model. Regardless of level of participation in the Living Well groups, all randomized participants will be eligible and contacted to schedule post treatment follow-ups for this study.

Medical Illness Education and Support Group (Comparison Condition):

We selected a comparison condition that would provide parallel focus (i.e. medical illness) but not include use of the core ingredients undergirding the Living Well intervention including behavioral action planning, problem solving, in-session and between session practice using specific disease self-management techniques and involvement of peer co-facilitators to enhance modeling and improve self-efficacy and activation. As with Living Well, the content of the intervention will have broad applicability across diverse chronic disease conditions. The comparison condition will be a once-weekly support and education group focusing on living with a chronic medical condition. All Medical Illness Education and Support group sessions will be video recorded. Groups will be led by a single professional interventionist and will include standardized didactic review of common challenges experienced by those living with a wide range of chronic medical illnesses and related behavioral and lifestyle self-management techniques. Each session will follow a basic structure that includes a review of the material presented in the previous session, new education content and discussion. This study is based on the intent-to-treat model. Regardless of level of participation in the Medical Illness Education and Support group, all randomized participants will be eligible and contacted to schedule post treatment follow-ups for this study.

2. Procedures Associated with the PROCRESS EVALUATION

We propose to complete a process evaluation based on the RE-AIM evaluation framework to better understand contextual factors that support the conduct of the proposed trial and that will affect future efforts to implement and sustain the Living Well intervention in the VA system of care. The proposed evaluation also provides a distinct and complementary avenue for understanding differential outcomes across conditions. This evaluation will integrate findings from two streams of inquiry: 1) A qualitative study that includes combines focus groups and/or individual interviews conducted both before and after the clinical trial, and; 2) a cost analysis focused on implementation/operating costs and cost consequences. The PROCESS EVALUATION will be conducted both BEFORE the EFFECTIVENESS

Trial and AFTER the EFFECTIVENESS TRIAL.

Pre-trial focus and methods:

Prior to initiating the effectiveness trial, we will conduct a series of qualitative focus groups and/or individual interviews with a range of key stakeholders to: 1) Identify obstacles and barriers that might impede the proposed trial, and; 2) collect contextual information that will inform future dissemination and sustainability of the Living Well intervention in the broader VA context. The discussion guide used to help facilitate these groups or interviews is attached to this protocol submission.

Methods: We will complete focus groups and/or individual interviews with local clinicians and administrators working in implementation sites. Queries will focus on clinician/administrator perceptions of how well they think Living Well fits with existing clinic services for Veterans with co-occurring medical conditions, and their perceptions of potential barriers and facilitators associated with adopting the Living Well intervention for use in their programs/clinics. The groups or interviews will also discuss how to best secure buy-in from program administrators, clinicians and service recipients to support Living Well during the trial and anticipated challenges to securing the resources needed to support and sustain Living Well beyond the trial. A facilitator guide to help focus group discussion is attached to this protocol.

All group meetings or interviews will be digitally recorded and transcribed by a staff member listed on this protocol. Copies of transcripts, along with field notes and observations made by focus group leaders, will be used to draft summaries for each group session. All participants will be invited to review these documents and their feedback will be used to refine our summaries.

Post-trial focus and methods:

After completing the EFFECTIVENESS trial, we will conduct focus groups and in-depth individual interviews with Veteran study participants, Veterans who served as peer co-facilitators in the Living Well condition, and various stakeholders involved in the pre-trail evaluation to: 1) extend and enhance our understanding of intervention outcome and processes, and; 2) inform the development of an implementation toolkit to support future dissemination efforts. The discussion guides for all of these are attached to this CICERO submission.

We will conduct a post-trial focus group with the same people who participated in the pre-trial groups. Specifically, this will involve re-convening the local clinicians and administrators. Preliminary results from the trial will be shared and discussed in relation to implications for local programming. Other questions will focus on their perceptions of how study participation impacted Veterans receiving services in their program, and what resources/assistance the programs feel would be needed to support continued implementation of the Living Well intervention. As such the post-trail focus groups will give us a distinct and complementary avenue (in combination with results from the trial) to understanding outcomes associated with receipt of the intervention and processes of implementation. All post-trial focus groups will be audio recorded, transcribed, reviewed by study team, and summaries distributed to participants for feedback before they are used to write summary documents.

Across both conditions, we will also complete in-depth individual interviews with a sub-set of Veterans who participated in the trial, purposefully selected to include some who completed the intervention (target n=10) and some who decided to discontinue (target n=10). These interviews will focus on why Veterans decided to enroll, their initial expectations, and what led to their decision to continue or discontinue. Among those who completed Living Well, we will explore the impact of the intervention on their self-

management challenges during the intervention and how they have made use of knowledge and skills learned from Living Well since completing the intervention. We will also complete in-depth individual interviews with individuals who served as peer co-facilitators for the Living Well intervention. These interviews will focus on understanding how leading the Living Well groups influenced their own self-management, and what they observed among the participants. Interviews will also focus on their experiences of the training and support they received in preparation and while delivering the Living Well intervention.

All the interviews will be semi-structured with open-ended questions, will last approximately 1 hour and will be conducted in private by study team members. They will be digitally recorded and transcribed. In addition, the interviewer will take notes during the interview and record her observations immediately after the session.

Analytic methods for both focus groups and interviews include coding the interview data (assisted by Atlas.ti software) into categories and using those categories to build higher order concepts and themes. Themes and categories will be sorted and synthesized and examined for interrelationships, checking back to the data frequently. These connections will potentially lead to the development of a conceptual or theoretical framework depicting how various elements of Living Well are experienced, the impact the intervention has on important Veteran level outcomes, and the role Veterans might play in future dissemination efforts.

The PROCESS EVALUATION will also include a COST ANALYSIS.

We will assess the average cost of a Living Well program, including implementation and operating costs, and complete an initial analysis of VA health care cost consequences of Living Well to assess whether participation in Living Well results in any savings (i.e., "cost offsets") to the VA healthcare system. The analysis will apply the opportunity cost approach from the perspective of the VA health care system (i.e., the "payer perspective"). The approach will be consistent with methods recommended for economic evaluation studies. All analyses will be use VA administrative and chart data collected as part of this study. Data from the Services Utilization Record Form (SURF) described and cited above, will also be used to inform cost analyses.

The PROCESS EVALUATION will also include consulting with an Advisory Board.

We will hold periodic calls with a board of advisors to discuss how to use what we learn in the study to inform future implementation considerations. Advisors will include key stakeholders at the local, VISN and National VA level. No individual level data or PHI will be shared with this board. Instead, the board will only discuss anticipated challenges and opportunities to support ultimate uptake within the VA system of care and the intervention being evaluated in the context of this study.

Detailed Description of Measures

Measures/Instruments included in the assessment battery

1. The Medical Outcomes Study (MOS) SF-12: The SF-12 (39), a widely used standardized instrument with strong psychometric properties, will be used to assess self-perceptions of general health functioning across multiple dimensions (including general, physical and emotional/psychiatric functioning). The SF-12 has shown good internal, consistency, stability, and concurrent validity in outpatients with serious mental illness. (instrument is attached to this protocol).

2. Illness Management Self-Efficacy: This questionnaire is based on the items used in the original Chronic Disease Self-Management Program (CDSMP) as part of that groups extensive evaluation of the curriculum (41). The original CDSMP measure has been shown to have strong test-retest reliability and internal consistency as well (41).

3. Patient Activation Measure: This 13-item questionnaire measures an individual's perceived ability to manage his or her illness and health behaviors and act as an effective patient. The measure has demonstrated reliability and validity (36).

4. Measure of Self-Management Behaviors: This questionnaire is based on the items used in the original CDSMP as part of that group's extensive evaluation of the curriculum (41). The original CDSMP measure has been shown to have adequate psychometric properties; the range of test-retest coefficients for the original illness management scales was .56 to .92, with internal-consistency coefficients ranging from .70 to .75.

5 Morisky Medication Adherence Scale: This 8 item self-reported medication adherence scale was developed from a well validated 4-item scale and supplemented with additional items to better capture barriers surrounding adherence behavior. This new scale has demonstrated psychometric properties (43).

6. Basis 24 – Modified: The Basis 24 – Modified is a self-report measure that asks participants about their symptoms and functioning within the time period of a week. Response sets range from "no difficulty – extreme difficulty", "none of the time – all of the time", and "never – always", each with 5 options.

7. Service Utilization and Resources Form (SURF): The SURF has been used successfully in several VA studies to assess service utilization relating to a range of medical services including ER, inpatient and outpatient services (40).

8. The Mental Illness Research, Education and Clinical Center (MIRECC) Demographic Form: The MIRECC Demographic form will be used to gather basic demographic information from the participant, including age, race, gender, living arrangement, etc.

9. Maryland Assessment of Recovery Scale : The MARS a 25-item self-report measure of recovery. Items are rated on a 5-point Likert scale (strongly disagree to strongly agree). The MARS has been shown to have good internal consistency (alpha=.95) and test-retest reliability (r = .868)

10. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) is a comprehensive neuropsychological screening battery that assesses memory, language, visuo-spatial/constructional ability, and attention. The RBANS has been shown to perform well as a clinical screening test and as an outcome measure for clinical trials in schizophrenia. As cognitive functioning may relate to study outcomes, RBANS scores will be used in exploratory analyses focusing on the relationship between various cognitive skills and related study outcomes. We will be using an abbreviated version.

11. Insomnia Severity Index (ISI): This measurement is a brief assessment (7 items) inquiring about the severity of a person's insomnia and sleep problems and patterns. It also questions their satisfaction level with their sleep, how worried or distressed they are, and how much they feel it is interfering in their daily functioning. All responses are on a 4 point Likert scale.

12. Medical Conditions (MCON): A series of interview items drawn from the National Health and Nutrition Examination Survey III solicits the presence of lifetime and current co-occurring medical conditions and whether the patient is currently receiving treatment.

13. PAIN Measure: This measure was created for this study. It consists of 4 Likert response questions from the Pain Numeric Rating Scale which is available on the Department of Veterans Affairs website under Clinical Tools for Pain Management that inquires about a person's level of pain. It also consists of a one yes/no question and one multiple choice response questions where both inquire about treatment of pain.

14. Participation with Services: This questionnaire was created for this study. It is comprised of yes/no and Likert-response item questions concerning participants' exposure to and involvement in peer facilitated groups or individual encounters with peer-counselors that focus on both mental health as well as physical and medical health and wellness.

15. Substance Use and Health Behaviors (SUHB): This instrument inquires about the use of substances and the effects on healthy behaviors, specifically illicit drugs, alcohol, tobacco, and caffeine. It also queries about the treatment for substance use or abuse, and regular physical activity and exercise.

16. Multidimensional Health Locus of Control (HLOC): An 18 item questionnaire with responses ranging on a 6 point Likert scale from Strongly Disagree to Strongly Agree that asks about self-perceived control over one's health, illnesses, and ability to take an active role in one's health.

17. General Medical and Psychiatric Services (GMED): This assessment measures how frequently participants utilize general heal services, including primary medical doctors, specialists, emergency services, mental health services, and inpatient hospitalizations.

Effectiveness Trial Assessment/Interview Study Schedule

	Consent	Randomization	Post-treatment	3-month Follow-up	Post-Trial Interview (N=20)
Assessments: • The Medical Outcomes Study • Illness Management Self-Efficacy • Patient Activation Measure • Measure of Self-Management Behaviors • Addiction Severity Index (ASI) • Morisky Medication Adherence Scale • Basis 24 Modified • Service Utilization and Resources Form (SURF) • Maryland Assessment of Recovery Scale (MARS) • General Medical and Psychiatric Health Services (GMED) • Multidimensional Health Locus of Control (HLOC) • Substance Use and Health Behaviors (SUHB) • Participation in Other Services (POS) • PAIN Measure • Medical Conditions (MCON) • Insomnia Severity Index (ISI)	R	R	R	R	
• The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) (randomization only) • MIRECC Demographics	R				

(randomization only)					
Interview					R

Treatment Procedures

This is not a treatment study. All assessments and group sessions will be conducted by Research Assistants carefully trained on all study-related assessments and the manualized study intervention.

Staff Training/Fidelity Monitoring

***Living Well* Interventionist Training and Fidelity Monitoring**

Our research team, including Drs. Goldberg and Lucksted has extensive experience developing psychosocial treatments and ensuring their fidelity. Drs Goldberg also has extensive experience training peer providers. All study interventionists (both peer and professional) will receive training that will include a thorough orientation to the *Living Well* curriculum and manual. This will include review of videotaped sessions of the intervention (created during our pilot work) and opportunities to practice and refine the skills needed to deliver the *Living Well* intervention. Our training includes modeling, role-plays, and practice facilitating mock group sessions. The peer interventionists will receive additional training sessions that are designed to enhance mental health peer providers' knowledge and further the development of their skills that will aid them in co-facilitating the *Living Well* Intervention. The training will be delivered in 3 full days and will cover a variety of topics including: Developing and using one's own recovery and wellness management story as a tool to assist others; strategies for effective communication; confidentiality/boundaries/dual relationships; advocacy; accessing and utilizing VA and community resources; suicide prevention awareness; group facilitation skills; and cultural competence.

To maximize the use of modeling and optimize peer support, all peer providers will have a co-occurring chronic medical condition. Non-peer co-facilitators will be selected from our pool of research interventionist all of whom have prior experience conducting psychosocial interventions with individuals with serious mental illness. If possible, we will select those who are living with a chronic medical condition to further maximize the effects of modeling and support based on a shared experience.
To aid with ongoing supervision and fidelity monitoring, we will develop a structured supervision strategy that includes audio/videotaping of all session, weekly supervision conducted by one or more of the investigators, and objective assessment of adherence and competence. To complete this aspect of fidelity assessment we have developed a facilitator adherence and competence rating scale. The adherence scale contains items (scored "excellent, "acceptable" or "unacceptable") assessing the presence or absence of core features of the intervention including instruction in and practice behavioral action planning, in-session practice of self-management techniques, and use of problem solving. The Competence scale contains items assessing more process-oriented aspects including effective use of peer modeling, use of confidence building techniques, and reinforcement and encouragement of self-management skills. Ratings will be completed by an independent rater from a randomly selected 25% of each peer/provider pair's audio/video-recorded sessions. A second rater, will independently rate a subset

of the tapes to assess inter-rater reliability. Both of these raters will be study staff directly involved with this project and listed on the protocol.

Medical Illness Education and Support Group (comparison condition) Training and Fidelity Monitoring

Study interventionists delivering the medical illness education and support comparison condition will all have prior experience conducting psychosocial/educational interventions with individuals with SMI. As with the interventionists delivering *Living Well*, they will receive training that includes an orientation to the medical Illness education and support group manual developed for this study. They will also receive ongoing supervision. To monitor fidelity and ensure that the two conditions remain distinct we will also video tape sessions and use independent raters to complete an objective assessment of intervention adherence. The independent raters used for this study will be directly involved with this project and listed on the protocol. The adherence scale will include items assessing the presence of condition specified core elements such as review of common chronic illness challenges and discussion about related behavioral and lifestyle self-management techniques, and absence of core elements associated with the *Living Well* Condition (e.g. use of behavioral action planning and in-session practice of self-management techniques). Similar to the *Living Well* condition, ratings will be completed on a randomly selected 25% of sessions delivered across the trial for each provider.

Reportable Events

All Unanticipated Problems, Serious Adverse Events and Deviations related to this study will be reported to the VA Central IRB within 5 business days of study staff becoming aware of the event. Adverse events that do not meet the criteria for reporting within 5 business days will be reported to the VA Central IRB at the time of continuing review in summary format.

Sample Size

For EFFECTIVENESS TRIAL:

This Randomized Controlled Effectiveness Trial is powered to detect differences on the two primary outcomes: (1) significantly reduced proportion of participants with an ER visit at the 3-month follow-up assessment (6 months post randomization) in the Living Well condition versus control, (2) significantly improved health functioning at post-treatment in the Living Well condition versus control as measured by the SF-12.

ER Visits. In our prior pilot the proportion with an ER visit in the Living Well condition at the 3-month follow-up was 10.7% and in the control condition it was 27.6%. For this power calculation we assumed that the proportion with an ER visit in the Living Well condition at the 3-month follow-up will be 10.7%. However, since we have an active control in this proposal, we specify a lower percentage in the control condition (versus estimate from the pilot study) equal to 25%, and thus a 14.3 percentage point difference. With a two-tailed, alpha .05 level test, and power = .80 to detect this 14.3 percentage point difference we calculate that we will need n = 250 (125 per condition). The percentage point difference that can be detected could be somewhat higher or lower depending on the inter-correlations among the covariates and ER response variable. As proportion with an ER visit will be obtained from VA electronic medical charts for all randomized participants, loss to follow-up is not a significant concern for this outcome. This calculation is conservative -- we would actually have power equal to .80 to detect a smaller difference because the above calculation is based on a basic z-test of proportions, whereas the analysis model

specified above is more powerful. Calculation was performed using PASS version 11.0 (from NCSS, LLC) software. We acknowledge that use of the ER may be different in the VA context given the co-location of medical and psychiatric care, but as evidenced in our previous work (see section A.3), we found that veterans with SMI used the VA ER for medical care at rates comparable to (even greater than) those in our community sample. Specifically, the rate of use in the VA sample was 43% and the baseline rate in the Living Well sample was 31.3%.

SF-12 functioning scales. Effect sizes (ES, Cohen's d at post-treatment--3 months post-randomization) in our pilot clinical trial for the SF-12 physical, emotional, and general functioning scales were .55, .66, and .68. For H1 we assume a consent sample size equal to the sample size determined for H2 and calculated the power we will have to detect a moderate but significant ES = .40 (i.e. to detect means that are .4 standard deviations apart) between Living Well and the control condition. ES = .40 was also selected as the ES for this trial may be smaller than our prior trial because we are using an active control. We assume there will be 12% loss-to-follow-up at the post-treatment assessment, hence we have conservatively assumed a net sample size of 250*(1-.12) = 220 (110 per condition) for the SF-12 outcomes. With a two-tailed, .05 alpha level test, and average correlation among longitudinal measurements equal to .50, and post-attrition n = 220, we would have power = .89 to detect an effect size equal to .40. Calculation was performed using the Sampsi command (for repeated measures) in Stata version 10 (from Stata Corporation).

For PROCESS EVALUATION

We will collect qualitative data from key informants and important stakeholders. As this effort isn't linked to a specific hypothesis and doesn't rely on quantitative analyses, no power analysis is specified to determine sample size.

Data Analysis

FOR EFFECTIVENESS TRIAL:

Primary Hypotheses (regarding functional and service-related outcomes):

Hypothesis 1 (H1): Compared to those receiving a general medical illness education and support group, participants receiving Living Well will demonstrate greater improved general health functioning including both physical and emotional functioning.

To test the null hypothesis of no difference in improved general health functioning, we will use a longitudinal mixed effects model to compare change in mean physical and emotional health functioning from randomization to post-treatment. Regression equation (random effects not presented) at each time point will be:

SF12 function = Intercept + site + covariates + study condition + time + study-condition•time + error

Notes: (1) Test of the null hypothesis of no difference in change from randomization to the post-treatment assessment will be conducted using a specified contrast. (2) "Study condition" is a dichotomous variable indicating study condition; (3) A random intercept and random slope (coefficient for time) will also be specified for the model; (4) The "time" variable will be entered as a continuous variable with possible values 0, 3, and 6 corresponding to the three assessment points (randomization, post-treatment, & 3-month follow-up); (5) The "covariates" terms represent adjustment for age, race, gender, and important potential confounders and will include Charlson comorbidity index score, chronic somatic illness

category, and any other covariate found to significantly differ at randomization (provided no significant collinearities are found). We are expecting few chance differences at randomization due to large sample size and random study condition assignment; (6) We have included a "site" term to adjust for site differences.

Hypothesis 2 (H2): Compared to the medical illness education and support group, the Living Well group will have a lower proportion of participants who will have had an emergency room visit for management of a chronic medical condition during the six months after randomization.

For proportion with ER use in the past 6 months, we will use a random intercept mixed effects model since this outcome is assessed at only 2 time points. We will use a model that assumes no difference at randomization given the large sample size and randomization to study condition. Thus we will not include study condition as a main effect which would correspond to an assumption of unequal randomization rate of ER use. Some chance variation is expected and we will test the assumption of equal randomization rates with a chi-square test comparing the ER use rates by study condition. This model is equivalent to adjusting for randomization in the continuous case and we are taking this approach to be able to have .80 power to detect a smaller percentage point difference in ER use (50) at the 3 month follow-up assessment than if we didn't assume equal rates at randomization. In the very unlikely scenario of a statistical difference at randomization we will add the study condition main effect to the model below, and the test of the null for H2 will continue to be the test that the coefficient for the study-condition-by-time interaction term is zero. To compare the two conditions on probability (p) of an ER visit, we let the outcome variable Y = 1 if the participant had an ER visit in the prior 6 months (at randomization or at 3-month follow-up) and Y = 0 if participant did not have an ER visit. Analysis model (logistic mixed effects model, random intercept not displayed) will be:

logit (E[Y]) = Intercept + site + covariates + time + study-condition•time

where E[Y]) = p = probability participant has an ER visit in the prior six months at either randomization or 3 month follow-up (depending on "time" variable).

Notes: (1) Test of H2 will be the F-test that the coefficient for the study condition-by-time interaction is zero; (2) Study condition indicator main effect is omitted based on assumption of equal rates at randomization as discussed above; (3) For this hypothesis, "time" is a binary variable indicating assessment at 3 months post-treatment versus assessment at randomization; (4) The "covariates" terms represent adjustment for age, race, gender, Charlson comorbidity index score, chronic somatic illness category and other potential confounders found to be significantly different at randomization, (5) We have included a "site" term to adjust for site differences.

In exploratory analyses we will categorize evident causes for emergency room admission and describe and compare the distribution of causes across the 5 chronic medical condition categories using a two-way table with row percentages. Associations between chronic medical condition and cause of emergency room admission will aid us in interpreting results for our ER primary outcome.

Secondary Hypotheses (3 and 4 - regarding more proximal attitudinal and behavioral outcomes):

Hypothesis 3 (H3): Compared to those receiving a general medical illness education and support group, participants receiving Living Well will report improved health-related self-efficacy and patient activation. Further, such improvements will mediate the effects on functional outcomes and ER use.

For self-efficacy and patient activation as outcomes, we will use a parallel model as for Hypothesis 1 to

compare the two study conditions. To test whether change in health-related self-efficacy or patient activation mediates the effect of Living Well we will estimate the mediated effect with a 95% confidence interval. When there is a mediating variable (i.e. mediator), the total effect of treatment can be divided into two components: (1) the direct effect of treatment (independent of the mediator), and (2) the mediated effect (i.e. indirect effect of treatment through the mediator (50). To estimate the mediated effect we will first estimate the total effect of Living Well and second, the direct effect of Living Well, and then estimate the mediated effect by subtracting the second from first. The estimate of the total effect of Living Well will be the treatment effect from the primary analysis model under either H1 or H2. The estimate of the direct effect of Living Well will be the treatment effect of Living Well after adjusting for the mediator. The mediator will be the change score of health-related self-efficacy or patient activation from randomization to post-treatment (for the functional outcomes) or randomization to the 3 month follow-up (for ER use). For statistical inference we will produce a 95% confidence interval around the mediated effect with a bootstrap procedure (51). We will interpret such a 95% confidence interval excluding zero as a statistically significant mediated effect.

Hypothesis 4 (H4): Compared to those receiving a general medical illness education and support group, participants receiving Living Well will report improved self-management behaviors. Further, such improvements will mediate the effects of the functional and service outcomes specified above.

We will use a parallel model as for Hypothesis 1 to compare the two conditions on the self-management behavior scales at post-treatment. The tests of mediation will be directly parallel to those described for the test of mediation in Hypothesis 3 for the functional and ER use outcome variables.

Secondary Hypothesis 5: Living Well participants will sustain improvements across functional, attitudinal and behavioral outcomes at follow-up (3 months post-treatment).

We will test sustained improvement by testing the null hypothesis of no difference in change from randomization to the 3-month follow-up assessment (2-sided test) which will be the test that the coefficient for the study condition-by-time interaction term in the primary model (see H1) is zero. This hypothesis applies only to outcomes obtained from interview, not for ER visit and other 6-month service utilization variables. All available data will be included in these intent-to-treat analyses. The aforementioned analysis plan regarding dropout will be used.

Exploratory analyses: We will conduct several exploratory analyses.

One, in the Living Well group we will utilize data collected at consent to examine outcome trajectories and change in trajectories in the transition from the pre-intervention period (2 months on average) to the intervention period (randomization to post-tx; 3 months) and the post-intervention period (post-tx to follow-up; 3 months) . For this analysis, time will be treated as continuous as time from consent to randomization will vary. A spline will be used starting at randomization to detect change in slope when the intervention commences. This analysis will allow comparison of the Living Well group to themselves prior to intervention. Two, we will examine whether improvements on primary and secondary outcomes in the Living Well condition relative to the control condition differ among 5 chronic medical condition subgroups: a) diabetes; b) a respiratory illnesses (including asthma and COPD); c) arthritis, d) a cardiovascular condition (e.g. congestive heart failure); or e) two or more of (a) thru (d). We will describe treatment effects by chronic illness sub-group, computing average treatment effect for each subgroup. We will also add the 3-way interaction term between study condition, time, and chronic illness category to the primary analysis models in order to perform a global test of differential improvement on outcomes by

chronic medical condition subgroup.

Two, we will examine potential covariate moderators of treatment effect (e.g. participant demographic and clinical characteristics-see list of measures above) on the effectiveness of the intervention. To do this we will utilize the primary models but add the 3-way interaction term between the participant characteristic of interest, study condition indicator and time and through a contrast, test the null hypothesis of no relationship between the covariate and improvement on study outcomes. Three, we will examine effects on additional medical services utilization outcomes (e.g. somatic inpatient hospitalization, outpatient visits) as well as on medication adherence. Models parallel to H2 (ER use) will be used to examine treatment effects on these secondary outcomes. Four, we will examine whether treatment effects differed by site. For these analyses we will include the 3-way interaction term between study condition, time, and site to test overall interaction with an omnibus F-test. If the F-test is significant we will report treatment effects by site, and assess site differences in participant characteristics and otherwise investigate and summarize site characteristics that might explain differences. Five, we will examine how "dose" of intervention (i.e. number of sessions attended) and participation ratings (measured using the Group Performance measure described in the measures section) relate to study outcomes. Separately, in both the Living Well and the control condition we will use regression models to examine whether the covariate (either number of sessions attended or the Group Performance measure) is associated with improvement on outcomes. Models for these analyses (whether outcome is assessed at all 3 time points or just at randomization and 3 mo f/u) will include time and the dose-by-time interaction term to assess the relationship between dose and trajectory over time. For ER use and other dichotomous service utilization outcomes this analysis will assess change in proportion with ER in relation to dose. Six, we will similarly examine how fidelity ratings of adherence and competence relate to the functional, attitudinal, behavioral, and service related outcomes specified. In models similar to those used above to examine dose response relationships we will examine the relationship between overall adherence (and competence) and change in outcomes separately for each condition.

FOR PROCESS EVALUATION:

Our PROCESS EVALUATION relies on the RE-AIM evaluation framework to better understand contextual factors that support the conduct of the proposed trial and that will affect future efforts to implement and sustain the Living Well intervention in the VA system of care. The proposed evaluation also provides a distinct and complementary avenue for understanding differential outcomes across conditions. This evaluation will integrate findings from two streams of inquiry: 1) A qualitative study that combines focus groups and in-depth individual interviews conducted both before and after the clinical trial, and; 2) a cost analysis focused on implementation/operating costs and cost consequences. Data from both, in combination with outcome data generated by the trial, will be synthesized and applied to the RE-AIM framework foci (see table below) and used to help draft an implementation toolkit detailing procedures, resources and considerations needed to successfully deliver Living Well in VA mental health settings.

Pre-Trial Focus: Prior to initiating the effectiveness trial, we will conduct a series of qualitative focus groups and/or individual interviews with a range of key stakeholders to: 1) Identify obstacles and barriers that might impede the proposed trial, and; 2) collect contextual information that will inform future dissemination and sustainability of the Living Well intervention in the broader VA context.

Post-Trial Focus: After completing the effectiveness trial (AIM 1) we will conduct both focus groups and in-depth individual interviews with Veteran study participants, Veterans who served as peer co-facilitators in the Living Well condition, and various stakeholders involved in the pre-trail evaluation to:

1) extend and enhance our understanding of intervention outcome and processes, and; 2) inform the development of an implementation toolkit to support future dissemination efforts.

Potential Risks/Discomforts

Risks associated with the EFFECTIVENESS TRIAL (and for each, provisions for minimizing risk):

1. Breach of confidentiality of research data:

There is a slight risk of a confidentiality breach related to data collected for research purposes from participant interviews and medical records. Study participants will be informed that information obtained through research interviews is confidential; potential risks to data security and the measures we take to protect it will be reviewed with them during the informed consent process. Numerous steps will be taken to ensure research interview data confidentiality and security. To protect confidentiality, coded hard copies of interview assessment data and data obtained from participants' medical records are kept in a locked file cabinet behind a locked office door. All hard copies of research assessment forms will be stored in a locked cabinet in a locked office in the University of Maryland, Division of Services Research. Only designated research staff has access to the password protected file that links participants' identities to their codes. This file is located on a secure server located in the VA Maryland Health Care System.

Consent forms which contain participants' names are kept in a locked cabinet in a locked office that is located in the VA Maryland Health Care System.

Electronic data are kept on a password protected computer server, of which the passwords are only known to the study team members. Electronic research data are backed up regularly. All electronic research data with identifiers will be stored behind the VA firewall.

In the event of any incidents, unauthorized access of sensitive data or storage devices or noncompliance with security controls, the PI or another member of the research staff will immediately contact the VAMHCS Information Security Officer, Privacy Officer and the VAMHCS Research Compliance Officer.

2. Distress During Assessments:

Before consent and before and during each data collection, participants are informed that they are free to decline to answer any interview question(s) or to discontinue the interview at any time. If participants feel uncomfortable or fatigued, or seem so to the RA, they are encouraged to take a break and continue again later, or to stop the interview. In our research with people with serious mental illnesses over the past several years, few research participants have expressed discomfort from participating in the interviews. Nonetheless, all RAs have been trained to stop the interview if a participant becomes distressed and will have the resources needed to assist him/her in obtaining the level of support or assistance they require, including crisis intervention if needed.

3. Distress During Groups:

Participants may feel self-conscious sharing their beliefs/thoughts while in groups. We will minimize this by reminding participants that they can choose to not answer questions if they feel uncomfortable. We will also remind participants that what is said in group should remain confidential and not be shared with anyone outside of group.

4. Participants may experience some discomfort in being recorded during study interviews and group meetings:

Participants will be told that the digital recorder may be turned off at any time during the group meeting or interview if this occurs. There is also a slight risk of a breach of confidentiality regarding the identities of the participant on the recording. To minimize this risk, research staff will label all digital recordings with a code. Access to the file that links participant names to their project ID number will be stored behind the VA firewall.

Risks associated with the PROCESS EVALUATION (and for each, provisions for minimizing risk):

1. Breach of confidentiality of research data:

There is a slight risk of a confidentiality breach related to data collected for research purposes from participant interviews and focus groups. Study participants will be informed that information obtained through research interviews is confidential; potential risks to data security and the measures we take to protect it will be reviewed with them during the informed consent process. Numerous steps will be taken to ensure research interview data confidentiality and security. To protect confidentiality, all digitally recorded interviews and focus groups are coded and are kept in a locked file cabinet behind a locked office door. Only designated research staff has access to the password protected file that links participants' identities to their codes. This file is located on a secure server located in the VA Maryland Health Care System.

2. Distress During Focus Groups:

Participants may feel self-conscious sharing their beliefs/thoughts while in focus groups or during interviews. We will minimize this by reminding participants that they can choose to not answer questions if they feel uncomfortable. We will also remind participants that what is said in the focus groups should remain confidential and not be shared with anyone outside of the focus group.

3. Participants may experience some discomfort in being recorded during interviews and focus groups:

Participants will be told that the digital audio recorder may be turned off at any time during the focus group or interview if this occurs. There is also a slight risk of a breach of confidentiality regarding the identities of the participant on the recording. To minimize this risk, research staff will label all digital recordings with a code number. Access to the file that links participant names to their project ID number will be stored behind the VA firewall.

Potential Benefits

Across both the EFFECTIVENESS TRIAL and PROCESS EVALUATION:

There may be no direct benefit to participants. However, Veteran participants may develop new skills to help manage their chronic medical conditions and learn ways to live a healthier lifestyle.

Staff and administrator participants may derive new information regarding how to improve the quality of their service delivery models.

Data generated from this study will contribute to the evidence base regarding the effectiveness of an illness self-management intervention for seriously mentally ill Veterans. The process evaluation data will also help with future efforts to disseminate the intervention across the entire VA Health System.

Consent Procedures

Veteran Participants in the EFFECTIVENESS TRIAL and PROCESS EVALUATION TRIAL:

Written informed consent will be secured from all participants. Our research staff are carefully trained on obtaining consent from participants with serious mental illness and supervised by senior staff members. Approval will be secured from the mental health clinician before a potential participant is approached, and the study staff will verify that any potential participant is sufficiently stabilized to provide consent before approaching him/her. After securing clinician approval, the study interviewer will meet the participant, introduce him/herself to the participant, and inform that participant that the clinician has given approval to approach them about our research. The study interviewer will use the clinician's name so the participant will not be confused. The study interviewer will then provide an overview of the project, and invite him/her to participate. Interested participants are provided an informed consent form. Staff members are trained to recognize symptoms of severe mental illness and cognitive impairment that could undermine a participant's ability to provide informed consent. The consent form is read aloud to all participants in tandem with their own silent reading, and the entire contents of the informed consent form will be reviewed verbatim. Research staff are trained in strategies for interacting with people with severe and persistent mental illness, including speaking slowly and clearly, stopping to summarize frequently, and providing time for questions.

After the consent form has been read aloud and all questions answered, the staff confirms that the participant is still interested in participating by soliciting a verbal response. Those who express willingness to provide consent must complete a brief questionnaire to assess competency and understanding of the consent form. If the participant is unable to answer the questions correctly, staff re-reviews the aspects of the study that the participant did not understand. The staff member asks the questions a second time. If the participant cannot answer all questions correctly, he/she will not be enrolled in the study. If the participant is able to give correct answers to each of the questions to assess, the participant will then sign and date the consent document. The person obtaining consent will then also sign and date the consent document.

Per IRB regulations, a copy of the signed consent form is given to the participant, a copy is placed in the participant's medical record, and the original is kept in the research office. Participants will also receive a Health Insurance Portability and Accountability Act Authorization to Obtain, Use and Disclose Protected Health Information for Research (HIPPA) that will be summarized for them. Staff will ask participants if they have any questions once the document has been read, and then participants will sign the authorization. A copy of this signed form will be given to the participant, and one will be place in the participant's medical record (where required).

Participants who are veterans recruited from will also be provided with VHA-Form 10-3203 (CONSENT FOR USE OF PICTURE AND/OR VOICE). This form and its purpose will be reviewed to participants. Staff will ask participants if they have any questions once the document has been reviewed. Then participants will sign the authorization. The study staff will keep the original signed copy, a copy of this signed form will be given to the participant, and one will be placed in the participant's medical record.

Participants will also provide basic demographic and contact information at the time of consent to ensure adequate and correct information for the purpose of keeping in touch with participants throughout the

duration of the study. This form, The Subject Locator Form, will be reviewed and signed by the participant and will be kept in a locked file cabinet in a locked room.

In keeping with the requirements put forth in the Department of Veterans Affairs: a) social security numbers of veterans will not be solicited; b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol; c) initial contact with veterans must be made in person or by letter prior to telephone contact; d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

Stakeholders (VA Clinicians) in the PROCESS EVALUATION TRIAL:

Written informed consent will be secured from all participants. Stakeholders and peer facilitators will be provided a consent form that they will be able to read over and review on their own. Study staff will be available to answer any questions they may have about the study. All informed consents will take place behind a closed door within the VAMHCS.

All stakeholder and veteran peer facilitator participants recruited from the Baltimore VAMC or the Perry Point VAMC will also be provided with VHA-Form 10-3203 (CONSENT FOR USE OF PICTURE AND/OR VOICE). This form and its purpose will be reviewed to participants. Staff will ask participants if they have any questions once the document has been reviewed. Then participants will sign the authorization. The study staff will keep the original signed copy and a copy of this signed form will be given to the participant.

Privacy

For those in EFFECTIVENESS TRIAL:

All VA participants will receive research information in a private room with the door closed within the VA Maryland Health Care System (VAMHCS) or the Washington, DC VA Medical Center.

Research assessments, group meetings and video recorded sessions will take place in private rooms with the door closed within the VA Maryland Health Care System (VAMHCS) or the Washington, DC VA Medical Center.

For those in PROCESS EVALUATION TRIAL:

All focus groups and interviews will be conducted in private rooms within the VAMHCS. All digitally recorded sessions will take place within a room with the door closed.

The purpose of the collection of this data is to conduct scientific research. No personnel involved in the study may identify, directly or indirectly, and individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

Confidentiality

All hard copies of coded research assessment forms will be stored in a locked cabinet in a locked office in the Division of Services Research (DSR), Department of Psychiatry, University of Maryland School of

Medicine. Consent forms which contain participants' names but not their project ID number are kept in a separate locked cabinet in a locked office at the VA. The file that links participant names to their project ID number will be stored behind the VA Firewall. Access to the link file will be limited to only study staff listed on this protocol.

All data, including the investigator's research records and any participant identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1), and will not be destroyed. After the study project is complete, all data, including hard copies and electronic files will be kept at the VA for final storage.

All video recordings and DVD's recorded during this study will be kept at the VAMHCS in a locked cabinet in a locked office.

Coded electronic data collected in this study will be stored and managed by an Integrated Research Information System (IRIS) developed by the Division of Medical Informatics at the University of Maryland School of Medicine Department of Epidemiology. This is a comprehensive system for managing research data from clinical studies. IRIS provides an infrastructure to help manage and assure the quality of clinical research at UMB. IRIS consists of an Oracle relational database and data management tools, which together can provide support for virtually all aspects of the study. For example, protocol information and data dictionaries stored in IRIS can be used to verify eligibility criteria, note the progress toward recruitment goals, and identify invalid data values. Other standardized reports generated by IRIS include protocol deviations (e.g. "out of window" encounters), an inventory of forms and data expected versus forms and data received, missed visits or events, and adverse events. The principal method for entering information into IRIS is through scannable forms created with Cardiff's TELEform system, which further reduces the potential for errors by minimizing manual data entry.

Consent forms which contain participants' names but not their project ID number are kept in a separate locked cabinet in a locked office at the VA. All data, including the investigator's research records and any participant identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1), and will not be destroyed.

Coded electronic data collected in this study will be stored and managed by an integrated research information system (IRIS) developed by the Division of Medical Informatics of the University of Maryland School of Medicine Department of Epidemiology. IRIS can be accessed over the internet and is housed within the campus wide computing facility. This facility has access limited to computing personnel only. For intrusion protection, IRIS sits behind the campus firewall and requires password authentication to provide access to those who are defined staff of a supported study. The confidentiality of information stored in the IRIS database will be protected by strictly controlling access to the file that links subject ID numbers to names and PHI. Level of access and functionality is determined based on need as defined by the staff member's role on the study. Access to research data stored in the database is limited to MIRECC investigators who have been granted user names and passwords by the MIRECC Research Core, which also will define the level of access for each researcher (i.e., what types of data will be accessible). Therefore, staff may only access data pertaining to studies in which they are involved and are only able to see data and perform functions appropriate to their study roles. Sensitive data are encrypted during storage and on transmission. Backups of the system and the database are performed daily.

Only the PI, co-investigators, and authorized research study staff will have access to the research data. Access to data will be terminated for study staff who are no longer part of the research study.

Please note that this project will keep within the following VA guidelines: a) social security numbers of veterans will not be solicited, b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol, c) initial contact with veterans must be made in person or by letter prior to telephone contact, and d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

In the event of any incidents, loss of data, unauthorized access of sensitive data, or non-compliance with security controls, the PI will immediately inform the VA Privacy Officer (PO) and VA Information Security Officer (ISO).

Cost/Payment

There will be no costs to any participants for their participation in this research study.

Participants receive money for completion of the research assessments.

Participants in this study are not being paid when the research is integrated with participants' medical care and makes no special demands on participants beyond those of usual medical care. The proposed payments in this protocol are reasonable and commensurate with the expected contributions of the participants. The participant payments are fair and appropriate, and do not constitute (or appear to constitute) undue pressure or influence on the prospective research participants to volunteer for, or to continue to participate in, the research study. In addition, the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study.

EFFECTIVENESS TRIAL:

Veterans will be paid $40 for completion of each of the four study interviews for a total of $160. The first interview will be completed at consent. The second interview (randomization) will be right before the groups start The third interview will be right after the group sessions are completed (post-treatment) and the fourth interview will be about 3 months after the participant completes group (3 months post-treatment assessment).

Some participants may be asked to come in for an additional interview with study staff after completing their group meetings. If they agree to come in for this interview, they will be paid an additional $40.

PROCESS EVALUATION TRIAL:

Clinicians who volunteer and sign consent for this phase of the study will not be paid for their participation.

Veteran peer facilitators who agree to participate in the one-time interview will be paid $40 upon completion of the interview.