Date: Sunday, June 16, 2019 10:09:59 AM

Print | Close

ID: IRB#18-001173 View: NEW 1.1 - Study Title and Key Personnel

This view has been locked by amendment(s)

Study Title and Key Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 ***Full Title of the Submission:**
Enhancing patient and organizational readiness for cardiovascular risk reduction among ethnic minority patients living with HIV

1.1 **Protocol Version Date and/or Number:**
March 8, 2018

2.0 ***Working or Lay Title:**
Enhancing patient and organizational readiness

3.0 **Principal Investigator:**

3.1 ***Name:** GAIL WYATT
Degree(s): If degrees are not shown here, please add them to the next section, Section 1.1a/Item 1.0, which will then update the Principal Investigator's webIRB account information.
PhD

3.2 **UCLA Title:**

3.3 ***Will the Principal Investigator conduct the informed consent process with potential study participants?**

- ○ Yes
- ◉ **No**
- ○ Not Applicable

3.4 ***Is the Principal Investigator an undergraduate student, graduate student, post-doctoral fellow, or resident physician?**

○ Yes ◉ **No**

3.4.1 **If you answered "yes" to the above question, indicate the Faculty Sponsor for this study.**

3.5 **UCLA Policy 900 defines types of UCLA employees who may be eligible to serve as a Principal Investigator. Check the policy to see if the Principal Investigator for this study needs an exception to the eligibility requirements.**

If an exception is needed, either attach the letter of exception here, or indicate a Faculty Sponsor in the above item.

Document Name	Document Version #
There are no items to display	

1. EXECUTIVE SUMMARY

Cardiovascular disease (CVD) has emerged as an increasingly important cause of morbidity and mortality among people living with HIV (PLWHIV). Now that HIV is considered a manageable chronic disease, the identification and treatment of comorbid medical conditions including CVD are increasingly the focus of research and clinical attention. What is missing, however, is yet another critical component of care for PLWHIV: integrated care for histories of trauma. Experiences of trauma increase the likelihood of HIV infection as well as CVD risk, yet health care for PLWHIV is rarely coordinated to address these three intersecting issues of HIV, CVD, and trauma, particularly among those disproportionately affected by HIV, i.e., ethnic minority patients. Histories of trauma among PLWHIV are associated with inconsistent treatment adherence and non-adherence, and trauma history alone is associated with poor CVD outcomes. Failure to address trauma poses significant barriers to the adoption of CVD risk strategies among PLWHIV. Health systems that coordinate and integrate care across HIV and chronic conditions such as CVD may provide the infrastructure needed to address the complex interplay of these conditions and their therapies. The investigators have designed a novel blended, culturally-congruent, evidence-informed care model, "Healing our Minds and Bodies" (HHMB), to address patients' trauma histories and barriers to care, and to prepare patients to engage in CVD risk reduction. Recognizing the need to ensure that PLWHIV receive CVD guideline-concordant care, the investigators have also identified implementation strategies to prepare providers and clinics for addressing CVD risk among their HIV-positive patients. Therefore, using a hybrid type II effectiveness/implementation study design, the goal of this study is to increase both patient and organizational readiness to address trauma and CVD risk among PLWHIV. The Specific Aims are: (1) to assess and enhance organizational readiness for addressing trauma and CVD risk among ethnic minority PLWHIV; specifically, a phased approach will drive the use of implementation strategies designed to educate, monitor, and support providers and staff in adhering to CVD care guidelines; (2) using mixed methods, to (a) evaluate the use and effectiveness of implementation strategies over time, and (b) identify barriers and facilitators to organizational adoption of guidelines, provider adherence to guidelines, feasibility, and sustainability; and (3) To evaluate the effect of HHMB on cognitive-behavioral, emotional, and clinical outcomes among 260 African American and Latino PLWHIV. The investigators will use the Replicating Effective Programs (REP) framework to guide the use of implementation strategies and the tailoring of the HHMB intervention within our participating implementation settings, and the Consolidated Framework for Implementation Research to guide the evaluation analyses.

2. OBJECTIVES

Cardiovascular disease (CVD) has emerged as an increasingly important cause of morbidity and mortality among people living with HIV (PLWHIV). The use of antiretroviral therapy (ART) has increased the survival of HIV-infected persons, but CVD mortality is rising in the face of lower overall mortality.[1] After adjustment for traditional CVD risk factors, PLWHIV have almost 50% higher risk for myocardial infarction than the general population.[2,3]

Now that HIV is considered a manageable chronic disease, the identification and treatment of comorbid medical conditions including CVD are increasingly the focus of research and clinical attention.[4] What is missing, however, is yet another critical component of care for PLWHIV: integrated care for histories of trauma. Experiences of trauma increase the likelihood of HIV infection as well as CVD risk, yet health care for PLWHIV is rarely coordinated to address these three intersecting issues of HIV, CVD, and trauma,[5] particularly among those disproportionately affected by HIV, i.e., ethnic minority patients. Indeed, African Americans living with HIV are also more likely to have a CVD diagnosis.[6] Histories of trauma among PLWHIV are associated with inconsistent treatment adherence and non-adherence,[7] and for both men and women, trauma history alone is associated with incident CVD and poor CVD outcomes.[8,9] This evidence suggests that failure to address trauma poses significant barriers to the adoption of CVD risk strategies among PLWHIV.

Traditional risk factor prevention and control remains the cornerstone of CVD risk reduction among PLWHIV, but several gaps in standard care have been identified. For example, among PLWHIV, use of aspirin, lipid lowering therapies, and anti-hypertensive agents is suboptimal and substantially lower than in HIV-negative adults.[10-13] Additionally, PLWHIV with acute myocardial infarction are less likely to receive coronary angiography, left heart catheterization, coronary artery bypass, or other procedures.

A recent systematic review of programs that integrated CVD, hypertension and diabetes with HIV services found that these programs showed promise in coordinating care for the rising number of patients living with HIV and CVD or its risk factors, often leveraging existing HIV and AIDS services.[14] However, few of these programs were based in the United States, and there was limited evidence on their long-term impact. Health systems that coordinate and integrate care across HIV and chronic conditions such as CVD may provide the infrastructure needed to address the complex interplay of these conditions and their therapies.

The investigators have designed a novel blended, culturally-congruent, evidence-informed care model, "Healing our Minds and Bodies" (HHMB) to address patients' trauma histories and barriers to care, and to prepare patients to engage in CVD risk reduction. Recognizing the need to ensure that PLWHIV receive CVD guideline-concordant care, the investigators have also identified implementation strategies to prepare providers and clinics for addressing CVD risk among their HIV-positive patients. Therefore, using a hybrid type II effectiveness/implementation study design,[15] the goal of this study is to increase both patient and organizational readiness to address trauma and CVD risk among PLWHIV. The Specific Aims are:

Primary Implementation Aims

1. To assess and enhance organizational readiness for addressing trauma and CVD risk among ethnic minority PLWHIV; specifically, a phased approach will drive the use of implementation strategies designed to educate, monitor, and support providers and staff in adhering to CVD care guidelines.
2. Using mixed methods, to (a) evaluate the use and effectiveness of implementation strategies over time, and (b) identify barriers and facilitators to organizational adoption of guidelines, provider adherence to guidelines, feasibility, and sustainability.

Primary Intervention Effectiveness Aim

3. To evaluate the effect of HHMB on cognitive-behavioral, emotional, and clinical outcomes among 260 African American and Latino PLWHIV.

Drawing on a multi-framework approach recently articulated by Damschroder and colleagues,[16] the investigators will use the Replicating Effective Programs (REP) framework[17] to guide the use of

implementation strategies and the tailoring of the HHMB intervention within our participating implementation settings, and the Consolidated Framework for Implementation Research[18] to guide the evaluation analyses. Assuming successful outcomes in this hybrid study, the care model and implementation strategies will be refined to support reach to vulnerable populations, e.g., ethnic minority PLWHIV who are not currently in care.

3. BACKGROUND AND RATIONALE

SIGNIFICANCE

Cardiovascular disease (CVD) and risk of CVD are serious concerns among people living with HIV. Cardiovascular disease (CVD) has emerged as an increasingly important cause of morbidity and mortality among people living with HIV (PLWHIV). The use of antiretroviral therapy (ART) has increased the survival of PLWHIV, but CVD mortality is rising in the face of lower overall mortality.[1] After adjustment for traditional CVD risk factors, PLWHIV have almost 50% higher risk for myocardial infarction (MI) than the general population.[2,3] Although the mechanisms underlying the association between HIV infection, ART, and CVD risk are not fully understood, several factors appear to contribute to this heightened risk: HIV infection is associated with dyslipidemia and inflammation; ART agents increase the risk of diabetes and dyslipidemia; and the HIV-infected population is living longer, resulting in higher rates of CVD risk factors.[19] Additionally, the HIV-positive population has high rates of traditional biologic, behavioral, and social risk factors, such as smoking, sedentary lifestyle, and low income, and high rates of non-traditional risk factors, such as hepatitis C infection and substance use.[20]

In PLWHIV, statin therapy improves lipid profiles,[21] reduces immune activation,[22] and improves high risk plaque morphology.[23] There is limited evidence, however, that these effects translate into differences CVD morbidity and mortality, and there are concerns about interactions between statins and some ART therapies. An ongoing randomized controlled trial, the REPRIEVE trial, is studying the efficacy of statins as primary prevention of HIV-related CVD.[24,25] A recent comparison of data from the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) and the general population, using the Atherosclerosis Risk in Communities (ARIC) cohort, observed higher incidence of MI in HIV-infected individuals.[13] Further, increased risk was associated with lower CD4 count and detectable HIV RNA, suggesting that early suppressive antiretroviral treatment and aggressive management of traditional CVD risk factors are necessary to maximally reduce MI risk.

There are gaps in CVD care and outcomes among PLWHIV. Traditional risk factor prevention and control remain the cornerstones of CVD risk reduction in PLWHIV, but several gaps in care have been identified. For example, among PLWHIV, use of aspirin, lipid lowering therapies, and anti-hypertensive agents is suboptimal and substantially lower than in HIV negative adults.[10-13] Additionally, PLWHIV with acute MI are less likely to receive coronary angiography, left heart catheterization, coronary artery bypass, or other procedures.

Compared to whites, racial and ethnic minorities in the US have higher rates of HIV and AIDS and worse outcomes. African Americans accounted for 45% of HIV diagnoses and 53% of deaths from the disease, though they represent 12% of the US population. Among Latinos, 24% have HIV, though they represent 18% of the US population.[26,27] African Americans also have higher risk of CVD and stroke, and the risk starts at an earlier age than for whites.[28,29] Although evidence on racial/ethnic disparities in CVD among PLWHIV is limited, a recent systematic review suggests that African Americans with HIV were more likely to have a CVD diagnosis.[6]

There is limited research on CVD among women living with HIV; however, there appear to be high rates of unmet need in this subpopulation in the United States. Epidemiologic data indicate that US women with HIV have higher risk of MI than observed in uninfected female controls, with a relative risk (RR) of 2.98.[30] Prospective analyses using cardiovascular disease risk equations predict that 12% of women living with HIV are at high 10-year risk of CHD.[20]

Integrated HIV and CVD care shows promise. A recent systematic review of programs that integrated CVD, hypertension and diabetes with HIV services found that these programs showed promise in coordinating care for the rising number of patients living with HIV and CVD or its risk factors, often leveraging existing HIV and AIDs services.[14] However, few of these programs were based in the United States, and there was limited evidence on their long-term impact. Health systems that coordinate and integrate care across HIV and chronic conditions such as CVD may provide the infrastructure needed to address the complex interplay of these conditions and their therapies.

A history of trauma may affect healthcare utilization and adherence among PLWHIV. Although PLWHIV may have access to HIV medical care, histories of trauma and adversity are associated with decreased healthcare utilization, inconsistent treatment adherence, and engagement in HIV-risk behaviors.[31,32] Trauma increases risk for treatment dropout and non-adherence among PLWHIV.[33] Studies estimate that between 50%-80% of PLWHIV do not fully comply with antiretroviral treatment protocols.[34,35] Although the reasons for non-adherence vary, trauma is thought to negatively impact provider-patient relationships; PLWHOV with severe trauma histories tend to experience medical care as both intrusive and re-traumatizing.[33] Programs that create supportive clinic environments and reduce exposure to trauma-related triggers are currently lacking.[36,37]

The majority of PLWHIV do not disclose past sexual trauma to HIV providers, despite extensive evidence that psychological and behavioral correlates of these experiences compromise HIV and other medical care engagement.[38] Sexual trauma has been described as a barrier to HIV care engagement due to symptoms of post-traumatic stress, particularly avoidance.[38] Symptoms of depression and post-traumatic stress frequently co-occur in PLWHIV and can interfere with HIV treatment adherence and increase disease progression, yet HIV care settings do not routinely screen for these significant barriers to care.[31,39-41]

Similarly, distrust of medical providers and institutions, particularly among African American PLWHIV, coupled with disparities in quality of care, are barriers to effective prevention and treatment efforts.[42] Trust in one's medical care providers is associated with increased clinic visits, treatment adherence, and greater health and mental health, regardless of ethnicity.[42] In the CHASE study of 611 HIV-positive individuals, 10% of respondents reported that they did not trust their doctor or clinic to provide them with the best possible care, suggesting the importance of addressing these issues in HIV treatment paradigms.[42]

The intersection between CVD, HIV, and trauma has received scant attention. Now that HIV is considered a manageable chronic disease, the identification and treatment of comorbid medical conditions, including CVD, are increasingly the focus of research and clinical attention.[4] Experiences of trauma increase the likelihood of HIV infection as well as CVD risk, yet health care for PLWHIV is rarely coordinated to address these intersecting issues.[5] Men and women living with HIV experience higher rates of sexual trauma, revictimization, and exposure to more than one type of trauma than individuals in the general population.[5,43,44] This elevation is hypothesized to be the result of behavioral and physiological changes that impede effective coping and increase risks for negative health behaviors.[4] These include engagement in sexual and substance use behaviors that increase risk for HIV, engaging in poor self-care, and an increased likelihood of living in poverty, which increases risks for other stressors (i.e., community violence).[5]

Symptoms of PTSD are also higher among PLWHIV who have histories of trauma than in the general population, as exposure to childhood trauma increases risks for PTSD. PTSD occurs 2 to 3 times more often in females than in males after experiencing trauma, yet most research on links between trauma, PTSD, and CVD has been conducted with men.[45] PTSD has been associated with adverse CVD outcomes, including risk for pulmonary disease and coronary artery disease.[46,47] Research has also documented associations between trauma, PTSD, and CVD, with evidence that for both men and women, exposure to trauma may lead to poor CVD outcomes. Among women, both childhood and adult abuse have been associated with increased risk for diabetes, heart problems, and chronic pain.[48] Gender differences have also been found in the links between low childhood SES, family instability, and poor health in adulthood. As an example, the risk of heart attack or other CVD is more strongly associated with adverse childhood conditions for women than for men.[49,50]

Even among those who have few or no symptoms of PTSD,[51] links between trauma and elevated CVD risk persist.[52] Regardless, both trauma and PTSD have been associated with physiological processes that affect CVD, including dysregulation in the autonomic nervous system and the hypothalamic-pituitary-adrenal axis, resulting in elevations in blood pressure, heart rate, dysregulation of cortisol, increased secretion of catecholamines, and inflammation.[51,53,54] These links may be heightened for African American and poor individuals, particularly women, who experience socioeconomic and racial/ethnic disparities in CVD risk.[55] Research is needed to examine the cumulative effects of trauma on CVD, as repeated

exposure may increase risk for heart attack and other CVD, even in individuals who display no or few symptoms of PTSD.[50,55]

Implementation Strategy Framework: Replicating Effective Programs (REP)

To guide our study of enhancing patient and organizational readiness to address CVD risk and trauma histories among PLWHIV, the investigators will use the Replicating Effective Programs (REP) framework,[17] which is grounded in theories of Diffusion of Innovation and Social Learning.[56] It provides a phased *framework* for implementation, with different discrete *implementation strategies* being employed in each of four phases. REP's demonstrated effectiveness in promoting uptake of evidence-based practices allows us to focus on its application in varied settings and care models.

The REP framework consists of four phases (Fig. 1): pre-conditions, pre-implementation, implementation, and maintenance/evolution. The investigators have accomplished the first two strategies in the pre-conditions phase: identifying the need for a new intervention (as justified above), and identifying an effective intervention, which the investigators describe below. Careful attention is paid to intervention packaging during pre-conditions and pre-implementation; training, technical assistance, and fidelity assessment during implementation; and recustomizing during maintenance/evolution. During each phase, local context is paramount, with varying deployment of the intervention depending on local priorities, needs, and resources. One of our implementation science goals will be to track the relative importance of each discrete strategy in each phase at each site and across sites.

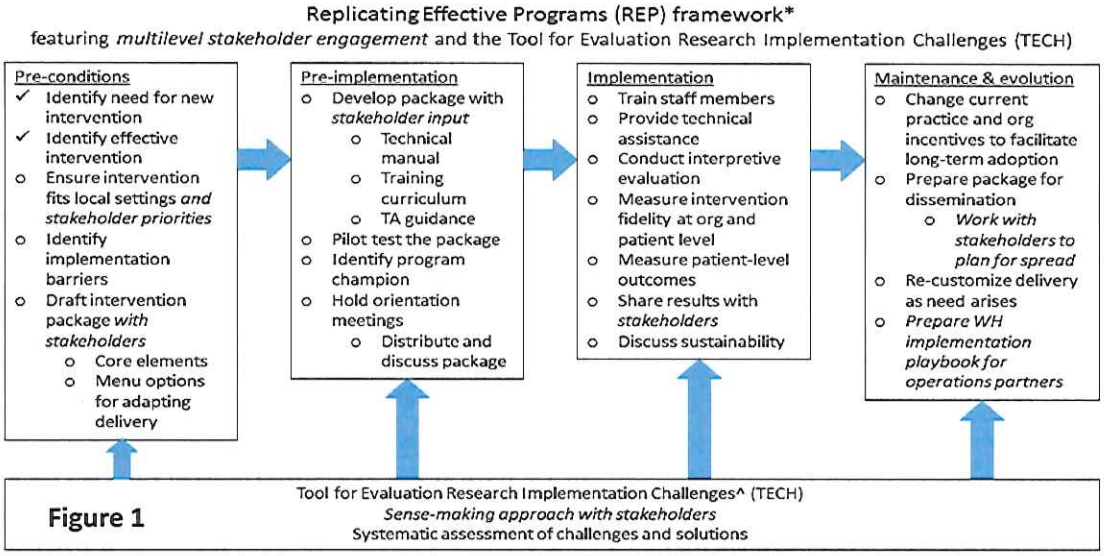

Figure 1

Enhancing REP with Multilevel Stakeholder Engagement and Complexity Theory. REP was originally designed to guide dissemination of evidence-based practices in community-based organizations. Kilbourne and colleagues[56] note that "it was not designed to address multilevel barriers to implementation," so they enhanced REP with facilitation, using implementation experts as external facilitators to provide guidance for overcoming implementation barriers. Interestingly, outcomes were favorable for enhanced REP for their primary implementation outcome of uptake (i.e., completed contacts with Veterans with serious mental illness who had been lost to care), but not for increased utilization of services by patients who had dropped out of care.[57] This prompted us to consider alternate REP enhancements that are: 1) more focused on participatory action[58] within complex adaptive systems,[59] and 2) potentially more effective in increasing patient engagement. Accordingly, the investigators draw on complexity theory and multilevel stakeholder engagement (Fig. 1). Complexity theory postulates that outcomes in complex adaptive systems are nonlinear and unpredictable; it is a highly relational theory, examining how multiple agents involved in implementation interact in complex ways and "make sense" of implementation in different ways.[60]

INNOVATION

This proposal offers several key innovations. First, the application seeks to shift current clinical paradigms by focusing on the nexus of HIV, CVD risk, and trauma histories among ethnic minority individuals in the US, who are disproportionately affected by each of these factors. The investigators will screen for trauma histories using Wyatt and colleagues' innovative composite trauma exposure risk index—the University of California, Los

Angeles (UCLA) Life Adversities Screener (LADS)[61]—that captures trauma experiences not typically asked about in healthcare settings. To the best of our knowledge, this will be the first study to examine how brief treatment of trauma histories can prepare PLWHIV to address concurrent health conditions such as CVD risk, within community-based healthcare contexts that are also being supported to address these health conditions. As noted above, integrated HIV and chronic disease services show promise for better outcomes among PLWHIV who have co-morbid conditions,[14] but to date, the investigators know very little domestically about how to integrate services, how to support guideline-concordant services for co-morbid conditions, and how to ensure that patients are ready to access those services and engage in appropriate care. This proposed study gives us an opportunity to shape and facilitate two complementary pathways to improved CVD care: the patient pathway and the organizational pathway. With blended, REP-guided implementation strategies[62] supporting both pathways, the investigators contend that CVD outcomes can be improved and CVD-related services can be strengthened and maintained.

Second, to address multiple co-morbidities, the investigators draw on recent implementation science literature that stresses the importance of multifaceted, modular, flexible interventions[63-65] rather than interventions focused on singular conditions and/or interventions that pose fidelity challenges in usual care settings. Our intervention, Healing our Minds and Bodies (HHMB), represents an improvement over existing interventions in that HHMB addresses multiple, interrelated conditions; draws on a combination of evidence-based and culturally congruent approaches to trauma, HIV, and CVD risk;[66] reduces barriers to accessing CVD care for a diverse cohort of patients with complex needs;[67,68] it is specifically intended for populations most impacted by HIV/AIDS (thus enhancing its relevance to our target population); it is group-based, brief, and tailorable to local context; and it can be facilitated by a trained staff member with minimal prior experience of delivering mental health/CVD interventions. As such, it falls within the concept of a "disruptive innovation,"[69] with its emphasis on simplicity, accessibility, and potential scalability should positive effectiveness and implementation outcomes be achieved.

Third, the investigators draw on our extensive implementation research experience across varied settings and with diverse populations,[70-72] proposing to use innovative methods to capture the complexity of implementation, adaptations to the intervention, and real-time use of implementation strategies, tailored to local contexts. A persistent challenge in implementation research has been to capture the dynamic nature of change over the course of implementation.[73] In this proposed study, as described further below, the investigators will operationalize complexity theory through use of the Tool for Evaluating Research Implementation Challenges (TECH),[74] which was designed to systematically assess impacts of implementation challenges and guide potential solutions. Furthermore, in addition to using established qualitative approaches in implementation research,[75] the investigators will capture real-time adjustments and adaptations using a "monthly reflections" guided discussion method that was developed by Hamilton and colleagues in their VA-based women's health national implementation initiative.

4. BASIC STUDY DESIGN

APPROACH

Overview of Study Design

The goal of the project is to increase both patient and organizational readiness to address trauma and CVD risk among PLWHIV in two healthcare organizations in Los Angeles County. These organizations have indicated their strong interest in being able to meet CVD-related needs of their HIV-positive clients and their capacity to do so, with training and support (see Letters of Support). Using an effectiveness/implementation hybrid research design,[15] this study will investigate: (1) organizational factors associated with implementation outcomes[76] (adoption, guideline adherence, feasibility, sustainability); and (2) effectiveness of the intervention as delivered to 260 PLWHIV receiving care in the two participating organizations. For purposes of this study, the investigators operationalize "successful implementation"[76] as a combination of number of individuals served (approximately 130 individuals per agency), a minimum of 12 completed cycles of the five-week intervention, delivery of the intervention with fidelity and documentation of adaptations, and high level of satisfaction with the intervention. The investigators will also study maintenance and evolution of the intervention, i.e., whether the participating organizations continue to offer HHMB and CVD-related services after the active implementation period.

To achieve our implementation aims (Aims 1 & 2), a mixed methods evaluation will be conducted throughout each REP phase, as detailed below. Staff and organizational characteristics will be assessed in Year 1, and engagement and training will be priorities. Following successful training, implementation will commence in both organizations in the first year. After a 26-month implementation phase, maintenance and evolution will be studied for six months, during which time only technical assistance will be provided. For our intervention effectiveness aim (Aim 3), the investigators will use an intra-change within subjects (pre/post change) design.

5. STUDY POPULATION AND ELIGIBILITY CRITERIA

5.1 Overview

Participants for this study will be patients at the two participating agencies, Oasis Clinic and Northeast Valley Healthcare Corporation. The investigators chose patients already in care in order to focus on providing new services rather than to recruit new patients to the clinics for HIV treatment. The latter new population would have to establish trust before assessing their readiness to be involved in their own health care and HIV treatment. The lack of trust is a factor in non-adherence to medication and to the recommendation of health providers. The investigators are targeting patients who have at least some relationship with health providers, and the investigators seek to enhance that trust.

Participating agencies & staff

Two large healthcare organizations in Los Angeles County have agreed to serve as sites for this study: OASIS Clinic and Northeast Valley Health Corporation (NEVHC), a federally qualified health clinic (FQHC). These agencies are well-established, serving large numbers of vulnerable HIV-positive African Americans and Latinos. Because of the needs that they have observed among their clients, these agencies have expressed enthusiasm about enhancing CVD- and trauma-related services. These agencies were identified as having met seven key elements identified in the literature as important in determining agencies' readiness to implement a new intervention.[87] These include: (1) a respected local community advocate; (2) strong administrative support; (3) formal organizational commitments and stability; (4) commitment of necessary resources to incorporate the program into existing services; (5) program credibility within the community; (6) adequate facilitators/staff; and (7) potential for the program to be self-sustaining or willing to seek additional funding. In addition, the organizations have adequate space for conducting private assessments and group sessions.

	Total # clients	% Hispanic/Latino	% African American	% women	% below Federal Poverty Level
OASIS	771	34	62	20	92
NEVHC	787	61	16	19	72

5.2 Inclusion and Exclusion Criteria

Agency sample

All 21 staff across the two agencies will be asked to complete the organizational-level measures described below. A subset of these individuals who are directly involved in implementation will be asked to participate in semi-structured interviews during the pre-conditions, implementation, and maintenance phases.

Client sample

The client participants will consist of 260 African American and Latino men and women who will be recruited from OASIS and NEVHC (~130 per agency), where they have received care on at least one occasion for testing or treatment. We will advertise at the agencies with flyers and brochures, developed in collaboration with agency leadership and staff. Patients will be eligible to participate if they are: 1) between 18 and 60 years of age; 2) HIV-positive; 3) are confident that they will remain in the city for at least five months; 4) have no plans to relocate beyond a reasonable distance from the study site; 5) agree to allow HHMB staff to view their medical records for test results having to do with CVD risks (e.g., high cholesterol, weight gain, a history of diabetes or high blood pressure, etc.); and 6) are willing to participate, speaking in English or Spanish. To be eligible, clients must also have greater than 0 on the LADS[61] (see Screening and Enrollment, below), and must identify at least one CVD risk factor on the worksheet.

6. INTERVENTION: PATIENT-LEVEL & ORGANIZATIONAL-LEVEL

This study targets change at both the patient and organizational levels. Accordingly, below the investigators describe our patient-level intervention (the Healing our Hearts, Minds, and Bodies [HHHMB] intervention, as well as our implementation strategies designed to foster organizational capacity to address CV risk reduction.

The Healing our Hearts, Minds, and Bodies (HHHMB) Intervention: HHMB is a blended psychoeducational, trauma-focused intervention derived from two evidence-based programs: Healing Our Women (HOW) and Emotional Emancipation (EE). HOW is an evidence-based intervention originally designed for HIV-positive women targeting sexual risk behavior, medication adherence, and psychological distress.[66] It has demonstrated efficacy and effectiveness, and was registered in the SAHMSA National Registry of Evidence-Based Programs and Practices (NREPP). (It is currently undergoing a second review as NREPP transitions from SAHMSA to CDC.) The investigators will adapt components of HOW to our current population (including males) and add components of the Emotional Emancipation (EE) Model,[93] which addresses the historical and contemporary traumas of slavery, oppression, subjugation, and discrimination. Together, these two models serve as a foundation for addressing the traumatic experiences that our ethnic minority study population is likely to have experienced in their personal histories. In terms of specific targets of change, HHMB targets cognitive, affective, and behavioral dimensions that ultimately affect the targeted psychological and biological outcomes (see table). For example, within the cognitive dimension, the intervention targets the following skills/practices: the role and disclosure of trauma; identifying triggers to poor health habits and decisions; counter-narratives, schemas, and cognitive self-monitoring. Through expressive writing[94] and guided discussion, participants will explore the role that trauma plays in their psychological and physical functioning, learn to identify triggers from previous trauma that precipitate poor coping and health practices, and develop counter-narratives and new schemas for more effective coping and management of health and wellness. Within the affective domain, the following skills/practices are targeted: relaxation techniques; mindfulness; and self-monitoring of mood states. In that module, participants will learn and practice relaxation techniques and a mindfulness approach of attention to the present moment, as well as how to monitor one's own mood states. These practices have demonstrated positive effects on anxiety reduction.

Targets of Change	Practices/Skills Domains	Based on Curriculum
Cognitive	Role/Disclosure of Trauma (Individual, Cultural)	HOW, EE
	Identifying Triggers	HOW,
	Counter-Narrative, Schemas, Cognitive Self-Monitoring	HOW, EE
Affective	Relaxation Techniques	HOW
	Mindfulness	EE
	Self-Monitoring of Mood States	HOW
Clinical & Behavioral	Action Plan for Health	HOW, DPP
	Strengthening Ties (Individual, Community)	HOW, EE, DPP
	Resiliency, Empowerment, Post-Traumatic Growth	EE, DPP

Within the clinical and behavioral domain, the intervention targets the development of an action plan for health, promotes the strengthening of ties to individuals and the community, and empowers the participant toward greater resilience and post-traumatic growth. These skills and practices are intended to build towards the goal of breaking down the barriers that traumatic experiences pose to seeking and enacting better health practices, namely, CVD risk reduction (smoking cessation, exercise, stress reduction, etc.). Additionally, to this end, the intervention will also draw upon relevant concepts in the evidence-based *Diabetes Prevention Program*,[95] including the use of health navigators or coaches who help participants navigate through decisions and systems to CV risk reduction services. Health navigators or coaches have been documented to improve and sustain health habits.[96] In the *Action Plan for Health* component of the intervention, participants will incorporate CVD risk reduction using a CVD scorecard based on the American Heart Association Life's Simple Seven/My Healthy Heart program.[83] The scorecard identifies seven biologic and behavioral risk factors for CVD and whether the participant is at goal, in the caution range, or not at goal for each risk factor. Five of the seven risk factors (blood pressure control, healthy weight, healthy diet, physical activity, and smoking) are either self-reported or measured as part of the study. Two risk factors (cholesterol and blood sugar control) will be obtained from the electronic health record (available at both agencies). The investigators will also construct two

composite scores: a 5-item score without blood sugar or lipid levels and a 7-item score consisting of all the items. The 5-item score will be used for those who have not had LDL cholesterol or glucose control measured during the relevant study period. The facilitator/navigator will help each participant develop an action plan and goal card for one risk factor that is not at goal. The action plan will be reviewed and modified as needed during the HHMB program. At follow-up visits, participants will be encouraged to review their goal cards with their primary care provider at routine visits, and the navigator will work with the study participant to reassess his or her understanding of CVD risk and whether there is improvement in the risk factor selected.

Organizational-Level Implementation Strategies

During the course of implementation, the Executive Committee and Implementation Teams will use a number of implementation strategies[73,109] to support organizational readiness for CVD risk reduction among HIV-positive clients. These strategies include: ongoing education about CVD guidelines, audit and feedback about guideline-concordant care, and external facilitation by Dr. Brown. Medical records of consenting participants will be reviewed to assess extent of guideline-concordant care. Providers will be informed—using appropriate communication venues identified by key stakeholders during the pre-conditions phase—of clients who are in need of CVD-related care, according to established guidelines. Approximately 13 months into implementation, key stakeholders will be asked to participate in mid-implementation qualitative interviews in order to evaluate the value of the implementation strategies, barriers and facilitators to implementation, and recommendations for the remainder of the implementation phase.

7. RECRUITMENT AND SCREENING PROCEDURES

Staff Recruitment: Staff will be recruited by one of the study PIs, Dr. Hamilton, by email. This email will ask providers and staff to complete a brief survey, and key stakeholders will also be asked to participate in a qualitative interview. The measures will be completed via an online survey, and Dr. Hamilton will coordinate the consent process and the completion of measures. Secure, password-protected links will be used to ensure confidentiality of all data. Baseline organizational data will be used to inform subsequent phases, particularly tailoring of strategies at each agency.

Client Recruitment and Screening: In response to study flyers and brochures, clients will make phone or in-person contact with project staff to express their interest in participating. Potential participants will then be screened to determine their eligibility (see Client sample, above) using two measures: (1) the 6-item *UCLA Life Adversities Screener (LADS)*, a validated brief assessment of trauma and adversity history that has demonstrated a strong relationship to post-traumatic stress symptoms, depression, and anxiety (Liu et al., 2015).[61] The six items include: childhood and adult sexual abuse; family adversity; family/community violence; discrimination; intimate partner violence; and lack of basic needs; and (2) the *Cardiovascular Patient Worksheet*, a one-page self-report form (developed for a VA-based CVD risk reduction implementation study) that asks clients about CVD-related illnesses, pregnancy complications, and family history, as well as smoking and exercise behaviors. To be eligible for HHMB, clients must have greater than 0 on the LADS, and must identify at least one CVD risk factor on the worksheet. Those who are eligible and interested in participating will be consented and then scheduled for the baseline assessment (see below). Sociodemographic information on individuals who do not meet eligibility criteria or refuse to participate and reasons for non-eligibility or refusal will be collected to permit comparisons between eligible participants and non-participants.

8. INITIAL STUDY EVALUATIONS

9. FOLLOW-UP EVALUATIONS

Below the investigators describe organizational-level evaluation/data collection, and then client-level evaluation/data collection (both initial and follow-up). This GANTT provides an overview of phases along with data collection:

Year	1												2												3												4											
Month	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Pre-conditions	X	X	X	X																																												
Key stakeholder interviews & measures			X	X																	X	X	X																				X	X				
Pre-implementation					X	X	X	X																																								
Implementation									X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X												
Client data collection									X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X											
Maintenance and evolution																																						X	X	X	X	X	X					
Data analysis					X	X																			X	X																	X	X	X	X	X
Steering Committee Meeting												X													X												X									X	X

Organizational-level data collection: enrollment and procedures

Staff who agree to participate in the survey will complete consent on the internet. By clicking the link (as stated in the recruitment email), they will be providing consent and enrolled. The electronic Staff Survey will capture basic demographics of staff (n~21) including education level and professional experience. The widely used *Maslach Burnout Inventory* (MBI)[88] will be used to assess staff experience of workload. The investigators will focus on brief, pragmatic measures of climate and readiness for implementation. The *Implementation Climate Scale* (ICS)[89] is an 18-item measure of the local strategic climate for implementation, capturing six dimensions of organizational context that reflect employees' ratings of the extent to which their organization prioritizes and values successful implementation of evidence-based practices. The *Implementation Leadership Scale* (ILS)[90] is a 12-item scale of clinic-level leadership for implementation. The *Implementation Citizenship Behavior Scale* (ICBS)[91] is a 6-item measure that captures critical behaviors employees perform to go above and beyond the call of duty to support implementation, including helping other employees on implementation-related activities and keeping informed about issues related to evidence-based practice and implementation efforts.

In addition to these structured measures, key stakeholders who provide written consent will complete semi-structured interviews. These interviews will be conducted with a subset of key stakeholders who will be directly involved in implementation (n~5/agency). *Pre-conditions phase interviews* will focus on perceived barriers and facilitators to implementation, familiarity with CVD and trauma among PLWHIV, and suggestions for education and other implementation strategies that the investigators intend to use. *Mid-implementation interviews* will include questions about feasibility, satisfaction, perceived fidelity, barriers, desired revisions, and expectations for maintenance and evolution. *Maintenance phase interviews* will include similar questions but will refer to the maintenance phase and stakeholders' satisfaction with and future expectations of the utility of HHMB as a long-term option for agencies' usual menu of services.

Organizational Implementation Evaluation

Several types of assessments will be used to track implementation processes, specifically with regard to fidelity, dose, and intensity of intervention. Throughout the intervention, the investigators will monitor: session attendance, session completion, and participant satisfaction with sessions. Facilitators/navigators will also complete short surveys noting adherence to the curriculum, level of participation, specific obstacles that may have arisen, and what components appeared to be most/least appropriate for the session's participants. Facilitators will also complete overall ratings of each participant's engagement, competency, and knowledge. To assess fidelity, sessions will be digitally recorded. For the first intervention cohort at each site, all recordings will be reviewed by Dr. Chin and feedback will be provided to facilitators/navigators. Subsequently, a random 15% sample of all session recordings will be reviewed and scored for fidelity to core elements, with a criterion of 80% or more of the total elements considered acceptable.[108]

To assess impacts of implementation challenges, the investigators will use the *Tool for Evaluating Research Implementation Challenges* (TECH),[74] which is recommended under three pre-conditions: 1) "implementation adaptations are expected due to the emergent nature of complex research settings;" 2) the research environment needs to encourage "spontaneous emergent solutions" and creativity; and 3) all research team members must be empowered to participate. Our settings and approach meet these pre-conditions. TECH, which has been used successfully in community studies, is codified into a series of interactive steps: identifying challenges (e.g., through observing day-to-day dynamics, listening to complaints, asking questions, etc.), interpreting the challenges in weekly meetings, generating and testing solution strategies, and, if necessary, addressing regulatory issues. Solution strategies are developed through open dialogue among the team members as well as others who might have perspectives on potential solutions. Although applicable to many different types of research, TECH is especially useful for research in complex adaptive systems as a tool for addressing unexpected challenges in systematic and collaborative ways. The investigators will complement the TECH with a *monthly reflections method* developed by Hamilton and colleagues to capture implementation progress and document use of implementation strategies. On a monthly basis, Dr. Hamilton will have a semi-structured "reflections" call with the Implementation Team and Site PIs, and separately with the Project Coordinator and facilitators/navigators. These calls will focus on key activities, events, and changes occurring over the course of implementation in the past month. Notes will be taken during the calls and analyzed per qualitative analysis procedures described below.

Organizational Interpretive Evaluation

Key stakeholders will have completed interviews with Dr. Hamilton regarding the perceived impact of HHMB on their clients, as well as the perceived impact of our implementation-phase strategies, including audit and feedback. During the final phase of the study, key stakeholders who are willing will be interviewed a third and final time, to obtain their perspectives on the value and feasibility of maintaining and evolving CVD- and/or trauma-related services.

Client-level data collection: enrollment and procedures

Clients who agree to participate will complete written consent for all study-related procedures and will thereby be enrolled. The self-report assessment protocol developed for previous studies and pre-programmed using audio computer-assisted self-interviewing (ACASI)[97] will take about 90 minutes to complete. ACASI provides both audio and video presentation of the questions and response options on a laptop computer. ACASI has been shown to significantly decrease social desirability bias.[98] If a participant becomes distressed during assessment, the session will be stopped, brief support will be provided, and participant will be referred for mental health services, if needed. Entries will be checked by the Project Coordinator. A hard copy of the data will be printed and the data will be saved into the master file after each assessment. Clients will be compensated $25 per data collection episode (pre-, post-, 3-month follow-up), for a total possible compensation of $75 for completion of study measures. Clients will also be asked to participate in brief qualitative interviews during each data collection episode, to capture information about knowledge of CVD risk, healthcare priorities, satisfaction with care, and challenges associated with treatment adherence. These interviews will be recorded and professionally transcribed.

Baseline and Outcome Measures

Psychological Health: *Depression symptoms* will be assessed with the 21-item *Beck Depression Inventory II* (BDI-II),[99] a self-report questionnaire designed to assess symptoms of Major Depressive Disorder. The BDI-II has yield Cronbach's alphas ranging from .81 to .86 among patient and non-patient samples. *Post-traumatic stress symptoms* will be assessed with the 17-item *Post-traumatic Diagnostic Scale* (PDS)[100] that yields a reliable (Cronbach's alpha = .92) sum score. *General anxiety* will be assessed with the *Patient Health Questionnaire-15* (PHQ-15),[101] based on the diagnostic criteria for anxiety. The PHQ-15 has been shown to have good validity and reliability among patient and community populations, with internal consistency (Cronbach's alpha) ranging from .86-.89. *Emotional regulation* will be assessed with the Short Form of the *Difficulties in Emotional Regulation Scale* (DERS).[102] This 18-item short version is highly correlated with the original 36-item form and demonstrates good validity and reliability (Cronbach's alpha=.91;Victor & Klonsky, E.,

2016). *Post-traumatic growth* will be assessed through analysis of participants' trauma writing[94] using the *Linguistic Inquiry and Word Count* program (LIWC), which counts certain linguistic classes of words associated with various outcomes of interest. For example, insight words such as "realize" and "see" are associated with reduced psychological distress and improvement in health status.[103] The investigators will calculate insight words as well as words associated with health and mental health (e.g. distress words, health habits).

Summary of Baseline and Outcome Measures	
Intervention Targets of Change	Measures
Cognitive	BDI-II, PDS, LIWC
Affective	DERS, BDI-II, PDS, PHQ-15, LIWC
Clinical	CVD risk factors and goal(s), 5-item and 7-item scores
Behavioral	LIWC, PSQI, ISI

Cardiovascular Health: Given the strong association between sleep and CVD risk,[104] the investigators will assess *sleep habits* will be measured with items from the *Pittsburgh Sleep Quality Index* (PSQI)[105] (hours of sleep and satisfaction with sleep) and the *Insomnia Severity Index* (ISI),[106] a 7-item measure assessing the nature, severity, and impact of insomnia. Additional CVD risk questions will ask about health metrics and behaviors. Participants will be asked about height and weight to evaluate *body mass index* (BMI), provider-diagnosed *diabetes*, and *CVD history* (heart attack, stroke, heart failure, congenital heart defects, vascular disease, coronary heart disease/chest pain). Health behaviors assessed include *smoking status* (current, quit in last 12 months, quit more than 12 months ago, never smoked), minutes of moderate or vigorous *physical activity* each week, and *diet* (fruit, vegetable, whole grain, sugar-sweetened drinks, and salt consumption and frequency of eating out). Participants will also be asked if they are aware of certain metrics of cardiovascular risk (i.e., whether they "know their numbers"), including *systolic blood pressure (SBP), diastolic blood pressure (DBP), total cholesterol, fasting blood sugar, and whether medications are taken to lower blood pressure, cholesterol, or blood sugar.* Participants will receive a card to monitor these levels. From the My Healthy Heart Program of the American Heart Association/American Stroke Association's Life's Simple 7® heart health factors, patients will enter their data which will serve as both an aspect of the intervention as well as a source of electronic data that describes their health habits and status that the study will access electronically.[107] The investigators will also measure covariates that may influence intervention outcomes, such as adherence to HIV and CVD medications and satisfaction with the HHMB intervention.

10. MEDICATION ADHERENCE

The investigators will obtain self-report of adherence to medications.

11. COST CONSIDERATIONS

Not applicable.

12. OUTCOME DETERMINATIONS

12.1 Primary Endpoints

As described above (§8 & 9), client-level outcomes will be assessed with regard to change in psychological symptoms (depression, post-traumatic stress, anxiety, emotional regulation) and cardiovascular health (e.g., sleep, BMI, smoking, physical activity, diet).

12.2 Secondary Endpoints

The investigators will also measure covariates that may influence intervention outcomes, such as adherence to HIV and CVD medications and satisfaction with the intervention.

13. PARTICIPANT SAFETY AND ADVERSE EVENTS

13.1 Institutional Review Board

All procedures are being reviewed by the UCLA Institutional Review Board, which will also serve as the IRB of record for the participating agencies. The study is divided into phases for review, with Phase 1 (slated for approval in October 2018) comprised of data collection at the organizational level, and Phase 2 (to be submitted as a modification in October 2018, following Phase 1 approval) comprised of data collection at the patient-level.

13.2 Informed Consent

All participants, both agency staff and clients, will have the capacity to give informed consent. The Principal Investigators, Co-investigators, HHMB Facilitators/Navigators, Agency PIs, and Project Coordinator will invite individuals to participate, discuss the study procedures and their rights and responsibilities as participants. Each prospective participant will be given the opportunity to ask questions. They will be asked to summarize their understanding of the purpose and procedures of the study. Individuals will then be asked to sign a consent form, and will be given a copy for their records. No information about the research purpose and design will be withheld from participants. Clients will not be denied HIV-related services regardless of their participation. Staff employment will not be affected by decision to participate.

13.3 Voluntary Withdrawal from the Study

Participation in this study is completely voluntary for both agency personnel and clients. Participants will be informed that they have the right to refuse to be in the study or to answer any question that they do not choose to. If they decide not to participate, they can drop out at any time without losing any benefits to which they are otherwise entitled and they will be reimbursed for their time and participation, as described above. Participants will not waive any legal claims, rights or remedies because of their withdrawal from participation in this study.

13.4. Adherence Assessments

The investigators will use the Morisky scale and the HIV adherence questions to assess adherence.

13.5. Summary of the Risks and Benefits

Potential Risks and Risk Estimate
For agency staff respondents, the most important risk is disclosure of their responses on the organizational survey and in the interviews, and any potential consequences to their employment if this were to occur. However, this risk is considered minimal because the focus of the implementation evaluation is not on the person him/herself, but rather on perceptions of the organization's readiness. Implementation climate, leadership, and the HHMB intervention. Nevertheless, several precautions will be used to ensure the confidentiality of the responses, including assigning each participating staff member a research ID number, and having them complete the agency-level measures online on a password-protected study website where their responses are only accessible to the project management team at UCLA. Also, all data will be analyzed and reported in the aggregate, with no identification of individuals or agencies. Agency leadership will not have access to their staff's data under any circumstances.

In a study of disease prevention, ethical issues that impact human participants' protection are of primary importance. The physical, psychological and medical well-being of all participants enrolled in this project is of ultimate concern. The research procedures have been designed to protect participants, respect their right to confidential participation, and ensure their safety at all times. In so doing, regardless of whether issues emerge during the orientation to the study, the ACASI administration of the pre- or post-test, or group sessions, participants can take breaks as necessary, be provided with refreshments, and will be encouraged to ask questions or request clarification of any information that they unsure of. Despite these precautions,

participation in this study involves a number of risks. Although unlikely, breach of confidentiality regarding HIV serostatus and/or trauma histories may cause participants some level of psychological, social or financial distress. Participant HIV serostatus will be kept strictly confidential and known only to the group in which s/he is participating (as all participants will be HIV-positive). Participants are also likely to experience some distress or embarrassment when responding to some of the questions in the assessment, although this is minimized considerably by using the ACASI methodology, which allows participants to respond to sensitive questions in complete privacy. Participants are also likely to feel some discomfort divulging personal information in the group sessions, especially initially. However, the groups will be led by trained facilitators/navigators who will be sensitive to helping participants to moderate this discomfort.

Potential Benefits of Participation

The potential benefits to agency staff who participate in the study are substantial. The agency staff who participates in the training will gain invaluable information and skills that can be utilized in other areas of their careers. The agency's capacity to properly implement this intervention at their agency will be increased. They will also gain capacity to address CVD risk among their HIV-positive clients. Client participants are likely to gain information and skills that can help them live healthier and more fulfilling lives. They may also increase their support networks by meeting others who may have similar CVD risks and/or trauma histories, are affected and infected by HIV, or have other life challenges. In addition, there are several potential benefits of this research to the field and to society with the generation of evidence about the effectiveness of a feasible, flexible intervention targeting multiple co-occurring conditions, as well as evidence about implementation strategies that can support agencies in enhancing their services to address co-morbid health issues.

13.6. Adverse Events

In the event of an adverse event that requires medical or professional intervention, referral to the participant's primary care provider or an appropriate specialist will occur. In emergency situations when a participant contacts one of the research personnel first, the particular research staff member will either make contact with the identified emergency personnel at that site, contact the clinical staff on the study (Drs. Wyatt, Brown, Loeb, or Chin), or advise the participant to do so immediately and follow up with the emergency personnel to ensure participant safety.

14. STATISTICAL CONSIDERATIONS

14.1 Data Analysis and Statistical Modeling Plan

Specific Aim 1. Qualitative data will document how the investigators support the participating organizations to implement and sustain the intervention. As a broad implementation aim, there are no hypotheses associated with this aim. Instead, the focus will be on describing the process of assisting the organizations with implementation and maintenance. This description and summary will be generated from interviews and notes from project calls, along with other qualitative data that is gathered throughout the study.

Specific Aim 2. To evaluate the use and effectiveness of implementation strategies over time, and identify barriers and facilitators to organizational adoption of guidelines, provider adherence to guidelines, feasibility, and sustainability, the investigators will draw on the Consolidated Framework for Implementation Research (CFIR),[18] which provides an analytic rubric for examining intervention and provider characteristics, as well as inner and outer settings. Data regarding acceptability, barriers, and facilitators will be derived from interviews and implementation-focused evaluation measures. As the investigators are examining implementation in two large healthcare organizations, barriers and facilitators will likely vary by agency. Descriptive statistics will be used to analyze the survey data, given the small sample size and the modest, practical goal of characterizing the agencies in preparation for implementation. In addition, the investigators will examine the facilitator/navigator and participant satisfaction ratings to characterize acceptability of the intervention. These ratings will be compared both within and across cohorts and organizations. Potential determinants of adoption and fidelity include but are not limited to training factors, competency at delivering the intervention, types of facilitators/navigators, participant "mix" (including gender and racial/ethnic diversity) in a given cohort, retention, and satisfaction. All of these factors will be examined when characterizing fidelity across agencies. In addition, based on interviews with facilitators/navigators and clients, the investigators will remain open to other determinants that may emerge during implementation. There are several possible determinants of maintenance. The investigators hypothesize that sustainability will be achieved in agencies that have their own trained staff facilitators who deliver the intervention with fidelity and who had positive experiences with the intervention during the implementation phase.

Qualitative data analysis: All interviews will be digitally recorded and transcribed by a professional transcription company. Analysis will be conducted primarily by Dr. Hamilton and Dr. Loeb (who has been trained by Dr. Hamilton), utilizing ATLAS.ti, a software package that allows for fluid "interaction" of data types and sources. Using constant comparison analytic methods,[110] a preliminary codebook will be developed both deductively using CFIR and inductively from a sub-sample of interviews within and across organizations at baseline. Qualitative findings at baseline will be augmented by preliminary analyses of staff-level data from the structured measures described above (e.g., burnout, organizational climate, etc.), and a baseline profile will be developed for each agency. These profiles will be reviewed by the Implementation Team, and will be used to tailor implementation strategies at each site (e.g., where there is a high level of burnout, additional attention will be paid to supporting staff and managing workload throughout implementation). This approach of using baseline data as diagnostic and informative for tailored implementation has been employed by Dr. Hamilton in a prior implementation study.[111] The codebook will be elaborated upon and adjusted as each round of interviews is reviewed until thematic saturation is achieved within and across cycles of interviews. Interviews will be compared within each organization, across organizations, across different types of respondents, and over time. Additional sources of qualitative data (i.e. meeting minutes, monthly reflections, archival information) will also be included in the data set. The investigators will analyze the data specifically for barriers to and facilitators of implementation, including but not limited to the ways in which the project's implementation strategies affect adoption, fidelity, and sustainability. In addition to identifying themes and patterns qualitatively, the investigators will examine statistical associations between important process and outcome variables such as satisfaction with the intervention, fidelity, and retention, and improvement in behavioral outcomes. Agency profiles will be revisited and further developed at the end of the active implementation phase, and again after implementation, thereby creating a story of implementation at each organization.

Specific Aim 3. To evaluate the clinical outcomes (e.g., improvement on a CVD risk factor or on the 5- or 7-item score) and the effects of the intervention, systematic data analysis and statistical modeling will be carried out: (1) For univariate analysis, the marginal distribution of each measure obtained will be calculated at each time point and across time. For categorical variables (e.g., gender, and race/ethnicity), the frequency distribution and modes will be calculated. For continuous measures (e.g., blood sugar levels/HbA1c), the investigators will calculate the central location (mean and median), variation (standard deviation, kurtosis, etc.), percentiles and range. Statistical tests (e.g., Shapiro-Wilk test) will be used to assess normality of the outcomes. The investigators will evaluate the degree and patterns of missingness, and perform imputation (e.g., multiple imputation), if needed. (2) Bivariate analyses of each outcome measure and independent variables will be carried out. Pearson and Spearman rank correlation will be used to correlate predictors with outcome measures. T-test, analysis of variance (ANOVA) or marginal regressions will be used for continuous measures. The change (delta) of outcome measures between timepoints will be calculated, and distributions of the deltas will be carefully examined. The bivariate analyses between the deltas and covariates will be carried out. Marginal repeated measures models (see model structure below in (3)) will be carried out between each independent measure and outcomes over time. (3) Multivariate repeated measures modeling[112,113]: To evaluate the relationships between outcome measures and independent variables over time, generalized linear mixed effect models (GLMEM) will be fitted $Y_i = X_i\alpha + Z_i\gamma_i + \varepsilon_i$, controlling for age and others factors. Graphical analyses (e.g., parallel plots) will be used to assist in examining the relationship between predictors and outcome measures over time. Potential non-linear relationships between the outcome measures and the continuous predictors will be explored through generalized additive mixed models.

15. STUDY ADMINISTRATION

15.1. Executive Committee

The project will function with an experienced multidisciplinary team. The Executive Committee consists of three PIs under a Multiple PI arrangement: Drs. Wyatt (HIV and trauma expertise), Brown (CVD expertise), and Hamilton (implementation expertise). The Executive Committee will work closely with an experienced Implementation Team of Co-Investigators (Drs. Chin, Loeb, Liu), a consultant (Dr. Grills), a Project Coordinator, and a trained Facilitator/Navigator at each organization (total of two Facilitators/Navigators, with the Project Coordinator also trained in the intervention). Designated leadership and staff at the participating organizations will collaborate and communicate regularly with the Executive Committee and Implementation Team to enhance implementation.

15.2. DSMB

The DSMB, comprised of CV, diabetes, trauma, and HIV experts as well as a community member, will be convened to oversee the conduct of this study and to monitor patient safety. The DSMB will meet twice a year, at which time the investigators will present data on enrollment, retention, and implementation progress. The DSMB will be responsible for reviewing with the project team the provided data, determine the safety of continuing the study, and will be given the authority to bring the study to a close if they deem it necessary. The PIs and biostatistician will provide to the DSMB any additional information on request. Materials will be circulated at the meetings and minutes will be maintained.

16. ETHICS AND GOOD CLINICAL PRACTICE

All investigators and project staff directly involved with participants will be required to maintain current, required CITI certification and any other ethics and good clinical practice compliance certifications.

17. REFERENCES

1. Feinstein MJ, Bahiru E, Achenbach C, et al. Patterns of Cardiovascular Mortality for HIV-Infected Adults in the United States: 1999 to 2013. *The American journal of cardiology.* 2016;117(2):214-220.
2. Freiberg MS, Leaf DA, Goulet JL, et al. The association between the receipt of lipid lowering therapy and HIV status among veterans who met NCEP/ATP III criteria for the receipt of lipid lowering medication. *Journal of general internal medicine.* 2009;24(3):334-340.
3. Pearce D, Ani C, Espinosa-Silva Y, et al. Comparison of in-hospital mortality from acute myocardial infarction in HIV sero-positive versus sero-negative individuals. *The American journal of cardiology.* 2012;110(8):1078-1084.
4. Nightingale VR, Sher TG, Mattson M, Thilges S, Hansen NB. The effects of traumatic stressors and HIV-related trauma symptoms on health and health related quality of life. *AIDS and behavior.* 2011;15(8):1870-1878.
5. Brief DJ, Bollinger AR, Vielhauer MJ, et al. Understanding the interface of HIV, trauma, post-traumatic stress disorder, and substance use and its implications for health outcomes. *AIDS care.* 2004;16 Suppl 1:S97-120.
6. Oramasionwu CU, Hunter JM, Brown CM, et al. Cardiovascular disease in blacks with HIV/AIDS in the united States: a systematic review of the Literature. *The open AIDS journal.* 2012;6:29.
7. O'Donnell JK, Gaynes BN, Cole SR, et al. Stressful and traumatic life events as disruptors to antiretroviral therapy adherence. *AIDS care.* 2017:1-8.
8. Gilsanz P, Winning A, Koenen KC, et al. Post-traumatic stress disorder symptom duration and remission in relation to cardiovascular disease risk among a large cohort of women. *Psychological medicine.* 2017;47(8):1370-1378.
9. Edmondson D, von Känel R. Post-traumatic stress disorder and cardiovascular disease. *The Lancet Psychiatry.* 2017.
10. Burkholder GA, Tamhane AR, Salinas JL, et al. Underutilization of aspirin for primary prevention of cardiovascular disease among HIV-infected patients. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America.* 2012;55(11):1550-1557.
11. Freiberg MS, Chang CC, Kuller LH, et al. HIV infection and the risk of acute myocardial infarction. *JAMA internal medicine.* 2013;173(8):614-622.
12. Okeke NL, Chin T, Clement M, Chow SC, Hicks CB. Coronary artery disease risk reduction in HIV-infected persons: a comparative analysis. *AIDS care.* 2016;28(4):475-482.
13. Drozd DR, Kitahata MM, Althoff KN, et al. Increased Risk of Myocardial Infarction in HIV-Infected Individuals in North America Compared With the General Population. *Journal of acquired immune deficiency syndromes (1999).* 2017;75(5):568-576.
14. Haldane V, Legido-Quigley H, Chuah FLH, et al. Integrating cardiovascular diseases, hypertension, and diabetes with HIV services: a systematic review. *AIDS care.* 2017:1-13.
15. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care.* 2012;50(3):217-226.
16. Damschroder LJ, Reardon CM, AuYoung M, et al. Implementation findings from a hybrid III implementation-effectiveness trial of the Diabetes Prevention Program (DPP) in the Veterans Health Administration (VHA). *Implementation Science.* 2017;12(1):94.
17. Kilbourne AM, Neumann MS, Pincus HA, Bauer MS, Stall R. Implementing evidence-based interventions in health care: application of the replicating effective programs framework. *Implementation Science.* 2007;2(1):42.
18. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science : IS.* 2009;4:50.
19. Boccara F, Lang S, Meuleman C, et al. HIV and coronary heart disease: time for a better understanding. *Journal of the American College of Cardiology.* 2013;61(5):511-523.

20. Kaplan RC, Kingsley LA, Sharrett AR, et al. Ten-year predicted coronary heart disease risk in HIV-infected men and women. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America.* 2007;45(8):1074-1081.
21. Silverberg MJ, Leyden WA, Xu L, et al. Immunodeficiency and risk of myocardial infarction among HIV-positive individuals with access to care. *Journal of acquired immune deficiency syndromes (1999).* 2014;65(2):160-166.
22. Funderburg NT, Mehta NN. Lipid Abnormalities and Inflammation in HIV Inflection. *Current HIV/AIDS reports.* 2016;13(4):218-225.
23. Lo J, Lu MT, Ihenachor EJ, et al. Effects of statin therapy on coronary artery plaque volume and high-risk plaque morphology in HIV-infected patients with subclinical atherosclerosis: a randomised, double-blind, placebo-controlled trial. *The lancet HIV.* 2015;2(2):e52-63.
24. Freiberg MS, So-Armah K. HIV and Cardiovascular Disease: We Need a Mechanism, and We Need a Plan. *Journal of the American Heart Association.* 2016;4(3):e003411.
25. Gilbert JM, Fitch KV, Grinspoon SK. HIV-Related Cardiovascular Disease, Statins, and the REPRIEVE Trial. *Topics in antiviral medicine.* 2015;23(4):146-149.
26. CDC. Diagnoses of HIV infection in the United States and dependent areas, 2015. *HIV Surveillance Report* 2016;27.
27. CDC. Deaths: Final data for 2014. . *National Vital Statistics Reports* 2016;65(4).
28. Daviglus ML, Talavera GA, Aviles-Santa ML, et al. Prevalence of major cardiovascular risk factors and cardiovascular diseases among Hispanic/Latino individuals of diverse backgrounds in the United States. *Jama.* 2012;308(17):1775-1784.
29. Djousse L, Petrone AB, Blackshear C, et al. Prevalence and changes over time of ideal cardiovascular health metrics among African-Americans: the Jackson Heart Study. *Preventive medicine.* 2015;74:111-116.
30. Triant VA, Lee H, Hadigan C, Grinspoon SK. Increased acute myocardial infarction rates and cardiovascular risk factors among patients with human immunodeficiency virus disease. *The Journal of clinical endocrinology and metabolism.* 2007;92(7):2506-2512.
31. Aaron E, Criniti S, Bonacquisti A, Geller PA. Providing sensitive care for adult HIV-infected women with a history of childhood sexual abuse. *The Journal of the Association of Nurses in AIDS Care : JANAC.* 2013;24(4):355-367.
32. Meade CS, Hansen NB, Kochman A, Sikkema KJ. Utilization of medical treatments and adherence to antiretroviral therapy among HIV-positive adults with histories of childhood sexual abuse. *AIDS patient care and STDs.* 2009;23(4):259-266.
33. Leserman J. Role of depression, stress, and trauma in HIV disease progression. *Psychosomatic medicine.* 2008;70(5):539-545.
34. Johnson MO, Catz SL, Remien RH, et al. Theory-guided, empirically supported avenues for intervention on HIV medication nonadherence: findings from the Healthy Living Project. *AIDS patient care and STDs.* 2003;17(12):645-656.
35. Spire B, Duran S, Souville M, Leport C, Raffi F, Moatti JP. Adherence to highly active antiretroviral therapies (HAART) in HIV-infected patients: from a predictive to a dynamic approach. *Social science & medicine (1982).* 2002;54(10):1481-1496.
36. Machtinger EL, Wilson TC, Haberer JE, Weiss DS. Psychological trauma and PTSD in HIV-positive women: a meta-analysis. *AIDS and behavior.* 2012;16(8):2091-2100.
37. LeGrand S, Reif S, Sullivan K, Murray K, Barlow ML, Whetten K. A Review of Recent Literature on Trauma Among Individuals Living with HIV. *Current HIV/AIDS reports.* 2015;12(4):397-405.
38. Watt MH, Dennis AC, Choi KW, et al. Impact of Sexual Trauma on HIV Care Engagement: Perspectives of Female Patients with Trauma Histories in Cape Town, South Africa. *AIDS and behavior.* 2016.
39. Ammassari A, Antinori A, Aloisi MS, et al. Depressive symptoms, neurocognitive impairment, and adherence to highly active antiretroviral therapy among HIV-infected persons. *Psychosomatics.* 2004;45(5):394-402.

40. Vranceanu AM, Safren SA, Lu M, et al. The relationship of post-traumatic stress disorder and depression to antiretroviral medication adherence in persons with HIV. *AIDS patient care and STDs.* 2008;22(4):313-321.
41. Gore-Felton C, Koopman C. Behavioral mediation of the relationship between psychosocial factors and HIV disease progression. *Psychosomatic medicine.* 2008;70(5):569-574.
42. Whetten K, Reif S, Whetten R, Murphy-McMillan LK. Trauma, mental health, distrust, and stigma among HIV-positive persons: implications for effective care. *Psychosomatic medicine.* 2008;70(5):531-538.
43. Wyatt GE, Myers HF, Williams JK, et al. Does a history of trauma contribute to HIV risk for women of color? Implications for prevention and policy. *American journal of public health.* 2002;92(4):660-665.
44. Kalichman SC, Sikkema KJ, DiFonzo K, Luke W, Austin J. Emotional adjustment in survivors of sexual assault living with HIV-AIDS. *Journal of traumatic stress.* 2002;15(4):289-296.
45. Olff M, Langeland W, Draijer N, Gersons BP. Gender differences in posttraumatic stress disorder. *Psychological bulletin.* 2007;133(2):183-204.
46. Dong M, Giles WH, Felitti VJ, et al. Insights into causal pathways for ischemic heart disease: adverse childhood experiences study. *Circulation.* 2004;110(13):1761-1766.
47. Spitzer C, Barnow S, Volzke H, John U, Freyberger HJ, Grabe HJ. Trauma, posttraumatic stress disorder, and physical illness: findings from the general population. *Psychosomatic medicine.* 2009;71(9):1012-1017.
48. Lutwak N, Dill C. Military sexual trauma increases risk of post-traumatic stress disorder and depression thereby amplifying the possibility of suicidal ideation and cardiovascular disease. *Military medicine.* 2013;178(4):359-361.
49. Hamil-Luker J, O'Rand AM. Gender differences in the link between childhood socioeconomic conditions and heart attack risk in adulthood. *Demography.* 2007;44(1):137-158.
50. O'Rand AM, Hamil-Luker J. Processes of cumulative adversity: childhood disadvantage and increased risk of heart attack across the life course. *The journals of gerontology Series B, Psychological sciences and social sciences.* 2005;60 Spec No 2:117-124.
51. Sumner JA, Kubzansky LD, Elkind MS, et al. Trauma Exposure and Posttraumatic Stress Disorder Symptoms Predict Onset of Cardiovascular Events in Women. *Circulation.* 2015;132(4):251-259.
52. Doom JR, Mason SM, Suglia SF, Clark CJ. Pathways between childhood/adolescent adversity, adolescent socioeconomic status, and long-term cardiovascular disease risk in young adulthood. *Social Science & Medicine.* 2017.
53. Vaccarino V, Bremner JD. Traumatic stress is heartbreaking. *Biological psychiatry.* 2013;74(11):790-792.
54. Everson-Rose SA, Lewis TT. Psychosocial factors and cardiovascular diseases. *Annual review of public health.* 2005;26:469-500.
55. Lewis TT. Trauma and PTSD: emerging risk factors for CVD in women? *Circulation.* 2015:CIRCULATIONAHA. 115.017432.
56. Kilbourne AM, Abraham KM, Goodrich DE, et al. Cluster randomized adaptive implementation trial comparing a standard versus enhanced implementation intervention to improve uptake of an effective re-engagement program for patients with serious mental illness. *Implementation Science.* 2013;8(1):136.
57. Kilbourne AM, Almirall D, Goodrich DE, et al. Enhancing outreach for persons with serious mental illness: 12-month results from a cluster randomized trial of an adaptive implementation strategy. *Implementation Science.* 2014;9(1):163.
58. Leykum LK, Pugh JA, Lanham HJ, Harmon J, McDaniel RR. Implementation research design: integrating participatory action research into randomized controlled trials. *Implementation Science.* 2009;4(1):69.
59. Jordon M, Lanham HJ, Anderson RA, McDaniel Jr RR. Implications of complex adaptive systems theory for interpreting research about health care organizations. *Journal of evaluation in clinical practice.* 2010;16(1):228-231.

60. McDaniel Jr RR, Lanham HJ, Anderson RA. Implications of complex adaptive systems theory for the design of research on health care organizations. *Health care management review.* 2009;34(2):191.
61. Liu H, Prause N, Wyatt GE, et al. Development of a composite trauma exposure risk index. *Psychological assessment.* 2015;27(3):965-974.
62. Cabassa LJ, Gomes AP, Lewis-Fernández R. What Would It Take? Stakeholders' Views and Preferences for Implementing a Health Care Manager Program in Community Mental Health Clinics Under Health Care Reform. *Medical Care Research and Review.* 2015;72(1):71-95.
63. Garland AF, Bickman L, Chorpita BF. Change what? Identifying quality improvement targets by investigating usual mental health care. *Administration and Policy in Mental Health and Mental Health Services Research.* 2010;37(1-2):15-26.
64. Weisz JR, Chorpita BF, Palinkas LA, et al. Testing standard and modular designs for psychotherapy treating depression, anxiety, and conduct problems in youth: A randomized effectiveness trial. *Archives of general psychiatry.* 2012;69(3):274-282.
65. Chorpita BF, Weisz JR, Daleiden EL, et al. Long-term outcomes for the Child STEPs randomized effectiveness trial: A comparison of modular and standard treatment designs with usual care. *Journal of Consulting and Clinical Psychology.* 2013;81(6):999.
66. Wyatt GE, Hamilton AB, Myers HF, et al. Violence prevention among HIV-positive women with histories of violence: Healing women in their communities. *Women's Health Issues.* 2011;21(6):S255-S260.
67. Yancy CW. Cardiovascular disease outcomes: priorities today, priorities tomorrow for research and community health. *Ethnicity & disease.* 2012;22(3 (Suppl 1)):1-7-S1-12.
68. Rodriguez CJ, Allison M, Daviglus ML, et al. Status of cardiovascular disease and stroke in Hispanics/Latinos in the United States. *Circulation.* 2014;130(7):593-625.
69. Rotheram-Borus MJ, Swendeman D, Chorpita BF. Disruptive innovations for designing and diffusing evidence-based interventions. *American Psychologist.* 2012;67(6):463.
70. Hamilton AB, Mittman BS, Williams JK, et al. Community-based implementation and effectiveness in a randomized trial of a risk reduction intervention for HIV-serodiscordant couples: study protocol. *Implementation science : IS.* 2014;9:79.
71. Hamilton AB, Brunner J, Cain C, et al. Engaging multilevel stakeholders in an implementation trial of evidence-based quality improvement in VA women's health primary care. *Translational behavioral medicine.* 2017.
72. Hamilton AB, Cohen AN, Glover DL, et al. Implementation of evidence-based employment services in specialty mental health. *Health services research.* 2013;48(6 Pt 2):2224-2244.
73. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implementation science : IS.* 2013;8:139.
74. Simpson KM, Porter K, McConnell ES, et al. Tool for evaluating research implementation challenges: a sense-making protocol for addressing implementation challenges in complex research settings. *Implementation Science.* 2013;8(1):2.
75. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research.* 2015;42(5):533-544.
76. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and policy in mental health.* 2011;38(2):65-76.
77. Myers HF, Wyatt GE, Ullman JB, et al. Cumulative burden of lifetime adversities: Trauma and mental health in low-SES African Americans and Latino/as. *Psychological trauma : theory, research, practice and policy.* 2015;7(3):243-251.
78. Collier KL, Colarossi LG, Hazel DS, Watson K, Wyatt GE. Healing our women for transgender women: adaptation, acceptability, and pilot testing. *AIDS Education and Prevention.* 2015;27(5):418-431.
79. Folsom AR, Yatsuya H, Nettleton JA, et al. Community prevalence of ideal cardiovascular health, by the American Heart Association definition, and relationship with cardiovascular disease incidence. *Journal of the American College of Cardiology.* 2011;57(16):1690-1696.

80. Dong C, Rundek T, Wright CB, Anwar Z, Elkind MS, Sacco RL. Ideal cardiovascular health predicts lower risks of myocardial infarction, stroke, and vascular death across whites, blacks and Hispanics: the northern Manhattan study. *Circulation.* 2012:CIRCULATIONAHA. 111.081083.
81. Kulshreshtha A, Vaccarino V, Judd SE, et al. Life's Simple 7 and risk of incident stroke. *Stroke.* 2013;44(7):1909-1914.
82. Folsom AR, Shah AM, Lutsey PL, et al. American Heart Association's Life's Simple 7: avoiding heart failure and preserving cardiac structure and function. *The American journal of medicine.* 2015;128(9):970-976. e972.
83. Fretts AM, Howard BV, McKnight B, et al. Life's simple 7 and incidence of diabetes among American Indians: the Strong Heart Family Study. *Diabetes Care.* 2014;37(8):2240-2245.
84. Muntner P, Judd SE, Gao L, et al. Cardiovascular risk factors in CKD associate with both ESRD and mortality. *Journal of the American Society of Nephrology.* 2013:ASN. 2012070642.
85. Thacker EL, Gillett SR, Wadley VG, et al. The American Heart Association Life9s Simple 7 and Incident Cognitive Impairment: The REasons for Geographic And Racial Differences in Stroke (REGARDS) Study. *Journal of the American Heart Association.* 2014;3(3):e000635.
86. Kronish IM, Carson AP, Davidson KW, Muntner P, Safford MM. Depressive symptoms and cardiovascular health by the American Heart Association's definition in the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study. *PLoS One.* 2012;7(12):e52771.
87. Elliot D, Mihalic S. Issues in disseminating and replicating effective prevention programs. *Prevention Science.* 2004;5(1):47-53.
88. Maslach C, Jackson SA, Leiter MP. Maslach Burnout Inventory Manual. *Consulting Psychologists Press.* 1996.
89. Ehrhart MG, Aarons GA, Farahnak LR. Assessing the organizational context for EBP implementation: the development and validity testing of the Implementation Climate Scale (ICS). *Implementation Science.* 2014;9(1):157.
90. Aarons GA, Ehrhart MG, Farahnak LR. The implementation leadership scale (ILS): development of a brief measure of unit level implementation leadership. *Implementation Science.* 2014;9(1):45.
91. Ehrhart MG, Aarons GA, Farahnak LR. Going above and beyond for implementation: the development and validity testing of the Implementation Citizenship Behavior Scale (ICBS). *Implementation Science.* 2015;10(1):65.
92. Towfighi A, Cheng EM, Ayala-Rivera M, et al. Randomized controlled trial of a coordinated care intervention to improve risk factor control after stroke or transient ischemic attack in the safety net: Secondary stroke prevention by Uniting Community and Chronic care model teams Early to End Disparities (SUCCEED). *BMC neurology.* 2017;17(1):24.
93. Grills CN, Aird EG, Rowe D. Breathe, baby, breathe: Clearing the way for the emotional emancipation of Black people. *Cultural Studies? Critical Methodologies.* 2016;16(3):333-343.
94. Pennebaker JW. Writing about emotional experiences as a therapeutic process. *Psychological science.* 1997;8(3):162-166.
95. Group DPPR. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl j Med.* 2002;2002(346):393-403.
96. Ackermann RT, Marrero DG. Adapting the Diabetes Prevention Program lifestyle intervention for delivery in the community. *The Diabetes Educator.* 2007;33(1):69-78.
97. Metzger D, Koblin B, Turner C, et al. Randomized controlled trial of audio computer-assisted self-interviewing: Utility and acceptability in longitudinal studies. *American Journal of Epidemiology.* 2000;152(2):99-106.
98. NIMH Multisite HIV/STD Prevention Trial for African American Couples Group. Behavioral and biological outcomes of a cluster-randomized trial. under review.
99. Beck AT, Steer RA, Brown GK. Beck Depression Inventory-ii (bdi-ii). *San Antonio, TX: Psychological Corporation.* 1996.
100. Foa EB, Cashman L, Jaycox L, Perry K. The validation of a self-report measure of posttraumatic stress disorder: The Posttraumatic Diagnostic Scale. *Psychological assessment.* 1997;9(4):445.

101. Kroenke K, Spitzer RL, Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. *Psychosomatic medicine.* 2002;64(2):258-266.
102. Gratz KL, Roemer L. Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the difficulties in emotion regulation scale. *Journal of psychopathology and behavioral assessment.* 2004;26(1):41-54.
103. Pennebaker JW. Putting stress into words: Health, linguistic, and therapeutic implications. *Behaviour research and therapy.* 1993;31(6):539-548.
104. Sofi F, Cesari F, Casini A, Macchi C, Abbate R, Gensini GF. Insomnia and risk of cardiovascular disease: a meta-analysis. *European journal of preventive cardiology.* 2014;21(1):57-64.
105. Smyth C. The Pittsburgh sleep quality index (PSQI). *Journal of gerontological nursing.* 1999;25(12):10-10.
106. Bastien CH, Vallières A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep medicine.* 2001;2(4):297-307.
107. Lloyd-Jones DM, Hong Y, Labarthe D, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction. *Circulation.* 2010;121(4):586-613.
108. Koblin B, Chesney M, Coates T. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. *Lancet.* 2004;364(9428):41-50.
109. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation science : IS.* 2015;10:21.
110. Strauss A, Corbin J. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques.* Newbury Park1990.
111. Hamilton AB, Cohen AN, Young AS. Organizational readiness in specialty mental health care. *Journal of general internal medicine.* 2010;25(1):27-31.
112. J.A. MPN. *Generalized Linear Models, 2nd Edition.* New York: Chapman & Hall; 1989.
113. S.R. MCES. *Generalized, Linear, and Mixed Models.* New York: Wiley; 2001.

18. APPENDICES

[Appendices of measures will be supplied when programmed, IRB-approved versions are available.]