A Clinic-Based Case Manager Administered Telephone Intervention to Reduce Cardiovascular Disease Risk in Persons Living with HIV

Pro00085562

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Building 31
31 Center Drive
Bethesda, MD 20892

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List of Abbreviations

HIV	Human Immunodeficiency Virus
ASCVD	Atherosclerotic Cardiovascular Disease
CVD	Cardiovascular Disease
MI	Myocardial Infarction
HINTS	Hypertension Intervention Nurse Telemedicine Study
CITIES	Cardiovascular Intervention Improvement Telemedicine Study
CCM	Clinical Case Manager
PLWH	People Living With HIV
LDL	Low density lipoprotein
SBP	Systolic Blood Pressure

Study Summary

Title	A Clinic-Based Case Manager Administered Telephone Intervention to Reduce Cardiovascular Disease Risk in Persons Living with HIV
Short Title	SWOBI-CVD
Protocol Number	Pro00085562
Phase	Phase 3
Methodology	Randomized Controlled Trial
Study Duration	24 months
Study Center(s)	Single-center
Objectives	To assess the impact of telephone-based case manager administered interventions in improving ASCVD risk factor outcomes among HIV-infected clinic patients.
Number of Subjects	50
Diagnosis and Main Inclusion Criteria	Patients diagnosed with HIV and either hyperlipidemia or hypertension
Duration of administration	24-weeks
Statistical Methodology	Generalized linear mixed regression models will be used to assess the changes in systolic blood pressure and LDL-c over the period of the intervention, accounting for repeated measurements within subjects as well as clustering of subjects within providers. Bivariable and multivariable analyses will be conducted for all covariates. To test for the effect of time on the differences in SBP and LDL-c between the groups, we will fit a constrained longitudinal data model (cLDA).57 We will fit models with time as a categorical variable (based on the time of outcome measure collection) and as a continuous variable, to determine the best model fit.

Introduction

1.1 Background and Significance

Scientific Premise: Atherosclerotic cardiovascular disease (ASCVD) is now a leading cause of mortality in persons living with HIV (PLWH), accounting for approximately 10% of deaths in large HIV clinical cohorts.[1-5] With widespread availability of effective antiretroviral therapy, deaths due to AIDS-related conditions will continue to decrease. Concurrently, ASCVD will continue to increase as a proportion of overall mortality among PLWH, especially in light of the aging HIV population.[6] Multiple cohort studies have shown a 40-50% higher incidence of myocardial infarction (MI) among PLWH with suppressed viremia compared to uninfected persons.[7-9,] These observations highlight the need to adopt a comprehensive approach to decreasing ASCVD risk in this population, beyond durable viral suppression. Although chronic immune activation is thought to drive vascular inflammation and atherogenesis in PLWH[10-12], the higher prevalence of reversible ASCVD risk factors (smoking, hyperlipidemia and hypertension) among PLWH is also well established.[13-16] Recent studies show that these risk factors are more deleterious in PLWH than in uninfected persons. As an example, in a large Danish cohort (n= 16,255), 72% of MIs observed among persons with HIV were at least partially attributable to smoking compared to 24% of MIs in uninfected persons.[17] These data emphasize the need for investigating models of HIV care that are responsive to the complexities of ASCVD risk among PLWH.

Despite the increased risk of major ASCVD events in PLWH, ASCVD primary prevention in this group may be inferior to that of uninfected persons.[18] A study at the University of Alabama showed that 17% of persons who were eligible for aspirin by USPSTF guidelines had received recommendations from their provider to take it.[19] Similarly, data from our group showed that PLWH were 30% less likely to receive statins, 47% less likely to receive aspirin and 37% less likely to receive anti-hypertensives when indicated than age, sex and race matched controls.[20] Unfortunately, behavioral interventions targeted at modifying provider practices pertaining to CVD risk reduction are often ineffective.[21-24] Using non-physician clinical staff to augment care is a potentially effective way to overcome barriers to improving CVD risk management in this setting.

Behavioral interventions conducted by non-physician clinical staff are effective in reducing ASCVD risk. A meta-analysis of 39 randomized controlled trials assessing nurse and/or pharmacist-led CVD risk-reduction interventions, reported that systolic blood pressure dropped by 7.6mm Hg from baseline readings compared to usual care. The mean duration of the interventions assessed was only 8.3 months (range 3-13 months), demonstrating the rapid impact these interventions can have on CVD risk parameters.[25] In a randomized study of 636 patients with hypertension, patients who received a 2-year nurse-administered behavioral intervention were 11% more likely to achieve blood pressure control than patients who received usual care.[26] *The scientific premise of the proposed intervention is that clinical encounter supplementation provided by telephone, and delivered by trained professionals, will provide additional time and opportunity to establish and reinforce behaviors associated with CVD risk reduction. A measurable manifestation of this intervention will be reduction of blood pressure and low density lipoprotein (LDL) levels*.[27,28]

Significance of the Expected Research Contribution: With the large sample size of the retrospective analysis from Aim 1, findings from our study will provide insight into what care delivery models have worked historically for ASCVD primary prevention in PLWH. Our proposed study will also look at the utility of leveraging the unique, multidisciplinary structure of the HIV clinical care team for improving ASCVD outcomes in this high-risk population. If the proposed telephone-based intervention proves effective, similar interventions could be applied to addressing other non-AIDS chronic diseases including non-AIDS-related cancer, chronic kidney disease and osteopenia/osteoporosis. Our findings will also give validation to the paradigm of incorporating, non-provider HIV clinical staff into longitudinal chronic disease management initiatives for HIV clinic patients.

1.2 Innovation

1) **Our study will be the first comparative analysis to examine ASCVD-related outcomes based on models of healthcare delivery in an HIV population.** By 2019, 50% of all patients with HIV in the United States will be aged 50 or older.[29,30] Understanding trends in chronic disease care delivery (particularly ASCVD primary prevention) in this aging population is critical to informing healthcare delivery interventions that are responsive to the ever-increasing burden of HIV clinical care. Although our data suggest that PLWH who receive medical care solely from HIV subspecialists are prescribed CVD medications less frequently than uninfected persons,[20] how these outcomes deviate from PLWH receiving chronic disease care from non-HIV PCPs is unclear. The retrospective analysis proposed in Aim 1 will provide valuable insight on whether or not the intervention proposed in Aim 3 (and other interventions aimed at improving CVD risk management) should be restricted to persons who receive all non-AIDS chronic disease care exclusively from their HIV provider. In addition, no studies to date have looked at whether receiving CVD preventative care exclusively from an HIV provider has an adverse impact on hard CVD risk factor outcomes (successful blood pressure and lipid control). Our study will be the first to address this question.

2) **The intervention design will be customized based on patient and provider input**. Telephone-based interventions have been previously shown to improve blood pressure in patients with hypertension.[26, 31-33] The framework of our proposed intervention will be based upon the nurse and pharmacist administered instruments from the Hypertension Intervention Nurse Telemedicine Study (HINTS) and the Cardiovascular Intervention Improvement Telemedicine Study (CITIES) respectively.[26,34] However, implementing such interventions in the context of HIV care presents unique complexities. To better understand the nuances of HIV care relevant to the development of the intervention, we will adopt a mixed methods approach. Semi- structured interviews and focus groups of HIV clinic patients and clinical case managers will be used to inform our research team of precise ways to modify our proposed intervention to best fit the needs of the HIV clinic population. This approach will provide the unique opportunity to tailor a previously validated ASCVD risk management intervention to specifically meet the needs of HIV-infected persons.

3) **The intervention will be generalizable, sustainable and time-efficient**. Unlike the HINTS and CITIES studies which were administered by nurses and pharmacists hired specifically for the research study,[26,34] we will pilot our proposed intervention with clinical case managers (CCMs) who are primarily employed by the HIV clinic, and are part of many HIV clinics.

Given the prominent role of CCMs in HIV care, our intervention (if effective) will be highly generalizable to a variety of clinical settings. The total telephone encounter time of the proposed intervention is approximately 30-45 minutes per encounter. In addition, the short duration of the intervention (24 weeks) also enhance ease of implementation in real-world practice. Most importantly, using clinic-employed CCMs will allow for easy incorporation of this strategy into practice, making it more sustainable over time, and immediately applicable.

4) **The intervention will leverage the therapeutic rapport between CCMs and HIV clinic patients to enhance the effectiveness of the proposed intervention.** CCMs typically have a nuanced knowledge of the HIV clinic patient's psychosocial barriers to care and how to resolve them. Of all the members of the HIV clinical care team, this depth of knowledge is usually exclusive to the CCM, given them the ability to quickly establish a unique therapeutic rapport with clinic patients. According to the New York State AIDS Institute, the goal of case management is "to promote and support independence and self-sufficiency".[35] This goal aligns with the central tenets of the HINTS and CITIES interventions predicated on enhancing self-efficacy in accordance with the Health Belief Model (HBM), one of the preeminent psychological theories of health behavior.[36] These parallel objectives make HIV CCMs ideal providers to implement the proposed interventions. The pre-existing therapeutic rapport between CCMs and their clinic patients is centered around the restoration of self-efficacy, a key component absent from both aforementioned studies. Given the work- time compression characteristic of the physician-patient interaction, CCMs may be more effective than providers in motivating lifestyle modification because they have more time to promote change in a systematic manner based on sound cognitive constructs. Although using CCMs will increase the amount of training needed to implement the intervention, the benefits of using these professionals to deliver chronic disease interventions have never been formally assessed. Examining the role of this therapeutic dynamic in the in the implementation of the behavioral intervention is novel and a primary focus of our study.

Study Objectives

The overall objective of this study is to assess the impact of telephone-based case manager administered interventions in improving ASCVD risk factor outcomes among HIV-infected clinic patients.

2.1 Primary Objective

To assess the effect of a telephone based CVD risk reduction intervention on decreasing systolic blood pressure (SBP) and fasting LDL-c levels from baseline.

2.2 Secondary Objective

To assess the effect of a telephone based CVD risk reduction intervention on weight loss and change in 10-year ASCVD risk score.

Study Design

3.1 General Design

Fifty *high CVD* risk clinic patients will be randomized 1:1 to receive either a series of educational pamphlets on CVD risk reduction plus a telephone-based CVD risk reduction

curriculum delivered over 24 weeks [intervention arm], or the educational pamphlets alone [control arm]. Anthropomorphic data, blood pressure and lipid profiles will be obtained from patients at baseline and at the end of the study (24 weeks) to assess the efficacy of the intervention in reducing blood pressure and serum low-density lipoprotein levels (LDL).

3.2 Design Team Consultations

We will conduct a series of participatory, iterative design consultation team meetings held over the course of 2-4 weeks. The design team will include a combination of 2-4 clinical social workers from Clinic 1K, 1-3 persons living with HIV. Each member of the design team will be recruited by personal invitation. The purpose of the design teams will be to provide refine the intervention designed by the study investigator and SW consultant. The design process will involve three main phases: brainstorming, conceptualization, and creation described below in study procedures. The results from the first two design team meetings will inform one additional design team meeting to iteratively refine the intervention. Informed consent will be obtained from all members of the consultation team. We anticipate that each design team session will take between 3-4 hours. Design team members will be compensated $150 per session completed.

Subject Selection and Withdrawal

4.1 Inclusion Criteria

1. Age 40-75 years.
2. In care at the Duke Infectious Disease Clinic for at least 12 months.
3. HIV+ and on antiretroviral therapy for at least one year, with six consecutive months of documented viral suppression (HIV-1 RNA <200 copies/ml at time of enrollment.
4. Diagnosis of hypertension or hyperlipidemia.
   Hypertension is defined as: a) "Essential hypertension", "Primary Hypertension" or "Hypertension" listed on their problem list in the electronic health record b) On antihypertensive medication for the indication of hypertension c) two consecutive ambulatory blood pressures of > 130/80 separated by 3 months or more.
   Hyperlipidemia is defined as: a) "Hyperlipidemia" or "Dyslipidemia" (with allowed modifiers) listed in patient's problem list in EHR b) On any of the following lipid-lowering medications: statins, fibrates, PCSK-9 inhibitors, niacin, ezetimibe.
5. Able to speak and read English at least at the 6th grade level

4.2 Exclusion Criteria

1. Prior diagnosis of acute coronary syndrome, stroke, peripheral vascular disease, and end stage renal disease, coronary revascularization (percutaneous coronary intervention or coronary artery bypass grafting) or congestive heart failure.
2. Pregnant, breastfeeding, or planning a pregnancy during study period.
3. Planning to move out of the area in the next 6 months.
4. No reliable access to telephone.
5. Terminal illness with life expectancy <4 months.
6. In a nursing home and/or receiving in-patient psychiatric care.
7. Severely hearing or speech impaired, or other disability that would limit participation in the intervention components.

8. Documented mental health diagnosis with component of psychosis.
9. Longitudinal follow up by a hyperlipidemia specialist (endocrinology or cardiology), hypertension specialist (nephrology or cardiology) or a cardiologist for any indication.

4.3 Subject Recruitment and Screening

Pre-screening: we will use the electronic medical records at our site to identify potential subjects for our study according to the inclusion/exclusion criteria. Potential subjects may also be recommended by providers within the Division of Infectious Diseases based on the inclusion/exclusion criteria. Potential subjects will initially be mailed a recruitment letter signed by his or her primary HIV provider. Potential subjects will have the opportunity to opt out of the study by calling a toll-free number.

In addition to receipt of letters, prospective participants will be approached with the permission of their providers during routinely scheduled clinical encounters, by a member of the study team. During such encounters, the study team will inform participants about the study and the reasons why they are eligible to participate. At that point, the patient will have the option to proceed with a baseline screening visit or not.

This study will also utilize cold-calling recruitment methods. This will include contacting the patients directly if they meet eligibility criteria to enroll them into this study. Research coordinator(s) will refer to patients' electronic medical records (EMR) to confirm that the patient(s) have not opted out from being contacted for research studies.

Screening: A research coordinator will contact all subjects who do not opt out. Following a telephone script, the research assistant will describe the study in detail, ensure the patient is eligible and willing to participate, and schedule a baseline study visit at the next clinical visit with an HIV provider where they will be enrolled following the informed consent process described below in section 5.1.

4.4 Early Withdrawal of Subjects

Throughout the course of the study, patients will be encouraged to complete the all study assessments. However, it is possible that a subject may discontinue study participation at any time for any reason. The reason for early withdrawal must be documented in the subject's case file, subject tracking document and subject withdrawal form on REDCap.

4.4.1 Reasons for withdrawal:

The voluntary nature of studies allows for participants to withdraw from the study at any point for any reason. Subjects may be withdrawn from the study if a serious adverse event (SAE) occurs. Subjects may be withdrawn if:

1. They withdraw their consent
2. In the opinion of the investigator, continuation of study participation would be hazardous to the participant, or compromise study findings.

The reason for any subject's discontinuation and the date of withdrawal will be recorded in the subject's case file. The subject's case file, which will be completed up to the point of withdrawal will be retained for six years. The study report will include reasons for subjects' withdrawals as

well as details relevant to the subjects' withdrawals. Any subject withdrawn from the trial prior to completion will undergo all procedures indicated in this protocol as being scheduled to occur at discharge or upon early withdrawal. Any subject withdrawn due to an adverse event (whether serious or non-serious) or any clinically significant abnormal laboratory test value will be evaluated by the principal investigator, and will be treated and followed up until the symptoms or values return to normal or acceptable levels, as judged by the Principal Investigator. Relevant post-study procedures will be performed, wherever possible, on subjects who elect to withdraw.

4.4.2 Handling of Withdrawals:

If a subject is withdrawn from participation in the study at any time at his or her request, at the IRB or Principal Investigator's discretion, the reason(s) for discontinuation shall be documented thoroughly in the source documents and subject's case file. If a subject is discontinued because of an adverse event, this event will be followed until it is resolved or the subject is clinically stable and will also be documented in the source documents and the subject's case file.

Study Procedures

5.1 Design Team Procedures:

This intervention adaptation aim will involve three phases: brainstorming, conceptualization, and creation:

During the brainstorming (meeting #1): the design team will review the mixed-methods data obtained during aim 2 of the study, which sought to gain detailed knowledge about HIV clinic patients' perception of their own CVD risk and the HIV clinic's role in CVD risk reduction. The following topics will be discussed: perception of CVD risk (perceived susceptibility), provider accessibility (perceived barriers), provider prioritization of CVD risk management (perceived barriers), and interventions likely to motivate risk reducing behaviors (perceived benefits and cue to actions). The team will discuss these findings and brainstorm ideas to refine the SWOBI intervention in response to the data. Possible targets for adaptation include a) targeting the staff training to include relevant aspects of perceived risk into the care coordination and adherence support; (b) developing and tailoring staff training to facilitate acceptance, uptake, and effectiveness; and (c) helping us to quickly identify and troubleshoot any problems with the implementation of the intervention.

During the conceptualization phase (meeting #2): the team will evaluate advantages and disadvantages of ideas generated during the brainstorming phase, and the educational material developed ahead of this meeting. The team will then develop concrete changes to the intervention. The feasibility of each of the discussed intervention modification will be discussed and finalized into the intervention by the study PI.

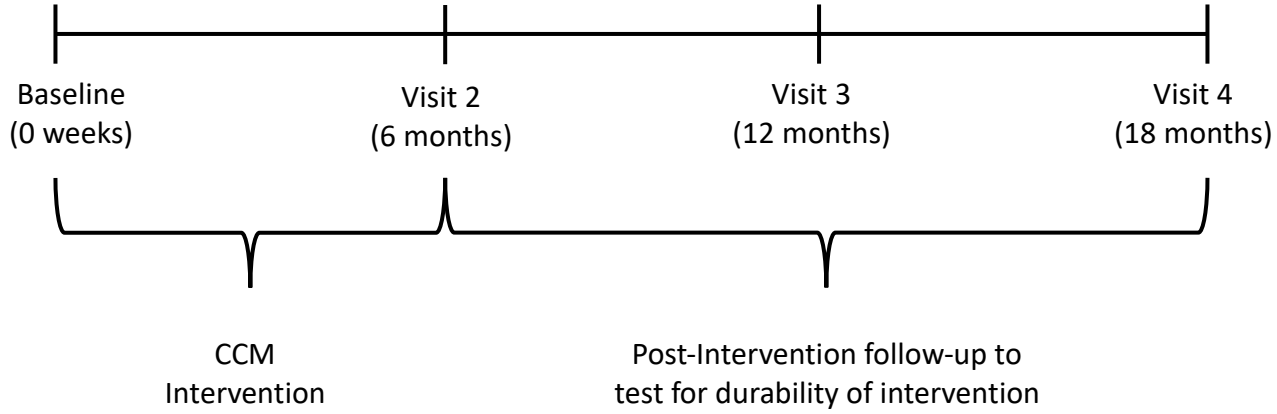
During the creation phase (meeting #3): the team will be involved in the creation of refined manuals of procedures and education materials. After the feasibility testing is completed, the design team will meet for a final time to discuss feasibility testing results from meeting #2 and refine the intervention as needed. At this meeting, the design team members who have given consent to participate in a focus group discussion will reflect on the design process.

5.2 Pre-trial demonstration

Prior to the commencement of the trial, we will recruit one clinic patient to participate in a demonstration of the study intervention telephone modules. The purpose of this demonstration is to give the study social worker the opportunity to execute the trial intervention modules and resolve workflow/logistical concerns with the intervention prior to study launch. The demonstration patient will be recruited by personal invitation of the study investigator. They will be consented prior to their participation in the process. The study patient will be expected to participate in no more than three demonstration sessions. They will serve as a mock recipient of the telephone-based intervention. After conclusion of the demo intervention call, the study team will ask the demo participant questions about the acceptability of the telephone call, as well as their perceived strengths and weaknesses of the telephone module. The demonstration participant will be compensated $50 for each session for a total of $150.

5.3 Study Timeline

All enrolled patients will complete 4 study visits as outlined in the flow chart below:



5.4 Informed Consent

Each subject will give informed consent, either using a hard copy consent in person or via the e-consent process in REDCap, prior to enrollment into study during the baseline visit. Research coordinator(s) will read, review, and discuss consent forms with all potential participants prior to asking them to sign. If the candidate appears confused or indicates a lack of understanding, the interviewer will attempt to identify the misunderstanding and to explain the form again. Any candidate who still does not comprehend the form will be excluded from the study. We will ask questions to confirm understanding of the material covered in the consent procedure, both open ended (e.g. “Could you tell me what’s going to happen of you enroll in this study?) and closed (e.g. “is your participation in this study voluntary?”). Persons who understand the consent form and agree to participate in the study will be asked to sign an authorization for the release of medical information to us. Interviewers will witness and date the signed forms and complete the corresponding informed consent checklist to document the participant’s understanding of the informed consent process. Consent procedures will take place in a private room or office. Consent forms will be kept in a locked file cabinet within a locked room.

5.5 Data collection

Data will be collected through the electronic data capture system – REDCap. Patients will have the option of providing e-consent on this platform. Participants will be asked to complete patient reported outcome measures via REDCap at various timepoints throughout the study including: single item health literacy, demographics, adherence, IPAQ physical activity, and perception of risk of heart disease scale. In addition, the clinical research coordinators will collect patient information for: medical chart screen, participant screening, BP and cholesterol medications, physical measurements, and outcomes. Adverse events will also be collected to track and ensure safety of the patient throughout the duration of their participation in the study.

5.6 Randomization

We will conduct a randomized controlled pilot trial of the intervention vs. education control group among 50 PLWH on suppressive ART who have either hypertension or hypercholesterolemia. Control participants will receive general prevention education. The intervention will consist of prevention education plus a 24- week intensive telephone-based, social work administered intervention focused on heart-healthy behaviors.

5.7 Control group

Participants assigned to the control group will receive usual clinical care enhanced with a series of 12 packets of educational handouts delivered to patients every two weeks for 24 weeks. . Educational pamphlets will be delivered on one of six topics on a rotational basis (two rotations over a 6-month study period). The topics to be covered by the educational material are as follows: CVD Knowledge and Risk Perception, Medication Reconciliation, Dietary Assessment and Education, Physical Activity and Weight Management, Smoking Cessation, Stress Management. On enrollment, participants will determine the optimal mode of delivery for the educational material (email, regular mail, or text). All participants in the control and intervention arm will complete the following study assessments: 1) in-office BP obtained by a trained research assistant (0, 6, 12, 18 months) 2) lipid profile (0, 6, 12, 18 months)(the default will be to collect data from lipid profiles done as part of routine clinical care, within 4 weeks of baseline visit; if lipid information is not available or exceeds acceptable time point, lipid panel will be collected by the research staff). 3) 10-year ASCVD risk score (0, 6, 12, 18 months 4) provider trust and communication survey (0, 6, 12, 18 months).

5.8 Study Intervention

In addition to the educational material delivered to the control arm participants, participants randomized to the intervention arm will receive a 24-week telephone-based intervention, customized for the delivery to PLWH by social workers (SW). Participants will be contacted every 2 weeks for a total of 12 calls in the 24-week period by the study social worker. During each call, the participant will have the chance to select a module from 6 modules in a rotating fashion on topics relevant to CVD risk (Table 2). Once a module is chosen, it can only be chosen once more for the duration of the study period. Each telephone session will involve the study SW providing education on the selected module to promote improved CVD health. For the diet, physical activity, and overview of CVD risk factors modules, there will be a low and high literacy version. At baseline the coordinator will assess whether the participant should be low or high literacy based on their discussions. The coordinator will then relay this assessment when notifying the social worker that the participant has been randomized to intervention. During the

first module, the social worker will make a secondary assessment of the participant's health literacy level. The social worker will have the final decision as to which version of the module the participants will receive. During the call, the social worker will follow the prompts of a telephone script. As part of the intervention, the SW will incorporate MI techniques at different times during the phone call based on the direction of the conversation. Towards the end of each call, the participant will have the option to review any or all of the corresponding educational materials relevant to the module. Each of these calls will take between 30-45 minutes to administer. At the conclusion of the study telephone visit, participants will be delivered a package of educational pamphlets similar to those administered to participants in the control arm. Like the control arm, a total of 12 packets will be delivered to intervention participants via their method of choice. Since this pilot study seeks to determine the independent effect of the SW-based intervention, SWs will be instructed not to feedback on study-related telephone interactions to the participant's provider. This will be facilitated by the physical separation between the SW offices and the provider work area. Recruitment efforts will also be tailored to inform providers about the study with the minimal amount of details on the intervention available to avoid undue influence on their practice patterns.

All study follow up visits will be conducted within a +/- 21 day window.

5.9 Social Worker Responsibilities

Responsibilities of interventionist social worker (ISW) are as follows:

a. The ISW will assist in the development of educational material and scripts for the intervention
b. The ISW will participate in all design consultation team sessions aimed at refining the modules for the intervention
c. The ISW will edit and review modified versions of the study intervention after feedback from the design consultation team is obtained.
d. The ISW will participate in post design consultation forums for finalization of the study intervention
e. The ISW will participate in all pre-intervention training associated with the intervention, including (and not limited to): training on medication side effects, simulation sessions for scripted material, review of all educational material, use of Zoom (or other teleconferencing platform for consultation)
f. The ISW will deliver the intervention as configured including: pre-telephone call documentation, study-telephone call, telephonic transmission of visual educational aids (when applicable), post-telephone call documentation (including use of SW-based techniques). The ISW will also be called to use their discretion in employing SW-based techniques for individual patients. All techniques used during the interaction must be documented as part of the study fidelity worksheet to be provided to the ISW by the study team
g. The ISW will answer questions posed by study participants to the best of their ability. Any questions that cannot be answered, and deemed outside their scope of practice by the ISW as part of the intervention will be documented and sent on to the study investigator for resolution. The ISW is specifically instructed not to answer detailed questions on:
    a. CVD medication interactions with current medications

b. Medical issues not directly related with CVD primary prevention related topics (hypertension, hyperlipidemia, diabetes, smoking cessation etc)
c. Medication dosing, up-titration or down-titration
d. Referrals to specialty providers with the exception of mental health practitioners
e. Medications or supplements not-approved by the US Food and Drug Administration
f. Other questions by the ISW's determination is outside the scope of routine social work practice

h. This documentation and transmission to the study investigator should be conducted as soon as possible, but no later than 24 hours after completion of the phone call. Notification will be conducted ideally via institutional e-mail or MyChart messaging. The study investigator will be expected to give a response to such questions within 48 hours of receipt.
i. The ISW will communicate all concerns about logistics of the study to the study coordinator in a timely manner
j. The ISW will report all potential adverse events to the study team (study coordinator and study PI) as soon as they are aware as delineated in Section 7.2.

The following documents will be provided to the ISW by the study team prior to study launch:

a. Telephone call intake forms
b. Educational material associated with module administration
c. Baseline assessment data for individual participants including participant's learning preferences
d. Current contact information (phone and e-mail) of the study PI and the study coordinator
e. A cell phone for the execution of study phone call with SMS transmission capability and associated data
f. List of CVD-related community resources in Raleigh-Durham Metropolitan area
g. Resource document with side effect profiles of major classes of medication used in cardiovascular disease primary prevention.
h.

5.10 Post study intervention

Participants will be followed after the 24-week intervention at 48 (6-month post intervention) and 72 weeks (1 year post intervention) to assess the durability of the intervention's impact. At those visits, we will collect blood pressures, anthropomorphic and lipid panels similar to the first two study visits. We will also conduct patient-reported data on the durability of the intervention using formal assessment tools for heart-healthy behaviors at each visit.

5.11 Post Intervention Interviews

After the 6 month intervention is complete, we will approach a convenience sample of 10 participants to participate in an additional key informant interview. All interviews will be completed between the end of the intervention and the participants 12 month visit. These interviews will take place at the participants 6 month visit or by phone at a mutually agreed upon time. Questions will address the participants perception of the intervention's characteristics and program outcomes. All interviews will take approximately 30 minutes and audio recordings using an encrypted recorder if participant agrees to be recorded, will later be transcribed using a

Duke-approved transcription service (rev.com) to transcribe the audio files. Audio recordings will be destroyed after results of study are published. An interview information sheet will be shared with participants asked to participate in interview. They will be verbally consented to participate or decline if they choose. Participants who complete this key informant interview will be compensated an additional $50 by check for their time and insights.

Statistical Plan

6.1 Sample size Determination:

Given that this is a pilot study, our goal is to determine the effect size of the intervention to determine the statistical power needed for subsequent larger studies. Based on our assessment of the recruitment pool and resources available through the award, we will enroll 25 patients in each arm (n = 50) with anticipated 20% dropout rate over 6 months for an estimated final analysis sample of 40 patients. Based on previous studies, [25] we can anticipate a mean systolic blood pressure change of 7.6 mmHg, and a standard deviation of 15 mm Hg, for an effect size of 0.51. An effect size of < 0.3 will be considered insignificant.

6.2 Statistical Methods

Data on the outcome variables (blood pressure, non-HDL/LDL, 10-year ASCVD risk score) for each arm will be collected at weeks 0, 6, 12 and 18 months. Summary statistics of the study cohort will be reported for every interim timepoint. Generalized linear mixed regression models will be used to assess the changes in systolic blood pressure and LDL-c over the period of the intervention. Models will be fit with an interaction term to account for the difference of differences (DID) at each timepoint in the study (on intervention and post intervention timepoints to assess durability of the intervention's effect) to assess the treatment effect between the two arms. The p-value of the interaction term will serve as significance testing for the difference between the outcome value difference of the two study arms. The same technique will be used for the secondary analysis of ASCVD risk scores.

Missing data will be handled as follows:

- Variables with more than 30% missingness will be dropped from the analysis regardless of reason
- Variables with less than 30% missingness will be evaluated by individual observations. If the data point is determined to be missing at random, then values will be imputed in its place using multiple dataset imputation methods. If the data point is determined to be not missing at random, then the observation of missingness will be reported in the summative reporting after the reasons for the patterns of missingness have been determined. The missing values will then be imputed by the predicted linear regression model.
- Any observations without data from the intervention completion (week 24) timepoint will be excluded from the analysis

6.3 Subject Population(s) for Analysis

All randomized subjects with at least partial outcome data for the baseline and week 24 timepoints will be included in the analysis, regardless of missingness of the post-intervention timepoints.

Safety

7.1 Potential Risks

Loss of confidentiality
The risks associated with potential loss of confidentiality are low. The staff obtaining data will be properly trained and supervised. Participant data, including audio recordings, will be stored in files on the Duke Division of Infectious Diseases private server, managed by the Duke Office of Information Technology.

Detection of clinically significant problems
Although not caused by study participation, it is possible that clinically significant problems will be detected by study staff. Subjects entering the study will have a history of hypertension or hyperlipidemia so abnormal systolic, diastolic and lipid values are expected. All values that reach a safety threshold (<90 or >180 systolic BP, or <40 or >110 diastolic BP) will be reported to the subjects' care provider immediately (See Section on Adverse Event Reporting).

Physical activity
During the course of the study, SWs may encourage participants to increase their physical activity, increasing the possibility of musculoskeletal injury or unmasking of ischemic heart disease. Risks from increased physical activity will be minimized by encouraging moderate rather than vigorous activity. Providers will respond to these patient problems per usual medical care.

Smoking
Smoking participants will be encouraged to quit smoking, increasing the possibility of withdrawal symptoms from nicotine dependence.

Psychological risks
For the purpose of the study assessments, participants will be asked about personal characteristics such as race/ethnicity, and socioeconomic status that may be uncomfortable to answer. Only questions that are important to inform the study outcomes will be asked during the course of the trial. Participants will be informed that they may refuse to answer any questions, and continue to participate in the study. It is also possible that participants may be uncomfortable talking to the SW about some topics that will be discussed as part of the intervention.

7.2 Protection against risks

Protection of participants' confidentiality
Since this study involves people with HIV, steps will be taken to protect patient data and identities. All research staff will be trained in initial, follow up and monitoring training specific to the trial in addition to the Research Ethics and Compliance training via Collaborative Institutional Training Initiative (CITI), which will ensure the understanding of all the ethical issues involved in research. All consent forms signed by the participants will be maintained in locked files with limited access, separate from any subject data and will only be accessible to the study team. Any personal identifiers linked to the data will be replaced with subject IDs in all patient records. Participants will be made aware of these risks at the time of informed consent, prior to study participation.

Blood Pressure

The participants will have a high risk for CVD and thus many will be prescribed hypertension medications by their health care provider at the outset of the study. It is likely that as a result of increased monitoring, we will detect more episodes of abnormal BP values. BP will be measured at each follow up visit. Participants will have access to their regular providers as well as the study investigator designated as the clinical contact for the study: Dr. Okeke (infectious disease physician; Duke Health). An average SBP at any study visit >180 mm Hg and/or diastolic is >110 mm Hg will be considered an alert value and will trigger assessment by the study clinician. Additionally, an average BP at any study visit that is <90 systolic of <40 diastolic would also be considered an alert value and would trigger an assessment by the study clinician.

Participants who have an alert BP reading during study visits will be directly assessed for cardiovascular symptoms during the visit. Once an alert value has been confirmed, the participant will be triaged according to follow-up recommendations from Joint National Committee Recommendations (JNC 8). If at any time, participants have symptoms of acute end organ damage (i.e. current chest pain, dyspnea at rest, new onset of blurry vision, or new neurological deficits consistent with a stroke) in the context of an elevated BP measurement (SBP >180, and/or DBP >110), participants will be asked to contact the clinician and will be advised and assisted in seeking emergency medical care.

For participants in the intervention group whose average SBP >180 and DBP >110 or SBP < 90 or DBP < 40 but are without acute symptoms, the participant's primary provider will be notified. Follow up contact with the study staff will occur within one week. All abnormal blood pressure results will be communicated to the clinic director at each site who will be an integral part of triage and ensuring follow up. The SW will then generate a note to be entered into the electronic medical record and will communicate directly with the subject's PCP.

Medication adverse effects

The usual health care provider of the participants on antihypertensive and/or on lipid lowering medication will take primary responsibility for counseling the patient about side-effects and ordering follow-up laboratories. In addition, each participant will be counselled by the SW about possible side effects, drug interaction with ART and adherence.

Adverse Event Reporting

An adverse event (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality: a) results in study withdrawal; b) is associated with a serious adverse event; c) is associated with clinical signs or symptoms; d) leads to additional treatment or to further diagnostic tests; or d) is considered by the investigator to be of clinical significance.

A serious adverse event (SAE) is any AE that is: fatal, life-threatening, requires or prolongs hospital stay, results in persistent or significant disability or incapacity, a congenital anomaly or birth defect, an important medical event (an event that may not be immediately life threatening, but are clearly of major clinical significance).

All subjects will be informed about their rights prior to participation and will be encouraged to report any incidents or adverse effects to the investigators and the Duke University Institutional

Review Board (IRB). Contact information for the investigators and the IRB will be provided in the consent forms. During assessments the research staff will inquire about AEs and complete an AE form for each subject. At baseline, clinically significant abnormalities will be recorded along with other preexisting conditions. If a preexisting condition is reported at baseline, it will be reported as an AE if the frequency, intensity, or the character of the condition worsens during the study period. All reportable AEs will be captured in the Electronic Data Capture (EDC) on the AE Case Report Form (CRF) where the responsible research staff will report the nature, the severity and the resolution of the AE. When an AE is considered to be a SAE and study-related, the study PI will be responsible for reviewing and signing off on the AE.

Research staff will be trained on procedures for AE identification, collection and reporting in detail. Study staff will also be trained to provide crisis intervention and referral as standard operating procedure within each clinic for such situations, should they become dangerous or life-threatening (i.e. suicidal ideation or attempts).

AEs will be managed in conjunction with clinic medical staff, with permission from the participant. All subjects will be ongoing patients at a study site clinic and thus subjects can be monitored and have access to medical staff through the study period.

All unresolved adverse events at the end of the study will be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator will instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator will notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study.

Data Handling and Record Keeping

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A signed subject authorization will be obtained on the informed consent document informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, will retain the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

8.2 Source Documents

Any source data (i.e. all information original records of clinical findings, observations, or other activities in a clinical trial necessary for the construction and evaluation of this trial) collected during the course of the trial, will be kept in a locked filing cabinet in a locked office. All subject

data with PHI will be kept separate from the master list that links subjects to their subject IDs. All data stored on the computer will be maintained on duke computers secured by duke firewall. All essential study documents will be retained for 6 years after study completion.

8.3 Case Report Forms

All study CRFs will be obtained via an electronic data capture (EDC) called REDCap. All data will be monitored by a designated data manager at the Duke Office of Clinical Research (DOCR), who will be responsible for developing, generating, and managing ongoing study data to ensure accuracy and complete acquisition of study data. To minimize data-entry error and data-management miscoding, questionnaire data will be collected via tablet computers and immediately uploaded to a secure web-based server, ensuring backup. Source documents and electronic data will also be checked for accuracy and adherence to study protocols.

Ethical Considerations

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Ethics Committee (EC) or Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the EC/IRB concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of EC/IRB members and their affiliate to the sponsor.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the EC/IRB for the study. The formal consent of a subject, using the EC/IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

Study Finances

10.1Funding Source

This study is funded by a grant through the National Heart, Lung and Blood Institute (NHLBI; K23HL137611).

10.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All Duke University investigators will follow the University conflict of interest policy.

10.3 Subject Stipends or Payments

All participants will be required to complete four study visits over the course of the pilot trial. For each completed visit, they will receive $25 primarily as a Duke Gift Card (ClinCard) or check when necessary. Remuneration will be received by the participant at the end of the study visit.

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APPENDIX

Table 1: Intervention Modules	
Timeline	Module and Content
Weeks 2 and 14	CVD Risk Knowledge and Perception (High or Low Literacy) • Perceived risk of MI and Stroke • Education on CVD risk factors • Education on HIV as a CVD risk • Benefits of therapy and lifestyle changes • Goal setting
Weeks 4 and 16	Medication Reconciliation • Review of medications and indications • Education on drug interaction with ART • Medication side effects • Barriers to adherence assessment • Strategies to improve adherence
Weeks 6 and 18	Dietary Assessment and Education (High or Low Literacy) • Dietary habits assessment • Addressing portion control • Healthy carbohydrate intake and increase in fiber and protein consumption
Weeks 8 and 20	Physical Activity and Weight Management (High or Low Literacy) • Reasonable weight management goals • Motivational interviewing for exercise goals
Weeks 10 and 22	Smoking Cessation • Benefits of smoking cessation • Initiating and maintaining smoking cessation goals • Quitting strategies
Weeks 12 and 24	Stress Management • Education on stress and CVD risk • Overview of stress reduction techniques • Counseling on healthy sleep habits

Key Informant Interview Guides for PLHIV

Introduction
[Remind about Audio Recording and not to use real names]

Thank you for talking with us today. We are interested in your thoughts and beliefs about a recent blood pressure and cholesterol study we tested in your HIV clinic. I am going to ask you some questions about the intervention to hear about your experiences and perspectives. Please know that there is no right or wrong answer. You will notice that I won't give you a lot of feedback on your responses because I don't want to influence your answers. Finally, you are under no obligation to talk about anything that you are not comfortable discussing with me. Do you have any questions or concerns before we begin?

I. Intervention Characteristics

What are your overall thoughts about the structure of the program? Was every two weeks too much? Could it have been less or more? Did you like the rotating format for the modules?

What did you think about the material that was covered? Was it too simplistic or too complicated? Were things explained in a clear and comprehensible manner to you? Which modules were the most helpful? Which modules were the least helpful?

What were the thoughts of the educational material you received? Was it helpful? What was most helpful? Did it come too often, would more or less have been better?

What did you think about the platform? Did you use video-conference or telephone? Did you like using this platform? [Why or why not]. Do you think this program would have been much improved if it was done in person?

What did you think of the interventionist (Keith)? [Tell me more] Were there any particular strengths? Were there things that could be improved upon?

II. Program Outcomes

A) Perceptions of Increased Knowledge

Do you feel like you know more about conditions related to cardiovascular disease (high blood pressure, blood sugar/diabetes, cholesterol) as a result of participating in the program? [Tell me more]

B) Perceptions of Increased Skill

Are there any skills that you feel more empowered to perform as a result of the program? [Tell me more]

Do you feel like you have more information to share with your relatives and friends about heart-healthy living as a result of the program?

C) Role of Identity as person living with HIV

Do you believe that being a person living with HIV influenced how important you regard the information that was presented as part of the program?

D) Beliefs about newly gained capability

Do you believe that you will have the ability to incorporate some of the heart-healthy habits you learned into your daily life? What will be the easiest to change? What will be the hardest. [Tell me more]

E) Beliefs about consequences of having HIV on importance of heart health behavior

Do you think that the habits you learned from this program will help you more because you have HIV? Why or why not?

F) Goalsetting as a result of program participation

Have you made any specific goals for change as a result of participating in this program? If no are you planning on making goals for yourself as a result of your participation?

What are your specific goals for change as a result of participating in this program? Is it losing weight, lowering your blood pressure or cholesterol or just participating in more physical activity? [Tell me more]

G) Expectations of learning recall from intervention

Do you ever have any concerns that you will forget anything you learned during this program?

Is the educational material we sent you helpful? What was most helpful? What was not as helpful?

H) Emotions triggered by intervention

Did any of the material covered in the program evoke an emotional response from you? Was it difficult or scary or sensitive to hear?

I) Adoptability of Intervention Learnings

Do you believe that the behaviors suggested to you for a more heart-healthy life were practical and attainable?

Is there anything else that you would like to share with us about the program?