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Protocol

Title: Culturally Sensitive, Primary Care Clinic-Based Interventions by Community Health Workers and Trained Physicians to Promote and Sustain Weight Loss among Black Women Patients with Obesity

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1. Abstract:

Black women have the highest prevalence of obesity in the U.S. with more than half (56.6%) of Black women experiencing obesity. This disease increases the likelihood of having diabetes and other chronic diseases, and decreases quality of life and life expectancy. The U.S. Preventive Services Task Force recommends that all adults who have obesity participate in an evidence-based, intensive, multicomponent behavioral treatment for this disease. Such treatment has been shown to produce clinically significant weight-loss among patients; however, this weight-loss is typically not sustained over time. Health care professionals nationally agree that treatment of obesity should be occurring and evaluated in primary care settings.

We will test the effectiveness of a culturally sensitive, evidence-based, multi-component, behavioral program for treating obesity called Health-Smart.™ This program will be implemented for 6 months in 20 UF Health Jacksonville primary care clinics by Community Health Workers (CHWs) with Black women patients who have obesity, and followed by either of two physician-implemented behavioral counseling weight loss maintenance programs that are applied quarterly over 12 months to prevent weight gain. Specifically, we will compare the effects on weight-loss and weight-loss maintenance of (1) Health-Smart

plus the Patient-Centered, Culturally Sensitive Weight Loss Maintenance Program (PCS-WLM), and (2) Health-Smart ***plus*** the Standard Behavioral Weight Loss Maintenance Program (SB-WLM). We expect that (a) the PCS-WLM will result in significantly greater weight-loss and weight-loss maintenance compared to SB-WLM, and (b) that the model used to integrate CHWs into the health care team at each clinic will result in high ratings of this integration by the CHWs and other clinic staff involved with this study.

2. Background:

Obesity has been called a modern epidemic.[1] Obesity increases the likelihood of experiencing various chronic diseases such as diabetes, hypertension, coronary heart disease, and some cancers, all of which negatively impact quality of life.[2-5] Thus, reducing and eventually eliminating obesity continues to be a national health priority.[6]

Approximately 75% of non-Hispanic Blacks are overweight or obese. This percentage is higher than other US racial and ethnic groups. The 2011-12 US National Health and Nutrition Examination Survey revealed that (a) the prevalence of obesity (BMI $\geq$ 30 kg/m^2) had increased to 34.9% and (b) this obesity increase was even higher among Blacks (47.8%) and Hispanics (42.5%).[7] Black and Hispanic women are affected by obesity more than their male counterparts. Notably, Black women (BW) have the highest obesity prevalence in the US. More than half (56.6%) of BW are obese, compared to 44.4% of Hispanic women and 32.8% of non-Hispanic White women.[7] Despite the high prevalence of obesity among BW, they have been underrepresented in weight-loss trials and weight-loss maintenance studies.[8]

Numerous reviews have found that lifestyle interventions are effective in helping individuals lose weight.[9] Generally, lifestyle interventions that are delivered in weekly group sessions over 4 to 6 months can help individuals achieve weight losses of approximately 5 to 10% of their body weight.[10] Unfortunately, many individuals who successfully lose 5% or more of their body weight gradually regain most, if not all, of the weight they lost.[11] Thus, the real goal of obesity treatment should be to help individuals achieve weight loss and keep the weight off over the long-term.[12]

Accordingly, several obesity researchers have called for a focus on preventing weight regain, <u>particularly in primary care settings.</u>[7] The Obesity Reduction Black Intervention Trial (ORBIT) provides important insights into weight loss and maintenance for BW.[10] The 6-month weight-loss intervention in this trial was implemented by trained interventionists and involved twice-weekly group discussions focusing on eating a healthy diet, restricting calories, and increasing physical activity and related goals, plus monthly 30-minute motivational interviewing (MI) sessions by the interventionists.[13] The 12-month weight-loss maintenance intervention in the ORBIT study included group sessions that decreased in frequency plus monthly MI sessions.[8] At the end of the 6-month intervention period, the intervention group had lost 3.0 kg, and the control group had gained 0.2 kg. Both groups gained weight between months 6 and 18 (1 kg in the intervention group and 0.1 kg in the control group). At month 18, only 24% of the intervention group and 12% of the control group had lost at least 5% of their initial body weight. The authors of the article reporting these findings concluded that the low weight-loss and unsuccessful weight-loss maintenance indicates that more research is needed to identify what contributes to meaningful weight loss and weight-regain prevention in BW.

3. Specific Aims:

The project has three primary aims. The **first primary aim** is to evaluate the effectiveness of the Community Health Worker (CHW)-implemented, clinic-located, evidence-based, 6-month Health-Smart weight-loss program as indicated by (1) participating patients' mean weight loss and (2) percentage of participating patients who show clinically significant weight loss (i.e., at least 5% of baseline body weight).

The **second primary aim** is to compare the outcomes of two 12-month, clinic-based weight-loss maintenance programs implemented by patients' respective physicians after the 6-month weight-loss intervention. The first program is the Patient-Centered, Culturally Sensitive, Weight-Loss Maintenance (PCCS-WLM) program, which is a weight-maintenance program implemented by physicians who receive patient-centered, cultural sensitivity training to enhance their ability to talk with patients about weight-loss issues in ways that enable patients to feel comfortable with, respected by, and trusting of their physicians. The second program is a standard behavioral weight-loss maintenance (SB-WLM) program that is recommended by the Institute of Preventive Medicine. The specific patient reported outcome measures related to this aim are continued weight loss or maintaining weight loss and changes in patients' perceived levels of (a) satisfaction with physician care, (b) provider cultural sensitivity, and (c) physician engagement in discussions of their weight and health-smart behaviors (e.g., eating and physical activity).

The **third primary aim** is to implement and evaluate a Medical Assistant (MA)-led program designed to integrate trained CHWs into the health care team in 20 primary care clinics so that these CHWs can implement the 6-month Health-Smart weight-loss program with BW patient participants who have obesity at these clinics. MAs at each participating clinic will train and mentor the CHWs assigned to the clinic to become integrated into the heath care team at that clinic. This training will be informed by the nationally-recognized TeamSTEPPS Program—an evidence-based set of teamwork strategies and tools developed by the Agency for Healthcare Research and Quality (AHRQ) aimed at optimizing patient outcomes by improving communication and teamwork skills among health care professionals. CHW integration effectiveness will be assessed using (a) ratings by CHWs, MAs, and physicians in the proposed study on the relevant subscales of a TeamSTEPPS team integration assessment tool, the AHRQ Office Survey for Patient Safety.

The **secondary study aims** are to determine if, at the end of the 12-month weight-loss maintenance programs, there are differences in the following participant health indicators in association with type of physician-implemented weight-loss maintenance program implemented by the participating patients' physicians: (a) blood pressure, lipids, HbA1c, and blood glucose; (b) healthy eating and physical activity engagement; (c) participant-perceived barriers to health-smart behaviors; and (d) health-related quality of life.

The **primary hypotheses** that will be tested are the following: (1) at the end of the 6-month Health-Smart weight-loss intervention, participating patients will show weight reduction of at least 5% of their baseline weight, and (2) at the end of 18 months, a significantly larger percentage of participants at clinics assigned to the 12-month PCCS-WLM program will maintain initial weight loss or show continued weight loss compared to participants at clinics assigned to the 12-month SB-WLM program.

4. **Research Plan:**

Target Population: The target population for this study is Black women patients with obesity and are current patients in the UF Jacksonville Primary Care Network. This population was selected because they have a high incidence of mortality due to obesity, and have the most potential direct benefit from participating in this study.

Inclusion/Exclusion Criteria: The participant inclusion criteria are: (1) African American/Black, (2) female, (3) age 21 years or older, (4) BMI of 30kg/m^2 or higher; (5) active patient of a participating clinic (i.e., at least 2 clinic visits in the last 24 months), and (6) willing and ready to change one's diet and physical activity level, and (7) willing to be randomized to either of the two physician-implemented weight-loss maintenance intervention groups. Exclusion criteria are (1) any serious medical condition that likely affects weight, such as end stage renal disease or cancer, (2) prior bariatric surgery within the last 5 years or plans for this surgery in the next 2 years, (3) use of prescription or over-the-counter weight-loss medication within the last 6 months, (4) currently pregnant or plan to get pregnant within the next 2 years, (5) plan to relocate from the areas served by participating clinics within the next 2 years (6) having had unintentional weight loss (≥ 5% of body weight) within 6 months of enrollment, and (7) taking a daily dose of an oral corticosteroid or anti-psychotic (clozapine, olanzapine, or risperidone) for less than six months.

Participant Recruitment: Participants will be recruited from the UF Jacksonville primary care network. At least 20 of these primary care clinics will be targeted for recruitment of eligible participants, and a multi-faceted approach will be used for recruitment. At the participating clinics, recruitment will involve distribution of marketing materials (e.g., posters and flyers) in the waiting room and exam rooms. These marketing materials will include a telephone number to call if interested in the study. The participating provider in each clinic may also discuss the trial with any potentially eligible patients if they already have an appointment during the recruitment period. If a patient is initially interested in participating and appears to be eligible, the medical staff will ask the patient to complete a short form indicating that she would like to be contacted by a study team member to learn more about the trial. Additionally, to systematically identify and recruit potentially eligible participants, the research team will conduct an IRB-approved query of the UF Health-Jax electronic medical record system (Epic), and organize targeted mailings of a study participation invitation letter to potentially eligible patients (based on their age, race, sex and BMI). The letter will provide an overview of the study and the phone number to call if they are interested in participating in the study.

Screening. A trained research coordinator or CHW will receive the phone calls from patients who are interested in participating in the trial and will perform a screening interview after having received verbal consent from the possible patient participant (interested caller). See copy of the screening script and interview tool. If the caller meets the screening criteria and is interested in participating in the study, a visit with their physician or physician extender (ARNP or Physician Assistant) will be scheduled to ensure there are no medical contraindications to their participation in the study. This screening visit will include a review of the patient's medication inventory, medical and hospital admission history for any exclusion criteria noted above as well as a physical exam that includes measuring blood pressure, radial pulse, and weight, administering a mini-cognitive assessment, and reviewing

the patient's health history. At the end of the screening visit, patients will be informed whether or not they qualify for the study. It is estimated that approximately 1,600 individuals will need to be screened in order to enroll 758 participants Participants will be enrolled in 3 waves: Wave1 will include 7 clinics averaging 34 enrollees each, Wave 2 will have 6 clinics with an average of 40 enrollees each, and Wave 3 will include 7 clinics with an average of 40 enrollees per clinic. See Table 1 for wave timing.

Table 1. Delivery of the Intervention Across Clinics

	2018				2019				2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
First wave												
Second wave												
Third wave												

Informed Consent. Once patients are cleared to participate in the study by their doctor, the CHW or research coordinator will review the informed consent form with them at the clinic, and the patient will be asked to give their written informed consent to participate in the clinical trial.

Study Intervention. We will test the effectiveness of a culturally sensitive, evidence-based, multi-component, behavioral program for treating obesity called Health-Smart.™ This program will be implemented for 6 months in 20 UF Health Jacksonville primary care clinics by CHWs with Black women patients who have obesity, and followed by either of two physician-implemented behavioral counseling programs that are applied quarterly over 12 months to prevent weight regain. CHWs will be hired by the primary care network as UF OPS employees and trained to be staff members of the clinic to which they are assigned. The CHWs will also receive extensive training on the Health-Smart program by the PI (Dr. Tucker) and her team prior to program implementation. A brief description of each intervention component used in this study is as follows:

Measurement Session 1. The patient's baseline biometric data (weight, height, blood pressure) will be measured by an MA at their physician's clinic. Additionally, blood will be drawn to assess total cholesterol, LDL- cholesterol, HDL-cholesterol, triglycerides, glucose, and HbA1c if this has not been done in the last 30 days or during the physician screening visit. These data will be entered into the Health Data Log. Every attempt will be made to obtain the blood sample while the patient has been fasting. However, when that is not feasible, it will be noted in the form that the patient has not been fasting. Next, a trained CHW at the patient's primary care clinic will provide a battery of questionnaires to be filled out on site (see Questionnaire/Instruments section for descriptions). The research coordinators assigned to the clinics for this project will input the patients' biometric and lab data from the Health Data Log form and store it in the dedicated IRB research drive to prepare the data for analyses. Patient name, the date the measurement was taken, and the name of the clinic they are assigned to will also be included in the database.

Participation in the 6-month Health-Smart weight loss program. Within two months after completing Measurement Session 1, patients will begin the Health-Smart weight loss program. ***The 6-month clinic-adapted Health-Smart intervention is part of both comparators*** and includes the following components/strategies: (a) assessment of each

participant's motivators of and barriers to health-smart behaviors using the Motivators of and Barriers to Health-Smart Behaviors Inventory[14]—which has been published by the study PI; (b) coaching by a trained CHW that involves using the inventory-identified motivators and barriers to facilitate the patient participant's goal-setting and identification of strategies to achieve their goals, teaching participants to monitor selected health-smart goals and related goal attainment strategies, reviewing the standard goals for all patients that include 5% weight loss and increasing or maintaining steps walked to meet the 10,000 steps per day walking goal, and facilitating a patient-family member/friend discussion during which the patient asks the family member/friend to engage in behaviors that will support the patient in implementing her health-smart goal achievement strategies; (c) three months of weekly group sessions and then 3 months of bi-weekly group sessions; (d) 150 minutes of physical activity each week via patient participant-arranged or CHW-arranged activities such as group walks and individual walking to achieve 10,000 steps per day, and/or other self-selected moderate physical activities, and documentation of the physical activities in addition to documenting steps walked. Furthermore, the walking steps should begin with any number of steps that can be walked without any physical discomfort (e.g., pain, difficulty breathing) and then gradually increased by a number of steps that can be walked without any physical discomfort. Additionally, for participants who cannot walk at all, the physical activity goal is to engage in any physical activity up to 150 minutes per week that does not cause any physical discomfort. During at least one of the sessions in the Health-Smart intervention, patient participants will be given the opportunity to anonymously or directly ask health-related questions to a panel of health experts (e.g., dietitians) and Black women community members who have lost weight and maintained this weight loss.

The first week of Health-Smart will involve having a trained CHW, employed by the clinic, to help participating patients set health-smart behavior goals and weight-loss goals and identify strategies for achieving these goals using the Motivators of and Barriers to Health-Smart Behaviors Inventory (MB-HSBI). The CHW will review the standard goals for all patients that include 5% weight loss and increasing or maintaining steps walked to meet the 10,000 steps per day walking goal. Patients are will be asked to bring a family member or friend support person to the first session of Health-Smart only. This support person will be asked to make a commitment to help achieve the patient's health-smart goals.

Patients will attend the CHW-led Health-Smart weekly 1 ½- to 2-hour group sessions for 3 months and then bi-weekly group sessions for another 3 months. During these sessions, patients will be weighed. Patients will view and discuss segments of a Health-Smart DVD that show culturally diverse families and community members, licensed physicians and other health care providers discussing health-smart behaviors and "real world" strategies for promoting these behaviors. Patients will be given a Health-Smart Resource Guide that is a supplement to the Health-Smart DVD—a guide that contains more detailed information about the discussed health-smart behaviors and "real world" strategies for promoting these behaviors. Patients will be encouraged to review sections of the Health-Smart Resource Guide that are relevant to each week's group discussion. Patients will also be encouraged to follow a reduced-calorie eating plan to promote a 5% loss of their current body weight during the 6-month weight-loss intervention. Sample reduced-calorie meal plans that provide approximately 1200 kcals from a well-balanced diet from a variety of foods emphasized in the 2015 Dietary Guidelines for Americans will be provided to patients. They will also participate in 150 minutes of physical activity each week - either on their own or arranged by

a trained Community Health Worker. Throughout the 6-month Health-Smart program, patients will be using a Food and Activity Diary to record their steps walked using a pedometer that will be provided to them as well as document other physical activity performed during each week. They will also be recording food and beverages consumed daily.

Measurement Session 2. After the completion of the 6-month Health-Smart weight loss program, patients' weight, height, blood pressure will be measured by a Medical Assistant at their physician's clinic. Additionally, patients' blood will be drawn to assess their total cholesterol, LDL- cholesterol, HDL-cholesterol, triglycerides, glucose, and HbA1c and they will complete the questionnaires previously completed as part of Measurement Session 1. The research coordinators assigned to clinics will input the patients' biometric and lab data from the Health Data Log form and store it in the dedicated IRB research drive.

Weight Loss Maintenance Support from Primary Care Physician. During the 12 months after completing the 6-month Health-Smart weight loss program, patients will have quarterly visits with their physician (at no charge to the patients) so that the physician can provide counseling and support to the patients that is designed to help the patients continue to lose weight or maintain the weight loss that resulted from participating in the Health-Smart weight loss program. In this phase, two different 12-month weight maintenance programs implemented by physicians will be compared (PCCS-WLM program and SB-WLM program). Both the patient and the CHW will be blinded on which program the patient will be participating in. The clinics will be randomly assigned to one of these two programs. The PCCS-WLM program (Comparator 1) will be implemented by the physicians of the participating patients at 10 clinics in this study, and the SB-WLM (Comparator 2) will be implemented by the physicians of participating patients at a separate set of 10 clinics in the study. Both of these programs consist of patient-physician clinical encounters every three months over a 12-month period, during which physicians in each program will review each of their participating patient's clinic-tracked weight/BMI and implement evidence-based provider behavioral counseling strategies for weight-regain prevention with each of these patients. A summary form that includes the patient's weight loss goals and health-smart goals will be provided to the physician prior to their first maintenance visit.

Focus Groups. Focus groups with Black women with weight concerns will be performed to identify specific ways providers can demonstrate cultural sensitivity that will be among the foci of the physician training for the PCCS-WLM program (Comparator 1). A minimum of two but no more than four focus groups will be conducted before the end of 2018. Each group will include 6 to 10 participants per focus group. Each participant will receive a $30 gift card for their participation and will be required to complete a gift card receipt form that includes their name, social security number, address, and phone number. Focus group participants will be recruited from the general population through disseminating flyers about these groups at local clinical settings (e.g., the participating clinics and at hospitals and walk-in health care sites), community settings (e.g., local Black churches), and meetings that are attended by large numbers of Black women. The snowball technique will also be used to recruit Black women to participate in the focus groups. This technique involves having individuals who to agree to be research (focus group) participants help recruit other focus group participants. Focus groups will be held at UF Health, or at an identified site closest to the participating women.

A focus group guide has been created to standardize what information will be collected during each session. Black women group facilitators for each focus group will follow the guide, which includes a standard introduction and focus group questions. These group facilitators will have had experience in conducting focus groups and will be trained in conducting the focus groups for this study. Each focus group discussion will be audio-recorded with notes taken on key issues by graduate students supervised by the one of the members of the research team. The audio-recordings will be transcribed and analyzed as described in the focus group guide. Information from the focus groups will help inform the physician training curriculum for the physicians in the PCCS-WLM program (Comparator 1). The audio-recordings of the focus groups will be destroyed 5 years after these recordings are made and will be stored in a locked file cabinet in the Psychology Building at the University of Florida's Gainesville campus until they are destroyed. The PI, Co-PIs, Co-Is and other study staff as well as a hired transcription company will have access to the audio recordings for transcription purposes only. After the transcriptions are made, the PI, Co-PIs, Co-Is and other staff will have access to the audio-recordings until they are destroyed. The audio-recordings will be destroyed by Shred-it—a UF authorized Destruction and Disposal Services Company.

Physician Training for Implementing the Weight Loss Maintenance Programs. Prior to beginning either of the physician-implemented weight-loss maintenance programs, the physicians who deliver each program will receive training on how to implement the program that will be provided in their respective clinic. The physician training time for implementing the PCCS-WLM program (Comparator 1) will be the same as the physician training time for implementing the SB-WLM program (Comparator 2). All of the physicians, regardless of which program they implement at their clinic, will experience the following in this order: (a) completion of the Tucker Culturally Sensitive Health Care Inventory – Provider Version, (b) 4-hour training that will include a 3-hour in-person training and a 1-hour on-line training, (c) 3 booster training sessions (in person and online), scheduled to occur at quarterly intervals (i.e., just prior to each quarterly physician-patient weight loss maintenance program visit), and (d) completion of the Tucker Culturally Sensitive Health Care Inventory – Provider Version at the end of the study. We will also implement a satisfaction survey for the physicians regarding the weight loss maintenance phase (i.e., at month 18). Dr. Tucker will lead the training for the physicians who will implement the PCCS-WLM program (Comparator 1), and Dr. Anton will lead the training for the physicians who will implement the SB-WLM (Comparator 2). In all of these trainings, the physician trainees will be instructed to remind their patient participants of the importance of reaching and/or maintaining the health-smart goal of reducing their body weight at least 5% from when they began the earlier 6-month Health-Smart program.

Description of the PCCS-WLM program (Comparator 1). This program is designed to enable physicians to: (a) talk with their Black women patients about their weight, weight loss goals and goal barriers, and strategies for overcoming their goal barriers, and deliver this talk in patient-centered, culturally sensitive ways (i.e., in ways that enable Black women patients to feel comfortable with, trusting of, and respected by the physicians talking with them), (b) assist their patients with engaging in self-identified strategies for achieving and sustaining their self-selected health-smart goals for weight loss and overall health, (c) be knowledgeable about health-smart behaviors (healthy eating

and drinking, physical activity, and managing stress/anxiety, and depression), (d) use behaviors and display attitudes in physician-patient interactions with Black women patients that are provider cultural sensitivity indicators in published literature [15,16,17] , but customized for use when counseling Black women patients with obesity—customized based on operationalization of these indicators by the Black focus group participants who were asked to identify specific ways to show these indicators when talking with Black women with obesity about their weight and weight loss, and (e) say and display behaviors and attitudes that Black women in the aforementioned focus groups identified as important when discussing obesity and losing weight with Black women patients who have obesity.

Description of the SB-WLM program (Comparator 2). This program is designed to enable physicians to: (a) implement motivational interviewing approaches when talking with their patients about their weight loss goals and behavioral strategies to achieve these goals, (b) become knowledgeable about empirically supported behavioral change principles that have been used to help patients maintain weight loss in previous interventions, (c) communicate how to use these empirically supported behavioral change principles to have patients initiate or maintain their self-selected health-smart goals related to weight loss and/or weight loss maintenance, and (d) use motivational interviewing approaches to communicate empathy and understanding with patients who are struggling to maintain their weight loss and/or accomplish a behavioral goal.

External Control Monitoring to Verify that the Physicians and CHWs are Following Provided Training. This external control monitoring will occur during the CHW integration period, the CHW implementation of Health-Smart, and the physician weight loss maintenance year. The CHW monitoring will be conducted by undergraduate student researchers in a research lab course taught by the PI and from among the study staff—all of whom will be trained to conduct this monitoring. This external control monitoring will involve observing health-smart group sessions, either in person or through teleconferencing, that are run by CHWs and using a monitoring form to rate whether or not the activities of the sessions were implemented by the CHWs. The study staff, either in person or through the telemedicine system, will observe the physicians to monitor fidelity to the weight maintenance program that they were trained to implement.

Measurement Session 3. After the completion of the quarterly physician visits, patients will have their weight, height, blood pressure, blood glucose, Hemoglobin A1c, and lipids measured again as well as complete the questionnaires previously completed at Measurement Sessions 1 and 2. The research coordinators assigned to clinics will input the patients' biometric and lab data from Health Data Log form and store it in the Dedicated Research Drive.

Participant Questionnaires/Instruments. The following tools will be administered during the measurement sessions. Most of these questionnaires will be completed at each measurement period except the following that will only be administered at the 2 and 3rd measurement period: Health-Smart Participant Satisfaction Questionnaire, Patient Survey of Provider Weight Management Practices, Patient Satisfaction Questionnaire – 18, and Tucker Culturally Sensitive Health Care Inventory – Patient Version. The questionnaires will be filled out electronically on a computer or tablet using Qualtrics and stored in a secure UF server. The survey data will include a patient identification number for tracking purposes. No PHI or medical records including lab results will be stored in Qualtrics, only patient

satisfaction and perceptions information. A CHW will be present when each patient is completing the questionnaires and will provide each patient with whatever assistance is needed when completing the questionnaires. A paper version will be available for those who cannot complete it online.

Motivators of and Barriers to Health-Smart Behaviors Inventory (MB-HSBI)–Adult Version (Tucker, Rice, Hou, Kaye, Nolan, Grandoit, Gonzales, Smith, & Desmond, 2011). The MB-HSBI—Adult Version is a 129-item inventory that assesses motivators of and barriers to engaging in specific health-smart (health promoting) behaviors within each of the following four domains: (1) Eating a Healthy Breakfast, (2) Eating Healthy Foods and Snacks, (3) Drinking Water and Other Healthy Drinks, and (4) Engaging in Physical Activity. For each of these four domains, the MB-HSBI includes a "Motivators" section that assesses what motivates respondents to engage in the identified health promoting behaviors and a "Barriers" section that assesses barriers to engaging in the identified health promoting behaviors.

International Physical Activity Questionnaire (IPAQ). IPAQ is a 27-item self-report questionnaire that assesses physical activity in five activity domains (job-related, transportation, housework/house maintenance/caring for family, recreation/sport/leisure time, and time spent sitting).[21]

Dietary Short Questionnaire (DSQ, NCI/NHIS CCS 2010 version). The DSQ is a 27-item survey that asks about the frequency of consumption of selected foods and drinks in the past month.[22]

Weight Control Strategies Scale (WCSS). The WCSS is a self-report measure to assess the use of specific strategies for losing weight or maintaining weight loss. The 30-item WCSS contains four subscales: Dietary Choices, Self-Monitoring Strategies, Physical Activity, and Psychological Coping.[23]

USDA Adult Food Security Survey Module (AFSSM). The AFSSM addresses conditions and behaviors related to one's experience of, and anxiety due to, limited instances and consequences of reduced food intake. [24]

World Health Organization (WHO) Quality of Life–Brief Form (WHOQOL-BREF). This 26-item survey assesses self-reported quality of life, defined by the WHO as "an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns." The questionnaire consists of an overall quality of life question, an overall health question, and questions that assess four quality of life domains (physical health, psychological health, social relationships, and environment); however, only the physical health (7 items) and psychological health (6 items) domain items will be used in this study.[25]

Demographic and Health Information Questionnaire. This researcher-constructed questionnaire is designed to obtain patients' basic demographic and health information (e.g., age, gender, race/ethnicity, annual household income, highest level of education completed, marital status, employment status, and weight- and obesity-related information and diseases).

Health-Smart Program Evaluation Questionnaire - Participant (6 month and 18 month) – This researcher constructed questionnaire is designed to measure the participants' satisfaction with the Health-Smart Program. These will be administered at Measurement 2 and 3 time periods.

General Satisfaction subscale of the Patient Satisfaction Questionnaire-(PSQ-18). This subscale assesses patients' level of agreement that they view their medical care broadly as perfect and level of agreement that they are dissatisfied with some aspects of their medical care. Items from this questionnaire that will be included in the present study are items 1, 2, 4, 6, 13, and 14.[18]

Tucker-Culturally Sensitive Health Care Provider Inventory-Patient Form (T-CSHCPI-PF). The T-CSHCPI-PF is a 27-item inventory that will be used to assess patient participants' perceived level of provider patient-centered cultural sensitivity. This inventory is comprised of three sub-scales: (1) Competence/Confidence, (2) Sensitivity/Interpersonal Skill, and (3) Respect/Communication.[19]

Patient Survey of Provider Weight Management Practices. This is an 18-item survey developed by the Oregon Rural Practice-based Research Network and the Oregon Health & Science University in collaboration with the Agency for Healthcare Research and Quality. Two items from the 18-item Patient Survey of Provider Weight Management Practices (items 8 and 13) will be used to measure participants' perceived levels of their physician's engagement in discussions of their weight and health behaviors.[20]

Table 2 lists the measures that will be completed at each Measurement Session.

Table 2. Schedule of Patient Participant Assessments

	Intervention-Phase Month			
Category		**0**	**6**	**18**
Informed Consent and Eligibility criteria	X			
Body weight (Primary outcome)	X	X	X	X
Patient Goals setting		X		
Physiological Measures		X	X	X
Lifestyle Change Behaviors		X	X	X
Psychological Measures		X	X	X
Measures of patient participants' satisfaction with Health-Smart			X	X

CHW Integration. To address the **third primary aim,** we will implement and evaluate the medical assistant led (MA-led) program designed to integrate the CHWs into the health care team so that these CHWs can implement the 6-month Health-Smart weight-loss program at these clinics. The Office Manager and MAs at each participating clinic will train and mentor the CHWs assigned to that clinic to become integrated into the heath care team at that clinic. This training will be informed by the nationally recognized TeamSTEPPS Program[26]—an evidence-based set of teamwork strategies and tools developed by the Agency for Healthcare Research and Quality and aimed at optimizing patient outcomes by improving communication and teamwork skills among health care professionals. CHW integration effectiveness will be assessed using ratings by CHWs, MAs, and physicians on the TeamSTEPPS Medical Office Survey of Patient Safety. In particular, two subscales from this survey (the Working in Your Medical Office subscale, and the Communication and Follow-up subscale) will be administered electronically using Qualtrics at the beginning of the project prior to TeamSTEPPS training and after the 6-month Health-Smart weight-loss program. The survey will be anonymous and no personal health information is collected.

Compensation. Participating patients can receive up to $150 in gift cards by participating in each of the three Measurement Sessions. Specifically, they will receive a $25 gift card after participating in the first Measurement Session (Baseline), a $50 gift card six months later after participating in Health-Smart and the second Measurement Session (Month-6), and a $75 gift card 12 months later after participating in the weight loss maintenance sessions with their physician and the third Measurement Session (Month-18).

Participant Safety. The data taken during the measurement sessions will also be used for safety measures. If a BP measurement is taken that is an alert value, as listed in the Table 3 below, repeat measurements will be taken per clinic protocol. An average of at least two measurements will be used to determine the appropriate plan of action. The machine that measures blood pressure often also provides a pulse rate reading. The patient's pulse rate is not an outcome measure in the study, but will be addressed if it is outside of the normal range. Total cholesterol, LDL- cholesterol, HDL-cholesterol, triglycerides, and HbA1c will be assessed through point of care (POC) testing, as specified in the Study Intervention section above. Based on the readings of these measurements, an appropriate plan of action will be taken. Table 3 below lists both Urgent (notify PCP within 24 hours) and Alert values (notify PCP immediately while patient is still in the office). If the patient has a result in the alert value range, the physician or non-physician provider will determine if 911 needs to be called.

Table 3. Safety Assessments and Action Needed During Health-Smart Intervention Sessions.

	Normal	Not Clinically Significant (Document as per study protocol)	Urgent (Notify PCP in <24 h)	Alert (Notify PCP Immediately)
Systolic BP (mm Hg)	90-130	130-160	Low: 80-90 w/o Sx* High: 160-180	Low: <90 w/ Sx or <80 High: >190
Diastolic BP (mm Hg)	70-90	60-94	Low: 50-60 w/o Sx High: 95-110	Low: <60 w/ Sx or <50 High: >110
LDL-c (mg/dl)	<100	100-190	>190	NA
Triglycerides (mg/dl)	<150	150-400	400-800	>800
Glucose (mg/dl)	80-125	70-140	Low: 60-70 High:141-300	Low: <60 High: >300
Pulse	60-100	60-100	Low: < 59 w/o Sx High: >100 w/o Sx	Low: < 59 with Sx High: >100 with Sx

*Sx = symptoms of low blood pressure or pulse such as light headedness, dizziness, syncope (fainting) near syncope, palpitations, headache, vision changes, chest pain, shortness of breath.

If the patient experiences a serious adverse event at any of the Health-Smart intervention sessions that occur outside the clinic or after clinic hours, the CHW will call 911 and

complete a Serious Adverse Event Form that will be sent to the patient's health care provider and to the PI.

Participant Privacy and Confidentiality. The following steps will be taken to protect participants' privacy and confidentiality:

- Prior to recruiting patients for this study, CHWs will complete the required HIPAA and CITI or NIH GCP trainings as required by the IRB as well as training on how to enroll participants and implement all aspects of the study intervention.
- All signed consent forms will be kept in a locked file cabinet in a locked office at the study team's office in Jacksonville (Tower II, Suite 6015).
- All electronic documents and data will be stored in secure, password-protected servers on the UF campus.
- All paper based study documents including patient surveys and data collection forms will be stored in a locked filing cabinet in a locked room in the Center for Health Equity and Quality Research office on UF Health Jax campus.

5. Statistical Analysis

The primary outcome is change in body weight (weight loss and maintenance of weight loss) in BW patient participants at the 20 participating primary care clinics. The unit of randomization will be the primary care clinic. Each clinic will be randomized into one of the two weight loss maintenance conditions (PCCS-WLM and SB-WLM).

Sample Size/Power. To detect a weight-loss difference of 5 pounds (between two groups) with a standard deviation of 12.5 pounds with 80% power and a 5% significance level, we will include 20 clinics and 25 study participants per clinic. Based on our pilot data, an intra-class correlation of 0.05 among patients within a clinic is used in these calculations. Based on the power calculation above, a total of 500 participants (20 clinics x 25 patient participants per clinic) will be needed for final analyses. Assuming a 25% dropout rate of patients per clinic, we will need 34 patients per clinic; thus, 680 patients will be enrolled in the study. However, based on Wave 1 (which involves 7 clinics) patient participant drop-out rate, the number of participants per clinic will need to be increased for Wave 2 and 3 to an average of 40 patients per clinic. Thus, the maximum number of patient participants enrolled in the study will be 758. Consequently, each of the two study arms will have a maximum of 379 patient participants.

Data Analysis. Shiva Gautam, PhD who has a doctorate in Biostatistics will perform data analysis. Analyses begin with numerical and visual summaries of baseline characteristics of the sample. Continuous variables will be summarized by means, standard deviations, and medians. Categorical variables will be summarized by frequencies and percentages. Visual summary may include graphs, charts and tables. The main outcome variable (weight change) will be analyzed using a 2-level hierarchical model within the framework of a linear mixed model. The 2 levels of hierarchy will be defined as patient-level and clinic-level. Data will be analyzed within the context of linear mixed model. Weight loss between 6 and 18 months will be evaluated and compared between groups by defining an appropriate contrast within the model. Similarly, weight loss from baseline to 6 months also will be estimated (but not compared) by defining a contrast. It is assumed that those participants with BMIs greater than 50 will lose weight at the same rate of those with BMIs between 30 and 50. However, we plan to analyze the weight loss rates in two ways: one with all of the participants in the analysis and another with BMIs greater than 50 excluded. Based on these two analyses, we

can see if the subset of participants with BMIs greater than 50 impacts the effect size. These data sets will be compared using a mixed model for categorical data (e.g., GLIMMIX procedure in SAS). Descriptive analysis will be used to evaluate the effect of age, BMI, poverty rate (according to zip code), insurance type, and HbA1c at baseline.

6. Data Safety and Monitoring Plan

The Principal Investigator and Co-Principal Investigators with the advice and assistance of the Advisory Board will monitor all aspects of the safety of the study intervention and assessment procedures. In addition to this ongoing monitoring by the study team, a Data and Safety Monitoring Board (DSMB) will be established to ensure the safety of all participants involved in the study and the validity and integrity of the data. The DSMB and its chair will be named and approved by the Advisory Board and ultimately PCORI. It is planned that the DSMB meets by conference call on a bi-annual basis.

The DSMB has access to all study data, documents and progress. The DSMB has the following charges:

- Review the study protocol.
- Review data (including masked data) over the course of the trial.
- Identify problems relating to safety over the course of the study.
- Identify needs for additional data relevant to safety issues and request these data from the study investigators.
- Propose appropriate analyses and periodically review developing data on safety and endpoints.
- Make recommendations regarding recruitment, treatment effects, retention, compliance, safety issues and continuation of the study.
- At any time, the DSMB may recommend discontinuation of any component/treatment group of the study. However, the IRB will decide whether or not to accept any recommendation from the DSMB to discontinue a component or components of the study.

Any serious adverse event that might be due to the study intervention will be reported to the patient's health care provider, the PI, the DSMB and the IRB.

7. Possible Discomforts and Risks

There may be possible discomforts or risks in obtaining a blood sample for the diagnostic lab tests. These possible discomforts or risks include discomfort at the site of puncture; possible bruising and swelling around the puncture site; an infection; and faintness from the procedure. The blood sample will be obtained at the participant's primary care clinic, and clinic staff are trained to handle any adverse event from the procedure.

Another possible risk is lack of privacy or confidentiality of PHI. A number of methods are employed to maintain confidentiality of participants. First, questionnaire data are collected in secure spaces where the interview cannot be overheard. Secondly, only study investigators and key research staff have access to the study database. Individual names will ultimately be removed from the study database, and consequently, only a unique study identifier will be used to distinguish participants in the database. Fourth, collected data are maintained in locked computer files and file cabinets to which only study investigators have access. Collected data will be used only for research purposes. Published data will not contain any individual identifiers.

Another possible risk is increased anxiety due to wanting to lose weight and not being able to lose as quickly as one would like. Another possible, but less likely risk, is weight gain. The CHWs and physicians who implement parts of the tested interventions will be trained to be supportive of patient participants' program participation regardless of their weight loss.

There will be no financial risk to the participant. All study related expenses, including physician visits and diagnostic lab tests, will be covered by the study sponsor.

8. Possible Benefits

Participants may personally benefit from taking part in this study since they will learn strategies to eat healthier, exercise more, get more rest, and manage stress and depression. They also may lose weight, which, for people with obesity, is often associated with improvements in health.

The information obtained in this study will help determine the effectiveness of Health-Smart and the physician-implemented weight loss maintenance programs for promoting and/or maintaining weight loss among Black women patients. If these interventions are found to be effective, they can be implemented at other primary care clinics with other Black women patients. Support would also be provided for testing these interventions with other women at primary care clinics who are not Black.

9. Conflict of Interest

There is no potential conflict of interest.

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