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Cardiovascular Risk Reduction in Persons Living with HIV: Treatment Development, Feasibility, and Preliminary Results

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Abstract

Persons living with HIV (PLWH) have elevated risks for cardiovascular disease (CVD). Our goal was to develop and pilot test a tailored intervention to improve CVD risk perception and the adoption of heart-healthy behaviors. In-depth qualitative interviews were conducted with 30 PLWH participants to examine learning needs and preferences. An intervention manual was developed and tested in an open pilot with 8 participants. Participants were stable on antiretroviral therapy and were recruited from two urban HIV clinics in the Northeast United States. Thematic analysis identified five major themes: (a) tailored structure and design for PLWH, (b) learning needs (specific to HIV), (c) desire for prompts/reminders (to exercise), (d) importance of participant resources, and (e) need for personal evaluation and goal setting. Feasibility and acceptability of the intervention were demonstrated with high session attendance and treatment satisfaction. Further testing is warranted.

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Disclosures

The authors report no real or perceived vested interests that relate to this article that could be construed as a conflict of interest.

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Keywords

cardiovascular disease; HIV; primary prevention; qualitative methods; tailored interventions

Cardiovascular disease (CVD) has emerged as a major cause of morbidity and mortality in persons living with HIV (PLWH; Sackoff, Hanna, Pfeiffer, & Torian, 2006) and PLWH have an elevated risk for CVD when compared to the general population (Drozdz et al., 2017). Acute myocardial infarction (AMI) rates are significantly higher in PLWH compared to age- and gender-matched controls (11.3 vs. 6.98 per 1,000 person-years), and the relative risk is 75% higher for those infected with HIV (Triant, Lee, Hadigan, & Grinspoon, 2007). One-third of adult PLWH are at moderate to high 10-year risk of having a cardiac event (Kaplan et al., 2007). Compared to uninfected matched controls, PLWH are twice as likely to have high predicted 10-year risk of AMI (Bergersen, Sandvik, Bruun, & Tonstad, 2004).

Although advances in the medical treatment of HIV over the past 30 years have led to an increased lifespan for PLWH, one-quarter of all non-HIV-related deaths in HIV-infected adults are now due to CVD (Sackoff et al., 2006).

Traditional risk factors for CVD significantly contribute to the elevated rate of risk in PLWH (Paisible et al., 2015). For example, smoking is much more prevalent in PLWH (50%–70%) compared to the general population where the smoking prevalence is approximately 18% (Cioe, Crawford, & Stein, 2014; Mdodo et al., 2015). Hypertension, diabetes, dyslipidemia, and obesity are also more prevalent in PLWH and contribute to CVD risk (Kaplan et al., 2007). Hypertension and prehypertension in PLWH have been associated with an increased relative risk of AMI (RR = 1.88) compared to uninfected controls (Armah et al., 2014). Similarly, increased body mass index (BMI) and larger waist circumference have been associated with elevated CVD risk (Janiszewski et al., 2011).

The American Heart Association (AHA) published primary prevention guidelines for the general population in which increased physical activity, healthy diet, blood pressure management, and smoking cessation were considered the cornerstones of CVD risk reduction (Eckel et al., 2013). The 2020 Impact Goal of the AHA focuses on cardiovascular health (as opposed to CVD) and places emphasis on prevention at all levels of cardiovascular risk. Specific health behaviors to achieve cardiovascular health on an individual level include 150 minutes or more of physical activity per week, a BMI less than 25, blood pressure less than 130/85 mm Hg, and abstinence from smoking. Studies focused on improving physical activity levels in PLWH have demonstrated some success. Webel, Moore, Hanson, and Salata (2013) showed that a self-management intervention improved physical activity levels by incorporating a socioecological model that included factors at the individual, interpersonal, and environmental levels. Cutrono et al. (2016) showed that a 3-month combined aerobic and resistance exercise training program improved muscular strength and metabolic risk factors. Alternately, a home-based physical activity intervention was not successful in improving physical activity levels in PLWH (Jaggers et al., 2016). Behavior change can be difficult; however, theories of behavior change, such as the Health Belief Model (HBM; Rosenstock, Strecher, & Becker, 1988), suggest that knowledge, perception of risk, self-efficacy for change, and motivation are key antecedents to behavior

change. Interventions that are focused on improving perception of CVD risk in PLWH have not been specifically designed, despite the significantly elevated risk for CVD in PLWH.

Studies in the general population (Homko et al., 2008) and among PLWH (Temu et al., 2015) have demonstrated that overall CVD risk factor knowledge and risk perception are low. Cioe et al. (2014) found that while general CVD risk factor knowledge was fairly high among urban PLWH in the United States, it was not predictive of CVD risk perception and, in fact, individuals tended to underestimate their levels of personal risk. Having a sedentary lifestyle is common among PLWH and some interventions to improve physical activity levels for PLWH have not been successful (Rehm & Konkle-Parker, 2016; Vancampfort et al., 2016; Vancampfort, Mugisha, Richards, De Hert, Lazzarotto, et al., 2017). Another study demonstrated that PLWH face unique challenges and barriers to adopting the lifestyle behavior changes that are required to lower CVD risk (Capili, Anastasi, Chang, & Ogedegbe, 2014). An intervention that specifically targets improving CVD risk perception in PLWH may help improve the adoption of multiple heart-healthy behaviors, such as physical activity, healthy diet, and smoking cessation.

Qualitative research methods have been shown to be useful in the development and revision of tailored interventions (Lewin, Glenton, & Oxman, 2009; O’Cathain et al., 2015), treatments that are specific for an individual or a group to improve health or change behavior. In particular, qualitative methods may elucidate the specific needs and content priorities of the targeted population. They can be used to address issues related to intervention messages and the mode of delivery, as well as to help establish study procedures to ensure meaningfulness and appeal of the proposed intervention (de Visser et al., 2015). Finally, qualitative methods can be used to evaluate and guide refinement of the tailored intervention (Lewin et al., 2009; Sandelowski, 1996).

The aims of our study were to (a) develop, using qualitative research methods and constructs of the HBM, a tailored intervention to improve cardiovascular risk perception and adoption of heart-healthy behaviors among PLWH; (b) test the feasibility and acceptability of the intervention with PLWH who had not been diagnosed with heart disease; and (c) refine the preliminary intervention manual and participant manuals based on qualitative feedback during the pilot-testing process. Institutional review board approval was obtained from Rhode Island Hospital and Brown University for both stages (1a and 1b) of this study.

Our study was conducted in three phases. First, we conducted qualitative interviews, using constructs of the HBM in the interview agenda, to examine perceived risk of CVD, perceived benefits of behavior change to improve heart health, and perceived barriers to behavior change. We also elicited education needs regarding heart health and preferences for an intervention. Second, we used the qualitative findings to modify a manual we had initially developed based on a motivational interviewing approach and the HBM. Third, we conducted an open pilot study to examine the feasibility and acceptability of the intervention content and procedures. Finally, we revised the content and procedures in preparation for a future randomized clinical trial. Each phase of the study is described separately.

Method: Phase 1a. Planning Stage

A Priori Manual Development

Prior to the qualitative work, we developed a brief outline of a provider manual that would deliver a two-session intervention to potentially improve CVD risk perception and adoption of heart-healthy behaviors. The manual was based on the constructs of the HBM (Rosenstock et al., 1988) and incorporated motivational interviewing techniques (Miller & Rollnick, 2002) and personalized feedback. The participant's Atherosclerotic Cardiovascular Disease (ASCVD) Risk Score would be calculated and discussed during the session, feedback would be elicited, and participants would be encouraged to make plans for behavior change. The qualitative interviews were designed to delineate specifics about delivery and content of the intervention. Revision of the preliminary provider manual and development of a participant manual came from the qualitative findings.

Procedures

We recruited participants from January to July 2015 at two outpatient sites - an academic health center-based immunology clinic and an internal medicine academic practice office that provided care to PLWH. We initially planned to enroll 30 to 40 participants, but, to ensure credibility, we determined that we would continue to enroll participants until no new themes were noted and data saturation was reached (Elo et al., 2014). To address dependability of the data, we enrolled only PLWH who had not had a cardiac event and met certain inclusion and exclusion criteria. Eligible PLWH participants were: (a) at least 30 years of age, (b) able to speak and understand English, and (c) able to provide written informed consent. Participants were excluded if they self-reported having (a) a diagnosis of CVD, including AMI, cerebral vascular accident, or peripheral vascular disease; (b) a history of coronary artery bypass graft surgery, angioplasty, cardiac stent placement, or peripheral vascular surgery; or (c) had a Mini-Mental Status Exam indicating inability to complete a semi-structured interview (i.e., score less than 24; Folstein & Folstein, 1975). Flyers were posted in clinic exam rooms and waiting areas at each recruitment site. Clinic staff also informed patients about ongoing recruitment and enrollment when they presented for medical appointments. The Principal Investigator (PI) was present at the clinic sites on specific days of the week and explained the study to potential participants in a private exam room. If interested, potential participants were screened for eligibility. Persons who were identified as eligible were asked to provide written informed consent for participation and were given the option of completing the indepth individual interview at that time or scheduling an interview at a more convenient day and time.

A qualitative descriptive design (Sandelowski, 2000) was used to explore perceptions of CVD risk and preferences for the intervention. In-depth face-to-face interviews were held in private exam rooms and followed a semi-structured interview guide developed from the study aims. Key content areas were explored during the interviews, including: perceived risk of CVD, perceived benefits and barriers to adopting heart-healthy behaviors, perceived knowledge deficits and learning needs, and preferences for an intervention that addressed CVD risk and the adoption of heart-healthy behaviors. For the purposes of designing the intervention, we asked each participant to describe what they knew about heart disease and

its risk factors. We asked about the information they thought needed to be included (or not included) in a program to help PLWH understand their heart disease risks. Finally, we asked about factors that needed to be addressed so that an intervention to improve heart health, including diet, smoking, and physical activity levels could be successful, including the use of pedometers to record step levels, and the use of health behavior prompts and reminders to sustain any health behavior change.

Interviews lasted approximately 60 minutes and were facilitated by the first author, who was trained in facilitation of in-depth interviews and accessed ongoing training and support throughout data collection, as needed. Each participant was compensated with a \$25 USD retail gift card for his or her time and participation. Following each interview, the facilitator wrote an interview debrief, including observations and emergent themes. The interviews were audio-recorded and transcribed verbatim by a professional transcription service. To address trustworthiness, the transcripts were reviewed and checked for accuracy with the audio recording, initially by a Master's-level research assistant and subsequently by the PI. A coding structure was developed from the semi-structured interview guide and was refined as the coding process continued. Each transcript was individually coded by the research assistant and reviewed by the PI using a thematic analysis approach (Guest, MacQueen, & Namey, 2012). Using an open coding process, the data were examined line by line to identify themes (Miles & Huberman, 1994). The first eight transcripts were double-coded by the research assistant and PI, and then every third transcript was double-coded. Our inter-coder agreement rating was 85.7%. Codes were refined as the analysis progressed, and codes were grouped to develop themes within the data. Using an iterative analysis process, the research team met weekly to discuss and resolve coding discrepancies and to identify points of consensus. All data and final coding were entered by the research assistant into NVivo, a qualitative software program, in preparation for final analysis.

Measures

Demographic variables, including age (in years), gender, education level (in years), self-reported race and ethnicity, employment status, and time since HIV diagnosis (in years) were obtained.

Results

Thirty-six patients presented for screening: one was ineligible due to an inability to read English, five were ineligible due to CVD diagnosis, and one was eligible but declined. Data saturation was reached at 24 participants, when no new themes emerged during the interviews. We chose to oversample to ensure saturation of the data (Elo et al., 2014), hence 30 persons were enrolled. Study participants had a mean age of 54.4 ($SD = 7.0$) and a mean 11.7 years of education ($SD = 2.9$). Nine participants identified as female (30.0%), 20 (66.7%) identified as male, and 1 (3.3%) person as transgender female. Fifteen participants (50%) identified as White, 14 (46.7%) identified as Black, and 1 (3.3%) identified as more than one race. Two participants (6.7%) identified as Hispanic/Latino. Twenty participants (66.7%) reported being single. Eighteen participants (60%) reported being disabled and not currently employed. Participants had been living with HIV for an average of 18.8 years ($SD = 8.6$); 100% were currently taking antiretroviral therapy (ART); and 15 (50%) had been

diagnosed as Hepatitis C antibody positive. Fifteen (50%) were current cigarette smokers, while 10 (33.3%) were former smokers.

Five major themes related to the development and implementation of an intervention to improve CVD risk perception and the adoption of heart-healthy behaviors emerged from the qualitative interview data, including, program structure & design, learning needs, prompts and reminders, participant resources, and methods of personal evaluation. We will first detail the themes with illustrative quotes and then explain how the themes led to modification of the a priori intervention manual.

Theme 1: Program structure and design—Participants indicated that tailoring was an important component of the program. They said that it was not only important for the interventionist to know their health history, but that personal data needed to be incorporated into the teaching and discussion during the treatment sessions.

Related to HIV, you know. So, if they're gonna come up with a program, you don't want it related to—to Joe Shmoe, down the street, that isn't battling that kind of disease. You want it related to somebody—you know... “this is the program we're doing for you because, for you, on HIV, this is gonna help this, this, this, and that,” you know. (55-year-old White male)

A 41-year-old White male said, “What I wanna know about heart disease is how it's gonna affect me. ... So I would wanna know, you know, things that were personalized to me about heart disease.” And a 65-year-old Black male said, “First of all, you got to know people's condition and their genetic makeup.”

Participants indicated that it was important for them to have choices about the material to be covered during the sessions, a further indication that tailoring was important. The importance of having a sense of control in any behavior change, consistent with a motivational interviewing framework, was suggested: “It [the program] would, uh...it would give you a choice. Um, whether you want the information. Uh, you know, whether you wanna do this or you don't wanna do this” (58-year-old Black male); and “You know, like, when you're talkin', you can't [say]—you—no, you can't have this. That's just like I'm a kid again” (52-year-old Black male).

Participants indicated further that the treatment session needed to be provided by a health care provider or someone with significant health knowledge. “People that know what they're talkin' about. Doctors, nurses, people that, uh, uh, study about it” (52-year-old White female); and “Someone that knows—really knows about it. It doesn't necessarily have to be a doctor” (49-year-old Black female).

Findings indicated that it was also important for the sessions to focus on making small changes to avoid frustration, and to emphasize living a healthy life, rather than solely on CVD risk reduction: “No, no, cuz just a little too much could just overwhelm one, just say, ah, I'm-I'm not doin' that” (48-year-old Black male); and

I think talk specifically about how the exercise is not just gonna help your heart, but it's also how—how there are exercises that people with HIV can do... These are the

exercises that probably could help you build up your white cell count. (55-year-old White male)

Participants felt strongly that the name of the program should not mention HIV and provided suggestions for the program name:

Well, you know, they just put HIV in everything. The less we see HIV, the better we feel. I wouldn't put HIV in the wellness program because that'll tell everybody who's in this program. I don't want it to be the name of the program" (62-year-old Black female).

Theme 2: Learning needs—Participants indicated that they needed general information about heart disease, and specific information about the relationship between HIV and heart disease. They felt it was important to learn about their current risk level for heart disease. They also indicated a need for knowledge about diet and nutrition guidelines, benefits of exercise, and smoking cessation resources. Participants said that learning about the effect of stress on the heart and stress management techniques was important. "Or make people aware of, uh—uh, that it pertains to having the HIV, too, you know. That, uh, now, if there is some kind of symptoms between HIV and heart disease" (51-year-old White male); "I would like to know... if my heart is strong ... But I mean, how-how strong is my heart? You know, I'd like to keep track of that" (56-year-old Black male); "Again, to—to tell you what you should be eatin', what you shouldn't be eating" (54-year-old White male); "Make people exercise. Exercise is the most important thing" (56-year-old mixed-race male); "I would wanna know what am I doing now that may, in 15 years, develop heart disease? Um, you know, am I eating too many fatty foods or things like that that would lead to heart disease?" (41-year-old White male); and

The stresses of life or whatever is going on, they - they do all this stuff. And people don't take care of themselves. They don't check their body. They don't keep their medical appointments. All these things, you have to look into... Some people don't care because they're so stressed. (65-year-old Black male)

Theme 3: Prompts and reminders—Participants were asked if prompts and/or reminders would be helpful to increase motivation to adopt heart-healthy behaviors. They overwhelmingly indicated that reminders would be helpful. They suggested phone calls from a nurse and text messages with encouraging and motivational health advice. They recommended that the text messages be tailored, bidirectional, and goal-directed, addressing the specific goals set during treatment sessions. Some participants provided sample text messages. "I think that would be helpful, having 'em text you, saying, 'Have you done your exercises today?' Yeah, definitely" (55-year-old White male).

Theme 4: Participant resources—Regarding resources to be provided during the study, participants indicated that they wanted a checklist to track their progress, and they wanted to record their activity in a binder, stating "Yeah, always – [it's] always helpful to have binders. " They said that the binders should be "colorful", include "lots of pictures," and the information should "use simple words."

Theme 5: Methods of personal evaluation—Participants indicated that they wanted to track their progress by evaluating their weight and blood pressure at each study session. They also said that they wanted to set their own goals for behavior change during study sessions, and that their goals needed to be recorded and re-evaluated during the study sessions. They indicated a willingness to use a pedometer to track daily steps. They requested that the interventionist summarize “what was learned in class” after each treatment session.

I wouldn't like nobody pouncin' on me. “Did you eat your vegetables today? Boo?” I don't like that pouncin' on me, you know, cuz you'd know just what your body could handle, and sometime people don't even wanna think how much their body can handle, so they won't do their best. But if you got somebody that you know does their best, you know, don't pounce on 'em, you know. I don't wanna be put on the spot and tell me what I can do cuz, half the time, I—I can't do it. (62-year-old Black female)

Yeah, but writing them down and doing them when you get home—if you're in a class and you get up and they teach you and you work with the teacher, you know, they give you a paper and you go home, eat this, and do these exercises. (51-year-old White female)

Modification of a Priori Treatment Manual

Our qualitative findings were used to tailor the procedures, specific content, and manuals of the *Cardiovascular Disease Perceived Risk Awareness Intervention* (CVD-PRAI). Based on feedback regarding the program structure and design, we planned for the study sessions to be individually delivered by a nurse in a private exam room. During the initial segment of the session, we decided to review pertinent recent laboratory results, including glucose, fasting lipid profiles, height, weight, and BMI. We decided to show a brief video, called *What is a Heart Attack*, which schematically demonstrated the course of events during AMI. We also revised our study flyers, removing the word *HIV*, and, as suggested, called the program the *Healthy Hearts Study*. We included didactic content about risk factors and mechanisms of heart disease in the session. We decided to calculate each participant's ASCVD risk score during the first treatment session, with a recalculation with any proposed behavior change (such as smoking cessation or improvement of blood pressure or lipid levels) so that each participant could clearly see how adopting a behavior change could impact their heart health. In addition, based on the qualitative feedback, we decided to calculate heart age during the first session. This tool, based on the Framingham Heart Study, incorporated traditional risk factors, including BMI, to present an easy to understand assessment of heart age for patients (Centers for Disease Control and Prevention, 2015). We used this discussion to provide personalized feedback and promote motivation for behavior change.

We also revised study procedures. For example, we added a check-in phone call from the research assistant at week 8 of the study, during which additional data were collected to potentially improve study retention and follow-up. While we were not able to accommodate all recommendations about text messaging (due to budgetary constraints), we added daily

unidirectional text reminders during week 1 and weekly text reminders during weeks 2–4, delivered by Qualtrics. Based on these data, we evaluated and recorded participant blood pressure, waist circumference, and weight at each study session. We decided to discuss goal setting during the study treatment sessions and encouraged each participant to set at least one behavior change goal to address during the 12-week study period. We provided instructions during the baseline session to maintain normal activity levels until the participant met with the interventionist, so that any change would follow 15 the treatment session and goal setting. We added a summary and review to the concluding remarks during each treatment session.

Further, based on the qualitative feedback, we modified the treatment provider and participant manuals for the intervention. We included four modules for the provider and participant binders, addressing the following components of CVD risk: diet (including *My Daily Plate* portion sizes); exercise (including physical activity guidelines from the AHA, and a map of local walking paths); smoking cessation (including Quitline referral sheets, FDA approved smoking cessation medications); and stress and the heart, including four stress management techniques (relaxed breathing, guided imagery, mindfulness meditation, deep muscle relaxation; Preventive Cardiovascular Nurses Association, 2013). We planned that all four modules would be covered during the first treatment session. We added a steps calendar to the participant binder for participants to log daily activity throughout each month, and a diet diary to track food intake in preparation for a nutrition appointment (that they could request from their health care provider). The binder was designed using primary colors, had many illustrations and pictures, and used plain language wherever possible. We designed and added a colorful goal setting sheet that encouraged each participant to set both short-term (in the next 4 weeks) and long-term goals (in the next 6 months).

The components of the CVD-PRAI intervention are shown in Figure 1. The qualitative data validated our intention to use constructs of the HBM and techniques of motivational interviewing, in which feedback and advice were provided in a nonconfrontational manner and stressed personal responsibility for change. The motivational interviewing relied heavily on the impact of unhealthy behaviors on CVD-relevant outcomes in building motivation for change. Consistent with the HBM, participants received education to increase their knowledge of CVD. The provider asked participants to describe their current diets, physical activity, exercise, and smoking behaviors; to assess perceived risk of heart disease; and were asked how they perceived these behaviors might impact their health and CVD risk. Participant statements that supported change in unhealthy behaviors were reflected and amplified. Personalized feedback was given by the nurse interventionist on the person's level of CVD risk and CVD risk factors, highlighting areas where the participant was doing well and where there were areas that could be improved. These data were used to address discrepancies between participant goals of living well with HIV and their unhealthy behaviors.

A summary of the discussion was given, reflecting the participant's stated pros and cons of adopting heart-healthy behaviors and the feedback results. The interventionist discussed each participant's level of confidence to make behavior change to assess self-efficacy for change. Each participant was encouraged to set a goal if s/he was ready to make changes and

was provided with a menu of alternative goals if s/he had difficulty formulating a goal. Participants who were not ready to set a goal to change at the time of the study session were provided with further education and information about heart-healthy behaviors and reduction of heart disease risk. The session focused on identifying people in each participant's social network who would be supportive of behavior change. Consistent with HBM, perceived barriers to change were highlighted and discussed. An information sheet, titled "Overcoming Challenges," was included to address perceived barriers to change.

Method: Phase 1b. Implementation Stage

Following development and refinement of the procedures and the treatment provider and participant manuals, and, based on qualitative findings from Phase 1a, we proceeded to the open pilot phase of the project. The primary objectives for this phase were to pilot test the feasibility and acceptability of the intervention, obtain qualitative feedback from open pilot participants, refine the procedures, and refine the treatment and participant manuals, in preparation for a pilot randomized clinical trial.

Recruitment for the open pilot phase took place from May through June 2016. The study setting was the same as for Phase 1a. Inclusion/exclusion criteria were maintained as well; however, having an undetectable HIV viral load and being stable (no hospitalizations in past 3 months) were added as safety measures in this phase where increased physical activity would be encouraged. Study flyers were posted in clinic exams rooms, study bulletin boards, and waiting areas at each recruitment site and instructed potential participants to call for screening.

The research assistant screened potential participants by phone per the inclusion and exclusion criteria and provided information about the study procedures, schedule, and compensation. If the participant appeared to be eligible, an appointment was scheduled in the clinic for screening, informed consent, and enrollment. Following informed consent and enrollment, the participant completed all baseline measures, consisting of surveys and vital signs. The HIV diagnosis was confirmed and current lab work, including CD4+ T-cell count, HIV viral load, glucose, and lipid levels, was obtained from the HIV clinic provider.

A pedometer was issued to each participant at the baseline session and they were instructed to wear it daily. They were given the following directions: *For this first week, it is very important that you maintain your normal level of study activity. This is a research study and we want to see what your baseline level of activity is, before you decide to make any changes or improvements in your level of activity.* They were also given a steps calendar on which they were instructed to record the number of daily steps each night. Participants were then scheduled for the first treatment session.

Procedures and Study Design

The first treatment session with the study interventionist (a board-certified nurse practitioner) occurred 1 week after the baseline appointment and took 60–75 minutes to complete. At the end of Session 1, an appointment was made for Session 2, which included assessments (obtained by the research assistant), followed by treatment components with the

treatment provider. Treatment Session 2 (at week 4), including assessments and treatment, was completed in 60 minutes. Follow-up assessments with the research assistant were completed by phone at week 8, and in person at week 12. Participants received text reminders daily during week 1 that said, *Don't forget to wear your pedometer today!* and weekly (on Mondays) during weeks 2–4 that said, *"Don't forget to wear your pedometer this week!"* Brief qualitative interviews were conducted by the research assistant at weeks 4 and 12.

Measures

Demographic and clinical characteristics—Demographic variables collected were the same as Phase 1a. In addition, laboratory data were extracted from the medical record, including most recent CD4+T cell count, HIV viral load (HIV-RNA by PCR), lipid parameters, and blood glucose levels. Height and weight were measured during each study visit and the BMI was calculated using the National Heart Lung and Blood Institute formula (National Heart Lung and Blood Institute, 2017). Blood pressure and heart rate were measured.

Perceived cardiovascular risk—The Perception of Risk of Heart Disease Scale is a 20-item instrument that measures an individual's perception of the probability of developing heart disease (Ammouri & Neuberger, 2008). Each item on the scale has a 4-point Likert scale response option ranging from 1 (*strongly agree*) to 4 (*strongly disagree*) and summed scores can range from 20 to 80. Higher scores indicate increased perception of risk. The scale has been shown to have internal consistency values ranging from .68 to .80 and total scale alpha was .80. Evidence of the instrument's stability over time has been supported by subscale test-retest reliabilities ranging from .61 to .76 (Ammouri & Neuberger, 2008). The scale has been used with PLWH (Cioe et al., 2014) and demonstrated good internal consistency (Cronbach's alpha 0.78).

Estimated risk of CVD—The 10-year risk for ASCVD was calculated using the American College of Cardiology/American Heart Association (ACC/AHA) Risk Estimator (Feinstein et al., 2016; Goff et al., 2014). The equation was developed to estimate the likelihood of having a CVD event in the general population, defined as coronary death or nonfatal myocardial infarction, or fatal or nonfatal stroke, and is based on the Pooled Cohort Equations and lifetime risk prediction tools. An ASCVD score greater than 7.5 is considered higher risk for CVD.

Treatment feasibility and acceptability—Treatment feasibility and acceptability were operationalized by measuring treatment satisfaction, treatment attendance (number of sessions and completion of all study sessions). The Client Satisfaction Questionnaire (CSQ-8) is an 8-item validated scale used to measure general satisfaction across various health and human services (Larsen, Attkisson, Hargreaves, & Nguyen, 1979). The scale has shown excellent reliability and internal consistency across diverse patient samples. It is self-administered and response options are based on a 4-point scale, with scores ranging from 1 = *quite dissatisfied* to 4 = *very satisfied*. The CSQ-8 has no subscales and measures overall treatment satisfaction. Total session attendance was measured as the number of

sessions completed (treatment and assessment) out of four possible total sessions. We also examined the number and percentage of participants who completed all four scheduled study sessions.

Goal setting—We measured goal setting as a dichotomous variable (*yes/no*), indicating whether the participant set a goal to work toward change in a chosen behavior over the course of the study period.

Level of physical activity—Weekly physical activity levels were measured using Omron Tri Axis Digital Pedometers. The Tri Axis technology allows step counting regardless of where the pedometer is positioned on the body. The pedometer recorded steps for a 24-hour period, reset itself each day at midnight, and stored 7 days of activity data. The research assistant or the study nurse practitioner uploaded step data at weeks 1, 4, and 12. Step data were self-reported by each participant at week 8 during the phone session.

Data Analysis

We used measures of central tendency (mean, standard deviation) to examine estimated risk of CVD and treatment satisfaction scores. Goal setting and session attendance results are presented as numbers and percentages. We examined trends in perceived risk scores and level of physical activity from baseline to week 4, week 8, and week 12. The open-pilot design of the Phase 1b study did not have a comparison group and, therefore, we did not conduct inferential statistics.

Results

Sample Demographics—Thirteen subjects were screened for eligibility and, of these, eight were found to be eligible. The 8 participants had a mean age of 53 years ($SD = 6.6$) and a mean of 11.4 years of education ($SD = 2.5$). Four participants identified as female (50%) and 4 (50%) identified as male. Four participants (50%) identified as White, three (37.5%) as Black, and one (12.5%) as more than one race. Two participants (25%) identified as Hispanic/Latino. Three participants (37.5%) reported being single; three (37.5%) reported being employed either full- or part-time. Participants had been living with HIV for an average of 23 years ($SD = 5.3$), all were currently taking antiretroviral therapy (ART) and were undetectable, and mean CD4+ T-cell count was 773 cells/mm³ ($SD = 388$ cells/mm³). Mean BMI was 28.6 ($SD = 3.3$) and four of the eight participants had a BMI greater than 30, consistent with a diagnosis of obesity. Mean systolic and diastolic blood pressure was 132.1 ($SD = 19.8$) and 82.8 ($SD = 7.5$), respectively. Six participants (75%) were current cigarette smokers, while two (25%) were former smokers who had quit more than 30 days ago. No participants had been diagnosed with diabetes, although one participant had metabolic syndrome. Mean ASCVD risk score was 6.2% ($SD = 5.3$) with three (37.5%) participants in the high-risk category ($> 7.5\%$).

Session attendance—Seven (87.5%) of eight participants completed all four study sessions and no participants chose to withdraw from the study over the 12-week course. One participant missed the week-4 treatment session; session attendance overall was high with the mean number of sessions completed at 3.88 ($SD = 0.35$).

Treatment satisfaction—Treatment satisfaction was generally high with a mean item score of 3.52 ($SD = .53$) and mean scale score of 28.25 ($SD = 3.5$) out of a possible total score of 32. Qualitative interviews at weeks 4 and 12 provided the following regarding treatment satisfaction: “It (the study) covered all the aspects that needed to be covered. I thought it was very thorough” (60-year-old White male); “It helped me to be more conscious of my weight and my health. It gave me a lot of information on how to be healthier” (54-year-old Black male); “I learned that walking is healthy for the heart. Also, the importance of quitting smoking to have a healthier heart” (44-year-old White female); “The session was eye-opening. I liked knowing how my heart is working, and how quitting smoking would affect heart age. Seeing my heart age was highly motivating” (54-year-old White female).

Goal setting—All participants set one to three goals for behavior change and seven of eight participants met at least one of their preset goals by week 4.

Perceived risk of CVD outcome—Perceived risk of heart disease was measured at baseline (prior to any treatment sessions), at week 4 (just prior to the second treatment session), and at the week-12 follow-up assessment. The mean score at baseline was 53.13 ($SD = 6.4$), at week 4 was 52.71 ($SD = 3.4$), and at week 12 was 54.63 ($SD = 3.6$), indicating minimal increase in risk perception at the end of the study.

Physical activity outcome—At weeks 1, 4, and 12, participants brought their pedometers to the study session to be reviewed by the research assistant. Daily step counts were recorded by the research assistant to obtain weekly totals for each participant. During the week-8 phone assessment, each participant reviewed his/her pedometer and reported each day’s step count for the past week to the research assistant. The mean weekly steps at baseline, weeks 4, 8, and 12, respectively, were: 36,669; 42,137; 51,357; and 32,997; indicating a peak in physical activity at week 8 with a decrease at week 12 to below the baseline level.

Qualitative data at exit interviews—At week 12, each participant completed a brief qualitative interview to assess positive and negative feedback about the study procedures and design, and the intervention components. Participants expressed that they liked having a pedometer and recording steps each night, and said that it motivated them to increase their activity levels. They liked having a binder of information to take home, saying it increased and reinforced their learning: “I liked the pedometer and knowing how much I walked. It made me want to walk more. To bring the numbers up. It felt good. I liked setting goals. The program was well organized” (60-year-old White male); “Keeping a record of the steps. It was pretty cool to see how many steps you take daily” (44-year-old White female); “I learned a lot in this [study]. I still go back and look in that book, you know” (56-year-old White female); and

I liked that I needed to be conscientious in remembering to put on the pedometer and track steps. The binder was helpful because it gave me lots of information to look over on my own to improve my understanding of heart health. (54-year-old Black male)

Participants also provided negative feedback about aspects of the study that they either didn't like or would change. Some participants seemed to indicate that step recording became burdensome as the study progressed. Participants said that Session 1 could be shorter in duration. They thought that appointment reminders would have been helpful. Finally, they indicated that they would have liked receiving texts more frequently and for a longer period over the course of the study: "Just remembering to jot down my steps every day" (44-year-old White female); "The session was long [Session 1] – [it was] better than filling out questionnaires though. It could be a bit shorter but it wasn't bad" (62-year-old Black male); "I like [name of treatment provider], the session went by quickly. A shorter session would be even better though" (49-year-old male); and

I didn't like to have to remember to write down steps. More texts would be helpful, up to 3 times a day, especially before meals. Would also like a daily reminder to write down the number of steps taken. (54-year-old Black male)

Discussion

Our study used qualitative methods to design and implement a systematic, tailored, nurse-delivered intervention to improve CVD risk perception and the adoption of multiple heart healthy behaviors in PLWH. Using qualitative methods in intervention development was valuable, as it provided clear affirmation of intervention elements that had been planned and provided information that guided the addition and modification of other intervention components. Exit interviews following the open pilot trial supported the acceptability of the treatment that provided CVD risk information, personalized feedback, and motivational interviewing in an attempt to improve risk perception and the adoption of heart-healthy behaviors in PLWH who were at risk for CVD. The results extended previous work by others that had demonstrated that PLWH were amenable to behavior change and to adopt heart-healthy behaviors, such as increased levels of physical activity (Bonato et al., 2017; Cutrono et al., 2016; Webel et al., 2013).

Participants in the open pilot phase reported high levels of treatment satisfaction and all participants completed the study. There was no study drop-out, and only one participant did not complete all sessions in the open pilot study. Other qualitatively-developed tailored interventions have seen similar success, including an exercise program developed for urban African American women, in which the developers used qualitative data from focus group interviews to tailor the intervention (Peterson & Cheng, 2011). A recent systematic review concluded that dropout rates from physical activity interventions in PLWH were generally high, in the 30–34% range (Vancampfort, Mugisha, Richards, De Hert, Lazzarotto, et al., 2017). While our study was not solely an exercise study, initiation of exercise and increased physical activity (based on AHA guidelines) were key components of the program to reduce CVD risk. We recognize that this was a small open pilot, but our completion rate remains worthy of mention.

Two studies have examined CVD risk perception and risk factor knowledge in PLWH (Cioe et al., 2014; Temu et al., 2015), and both studies indicated that risk perception was low and inaccurate. This was consistent with other groups at increased risk for CVD, such as persons

with diabetes (Homko et al., 2008; Homko et al., 2010; Martell-Claros et al., 2013). Further work is needed to determine the most effective means of improving CVD risk perception to facilitate the adoption of heart-healthy behaviors. One study (Bove et al., 2011) demonstrated that nurse management of CVD risk reduction (4 visits over a 12-month period), in which subjects received counseling regarding healthy lifestyle behaviors, improved CVD risk levels in urban and underserved populations, further supporting the efficacy of nurse-delivered interventions. Other studies have also shown that comparable outcomes can be achieved in patients with or at risk for heart disease when non-physician providers, such as nurses and nurse practitioners, were included as integral members of the collaborative care team (Berra, Fletcher, Hayman, & Miller, 2013; Virani et al., 2015).

We observed a drop-off in weekly physical activity levels after week 8 in our study, demonstrating that the increased physical activity levels observed during the active portion of the study were not maintained. Others have noted similar results (Vancampfort, Mugisha, Richards, De Hert, Lazzarotto, et al., 2017). We hypothesize that the dose of the intervention may be too low (2 single 1-hour sessions 4 weeks apart) and perhaps a longer study period with more frequent nurse-patient contact and ongoing attention to behavior change (as is possible in a real-world clinical setting) is required. Vancamfort, Mugisha, Richards, De Hert, Probst, et al. (2017) demonstrated that perceived benefits of physical activity were associated with higher physical activity levels in PLWH, lending support to the value and importance of providing continued personalized feedback on the benefits of physical activity for CVD risk reduction and improved CVD health.

Revision Stage

The intervention and participant manuals we will use in a future randomized trial will incorporate changes based on qualitative feedback from the open pilot trial. Many participants reported that they were unaware of the symptoms of a heart attack and asked for this information routinely during the first treatment session. We, therefore, will add a *Signs and Symptoms of Heart Attack* sheet to the participant binder. Participants indicated that some information in the participant binder was not useful, so we will exclude 12 sheets from the binders, including the 5A's of smoking cessation, a list of local smoking cessation studies, and a healthy foods shopping list. We also will exclude the measurement of waist circumference from the assessments as it was found that there was significant variability in the acquisition of the circumference by study research assistants, rendering the measure meaningless.

The most significant modifications that will be made for the randomized trial will relate to the study procedures. Qualitative data from week 4 and 12 interviews indicated that participants desired shorter treatment sessions, repetition of content, and a summary of presented information at the end of each session. These requests may be reflective of recognized cognitive deficits that are often overlooked when working with patients who have been living with HIV as a chronic illness. Session 1 will be modified so that instead of covering all risk factor content and four behavior change modules, as we did during the open pilot, we will cover risk factor content, personalized risk assessment and two modules for behavior change (of participant choice). This change will reduce the length of the session to

less than 60 minutes (from 75–90 minutes). Participants will also be given the option of covering different modules during the second treatment session. Some participants expressed that recording steps was tedious and an electronic method of record keeping may be considered for future studies.

Conclusion

The use of qualitative methods was shown to have significant value in designing and modifying an intervention specifically for PLWH to improve CVD risk perception and the adoption of heart-healthy behaviors to reduce CVD risk. Treatment satisfaction and session attendance rates were high. The next step in this process is to conduct a randomized clinical trial to compare the efficacy of CVD-PRAI to a standard condition (consistent with medical advice given during a routine clinical visit) that does not incorporate personalized feedback and motivational interviewing techniques.

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Key Considerations

- Persons living with HIV are at increased risk for cardiovascular events when compared to the general population.
- The American Heart Association has recommended lifestyle modification for the general population to reduce cardiovascular risk.
- Open pilot testing of the CVD-PRAI (CVD-perceived risk awareness intervention) demonstrated initial feasibility and acceptability among PLWH.

Treatment Session 1 (Week 1)	Treatment Session 2 (Week 4)
Welcome, structure of program, binder	Welcome
Prevalence of CVD; relationship of HIV	Review of goal setting/attainment
"What is a heart attack?" video	Review of physical activity (steps)
CVD risk factors Motivational interviewing and personalized feedback	Benefits of behavior change/Challenges encountered/Strategies to overcome challenges
Personalized CVD risk assessment/ASCVD risk score calculation/Heart Age/feedback	Review of personalized feedback from Session 1
Risk reduction modules <ul style="list-style-type: none"> - <i>Physical activity – review of baseline steps</i> - <i>Diet</i> - <i>Smoking cessation</i> - <i>Managing stress</i> 	Address any other areas for change
Goal Setting	Offer to set new goals/Reward progress
Wrap Up/Closing	Wrap Up/Closing

Note. CVD = cardiovascular disease; CVD-PRAI = Cardiovascular Disease Perceived Risk Awareness Intervention; ASCVD = atherosclerotic cardiovascular disease.

Figure 1.
Perceived Risk Awareness Intervention (CVD-PRAI) treatment core components.

Table 1Phase 1a. Sample Demographics at Baseline ($N = 30$)

Age, M (SD)	54.4 (7.0)
Education Level, M (SD)	11.7 (2.9)
Years living with HIV, M (SD)	18.8 (8.6)
<hr/>	
	N (%)
<hr/>	
Female Sex	9 (30.0)
Race/Ethnicity	
Hispanic/Latino	2 (6.7)
White	15 (50)
Currently Employed	8 (26.6)
Currently Single	20 (66.7)
Current Smoker	15 (50)
Current ART	30 (100)

Note. ART: antiretroviral therapy.