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Promoting weight-loss maintenance among Black women primary care patients: A cluster RCT of a culturally sensitive versus standard behavioural approach

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Summary

The prevalence of obesity is higher among Black women (56.6%) compared to Hispanic women (50%) and non-Hispanic White women (42%). Notably, interventions to reduce obesity typically result in initial weight loss that is not maintained. This study tested (a) the effectiveness of a 6-month Health-Smart Weight Loss (HSWL) Program for Black women patients with obesity implemented by community health workers (CHWs) within primary care clinics and (b) the comparative effectiveness of two 12-month physician-implemented weight loss maintenance programs—a Patient-Centred Culturally Sensitive Weight Loss Maintenance Program (PCCS-WLM Program) and a Standard Behavioural Weight Loss Maintenance Program (SB-WLM Program). Black women patients ($N = 683$) with obesity from 20 community primary care clinics participated in the HSWL Program and were then randomized to either maintenance program. The HSWL Program led to significant weight loss (i.e., 2.7 pounds, 1.22 kg, $p < .01$, −1.1%) among the participants. Participants in both the PCCS-WLM Program and the SB-WLM Program maintained their weight loss; however, at month 18, participants in the PCCS-WLM Program had a significantly lower weight than those in the SB-WLM (i.e., 231.9 vs. 239.4 pounds or 105.19 vs. 108.59 kg). This study suggests that (a) the HSWL Program can produce significant weight loss among Black women patients with obesity when implemented in primary care clinics by CHWs, and (b) primary care physicians can be trained to successfully promote weight loss maintenance among their Black women patients.

KEYWORDS
African American, community health, cultural sensitivity, primary care, weight loss, women

What is already known about this subject

- Black women have disproportionately high rates of obesity.
- Despite widespread calls for culturally adapted treatment of obesity for Black women, few such interventions have been developed, implemented and evaluated.
- The U.S. Preventive Task force recommends that all individuals with obesity participate in an evidence-based, intensive and multi-component behavioural treatment.

What this study adds

- Community health workers within primary care settings can deliver an empirically supported, behavioural, multi-component weight loss program for Black women with obesity.
- Physicians can successfully deliver a Patient-Centred Culturally Sensitive Weight Loss Maintenance Program and a Standard Behavioural Weight Loss Maintenance Program for Black women patients with obesity.
- Culturally sensitive weight loss maintenance programs are likely to produce greater weight loss maintenance than standard behavioural weight loss maintenance programs.

1 | INTRODUCTION

The U.S. Preventive Services Task Force recommends that all adults who have obesity participate in an evidence-based, intensive, multi-component behavioural treatment for this disease.[1] The prevalence of obesity is higher among Black women (56.6%) compared to Hispanic women (50%) and non-Hispanic White women (42%).[2] Cultural differences in attitudes towards food intake have been found,[3] leading many to conclude that efforts to address obesity in Black women must be tailored for these women.[4–6] Despite the higher prevalence of obesity among Black women, and findings that cultural differences exist, there have been few interventions that have focused exclusively on Black women and obesity.[7]

One notable exception was the Obesity Reduction Black Intervention Trial (ORBIT), a culturally adapted trial, which addressed both weight loss and weight loss maintenance (WLM) among Black women with obesity. In this trial, a 6-month lifestyle-based weight loss intervention was followed by a 12-month WLM intervention that included group sessions plus monthly motivational interviewing sessions.[8,9] At the end of the initial 6-month lifestyle intervention, the intervention group lost a mean of 3.0 kg, and the control group gained 0.2 kg. In line with similar interventions among other populations,[10] there was weight regain among the Black women with obesity in ORBIT between months 6 and 18 in the intervention and control groups (1.01 and 0.15 kg, respectively). This unsuccessful WLM led the authors to conclude that more research is needed to identify contributors to meaningful weight loss and WLM among Black women.[8] In addition, the authors indicated that on average, the intervention group participants only attended 27.1% of the group-based meetings during the maintenance phase. The authors highlighted difficulties in scheduling participants and drew attention to the success of flexible, one-on-one meetings to promote attendance.

Although little is known about how to successfully promote and maintain weight loss among Black women, there is widespread agreement among experts that weight loss and WLM efforts among Black women will benefit from a systems approach—an approach that incorporates individual, family, and community members, as well as the patient's primary care provider.[11] Many experts have also called for implementing weight loss and WLM interventions in primary care settings.[12] Implementing these interventions with physicians is supported by research indicating that 82% of adults have a yearly encounter with some type of healthcare provider and that primary care may be the only care many adults receive, particularly low-income adults.[12] In addition, a physician-implemented intervention may promote adherence by fulfilling the one-on-one recommendation described by the authors of the ORBIT. Furthermore, there is currently a widely accepted research gap identified by the Affordable Care Act regarding how to integrate community health workers (CHWs) into healthcare teams, particularly through the use of evidence-based techniques.[13] It is likely that incorporating these expert recommendations, in addition to anchoring the effort in patient-centred, culturally sensitive health care (i.e., health care that enables patients to feel comfortable with, trusting of, and respected by the physicians talking with them) will yield promising weight loss and WLM results among Black women with obesity.

Patient-centred, culturally sensitive health care has been identified as a best-practice approach for improving health outcomes and reducing health disparities.[14] This type of health care involves assessing and acting on patients' views regarding providers' verbal and nonverbal behaviours that enable them (i.e., the patients) to feel comfortable with, trusting of, and respected by providers in patient–provider interactions.[15] In a recent focus group study, a predominately overweight/obese sample of Black women with weight concerns identified desired (i.e., behaviours congruent with patient-centred, culturally sensitive health care) and undesired verbal and nonverbal behaviours in clinical encounters with their providers that are important for weight loss and WLM.[16]

The overall aim of our study was to evaluate a weight loss intervention and two WLM interventions for Black women with obesity implemented at primary care clinics. The specific aims of this study

were: Aim 1—evaluate the effectiveness of the CHW-implemented, clinic-located, evidence-based, multi-component, 6-month Health-Smart Weight Loss (HSWL) Program as indicated by participants' mean weight loss; and Aim 2—compare the outcomes of two 12-month, clinic-based WLM interventions implemented by patients' physicians after the 6-month weight loss intervention called the Patient-Centred Culturally Sensitive Weight Loss Maintenance Program (PCCS-WLM Program) and the Standard Behavioural Weight Loss Maintenance Program (SB-WLM Program). It was hypothesized that:

1. The patient participants would experience weight loss following their participation in the 6-month HSWL Program.
2. A greater proportion of participants in the 12-month PCCS-WLM Program would exhibit WLM (i.e., defined as gaining no more than 1 pound [0.45 kg] or continuing to lose weight) than the participants in the 12-month SB-WLM Program.

In addition, the following exploratory questions were asked:

1. What percentage of participants in the 6-month HSWL Program lost 5% or more of their baseline body weight at the end of this program and at the end of the 12-month WLM program in which they participated?
2. What was the difference in weight at 18 months (i.e., the time at which the two 12-month WLM programs ended) between the group of patients who experienced the 12-month PCCS-WLM Program and the group of patients who experienced the 12-month SB-WLM Program?

2 | MATERIALS AND METHODS

2.1 | Participants

Black women with obesity who were patients at one of the 20 primary care clinics that are part of a larger academic primary care network in Florida were recruited for this study. The key eligibility criteria were: (1) African American/Black, (2) female, (3) age 21 years or older, (4) BMI of 30 kg/m^2 or higher; (5) active patient at a participating clinic (i.e., at least two clinic visits in the last 24 months) and (6) willing and ready to change one's diet and physical activity level. Exclusion criteria were: (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 past 6 months, (4) currently pregnant or plan to become 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 enrolment and (7) taking a daily dose of an oral corticosteroid or anti-psychotic for less than 6 months. All of these criteria were verified during the initial screening process by the research coordinator who reviewed the participant's medical records. A total of 683 Black women patient participants were recruited and enrolled in the study; however, only 81.8% (n = 559) of these enrolled patients began the first intervention phase of the study.

2.1.1 | Clinic and physician recruitment

A review of the patient population in each of the primary care practices in the University of Florida (UF) network was conducted to determine how many active patients who met the eligibility criteria were available in each practice. Those practices that had at least 250 Black women patients with a BMI of 30 or greater were approached by the Chair of the Community Health and Family Medicine Department to assess interest in participating in the study.

2.1.2 | CHW recruitment

Seventeen Black women CHWs ages 20–67 years were recruited through an email advertisement to members of the Florida CHW Coalition, the UF Jobs website, and word-of-mouth. The CHWs were paid for their role as part-time UF employees and no other incentives were provided. For Wave 1, each CHW was assigned to one clinic. Once Wave 2 was started, CHWs were assigned an additional clinic, and by Wave 3 they were assigned to multiple clinics.

2.1.3 | Participant recruitment and screening

Several recruitment strategies were used in this study. One such strategy was the distribution of marketing materials in the waiting room and exam rooms at the participating clinics. The participating provider at each clinic also discussed the study with potentially eligible patients. In addition, a study participation invitation letter to potentially eligible patients was sent from each participating provider. Finally, the research team conducted an institutional review board (IRB)-approved query of the electronic medical record system and organized targeted mailings to potentially eligible patients.

A trained research coordinator received phone calls from patients interested in participating in the study and performed a screening interview after receiving verbal consent. This screening visit included (a) a review of the patient's medication list, and medical and hospital admission history to identify any exclusion criteria and (b) a physical exam that included measurement of blood pressure, radial pulse and weight, administration of a mini-cognitive assessment, and review of the patient's health history. At the end of the screening visit, patients were informed whether or not they qualified for the study. If the caller met the screening criteria and was interested in participating in the study, a visit with their physician within 1 month was scheduled to ensure there were no medical contraindications to their participation. The study received funding to pay for the screening visits including copayments. Once cleared to participate by their physician, the CHW

or research coordinator reviewed the informed consent form with them at the clinic. The patient was asked to give their written informed consent. The participating clinics, and thus the participating patients and physicians, started/enrolled in the study in one of the three waves with recruitment spaced 3 months apart for each wave. Initial recruitment for the first wave began in April 2018 and the weight loss intervention began in June 2018.

2.2 | Measures

The outcomes of this study were assessed using weight measured in pounds, as pounds are understandable to the patients and CHWs participating in the study and to the lay community stakeholders with whom study findings were shared. The participant's weight was measured by a medical assistant at the patient's primary care clinic using clinical scales. Scale type varied by the clinic, but each participant went back to the same primary care clinic for each of their weight measurements. Exceptions were made during the COVID-19 pandemic; for example, participating patients who did not want to come to their primary clinic to get their weight measured out of fear of contracting COVID-19 took a picture of their weight on their home scale during a telemedicine visit.

2.3 | Procedure

2.3.1 | Study intervention

This study received IRB approval at the UF. This was a two-phase intervention. The first phase tested the effectiveness of a culturally sensitive, evidence-based, multi-component, behavioural program for treating obesity among Black women called the HSWL Program. The HSWL Program was implemented over a 6 months by trained CHWs. The second phase (from Month 6 to 18) tested the impact of two 12-month physician-implemented behavioural counselling programs to maintain the weight loss that occurred following the 6-month HSWL Program and to promote further weight loss. The trial concluded at the end of the 12-month maintenance phase as intended in the study protocol. See Figure 1 for the relevant CONSORT diagram. Twenty-one clinics in total were recruited because one clinic left the UF network, and thus dropped out, before beginning the WLM phase.

2.3.2 | HSWL Program

The in-person group-based, clinic-adapted HSWL Program is a program rooted in Health Self-Empowerment Theory (HSET),[17] a theory of health promotion that recognizes the intractable nature of social/environmental factors on health promotion and highlights the importance of five (i.e., health motivation, health self-praise, adaptive coping, health responsibility and knowledge and health self-efficacy) self-empowerment oriented factors. There is evidence that weight loss interventions based on HSET have been effective, particularly among underserved groups,[18,19] although this has not been tested among a sample entirely composed of Black women with obesity and implemented by CHWs. This study implemented the HSWL Program through 17 Black women who were already CHWs. These CHWs were trained on the HSWL Program by the study team.

The HSWL Program included the following components/strategies: (a) assessment of each participant's motivators of and barriers to health-smart behaviours (i.e., health promoting behaviours) using the Motivators of and Barriers to Health-Smart Behaviours Inventory[20]; (b) coaching by a trained CHW that involved using the inventory-identified motivators and barriers to facilitate the participant's goal-setting and identification of strategies to achieve their goals, teaching participants to monitor selected health-smart goals and use of related goal attainment strategies, and facilitating a participant-family member/friend discussion during which the participant asks the family member/friend to engage in behaviours that would support the participant in implementing health-smart goal achievement strategies and in achieving their health-smart goals; (c) 3 months of weekly group sessions (1.5 - to 2-h per session) and then 3 months of biweekly group sessions to discuss and brainstorm strategies to engage in health-smart behaviours; (d) 150 min of physical activity each week via arranged activities such as group walks and individual walking to achieve 10 000 steps per day, and/or other self-selected moderately intense physical activities, and documentation of the self-selected physical activities in addition to documenting steps walked.

The HSWL program targeted a 5% weight loss over the initial 6-month intervention. Although there was no level of caloric restriction recommended, we anticipated that participants would naturally reduce their caloric intake by following the dietary recommendations of the HSWL to reduce salt, fat, and sugar intake.

The HSWL Program is culturally sensitive in that: (a) the HSWL Program was implemented by CHWs from among the communities of the target study participants, (b) these CHWs also enrolled the target participants into the HSWL Program, (c) all of the CHWs were trained to be aware of their cultural biases and stereotypes and to engage in behaviours that do not convey such biases and stereotypes, (d) the HSWL Program materials used in the intervention included pictures of Black adults/children and other racial/ethnic minority groups and (e) the HSWL Program involved CHWs in every aspect of planning the intervention and study as they are the experts on their lives and the barriers to healthy eating, physical activity and weight loss.

Participants were compensated $25 for providing baseline data and $50 for providing post-intervention data after participating in the HSWL Program. In addition to compensating participants for attending these visits, the following strategies were used to encourage participant retention. First, all participants who missed more than one meeting with their group leader and/or physician were contacted and rescheduled for a make-up session whenever possible. In addition, the participants established a buddy system to encourage each other to attend group sessions. For participants who were unable to attend sessions due to transportation costs, funds were provided to cover the cost of travel.

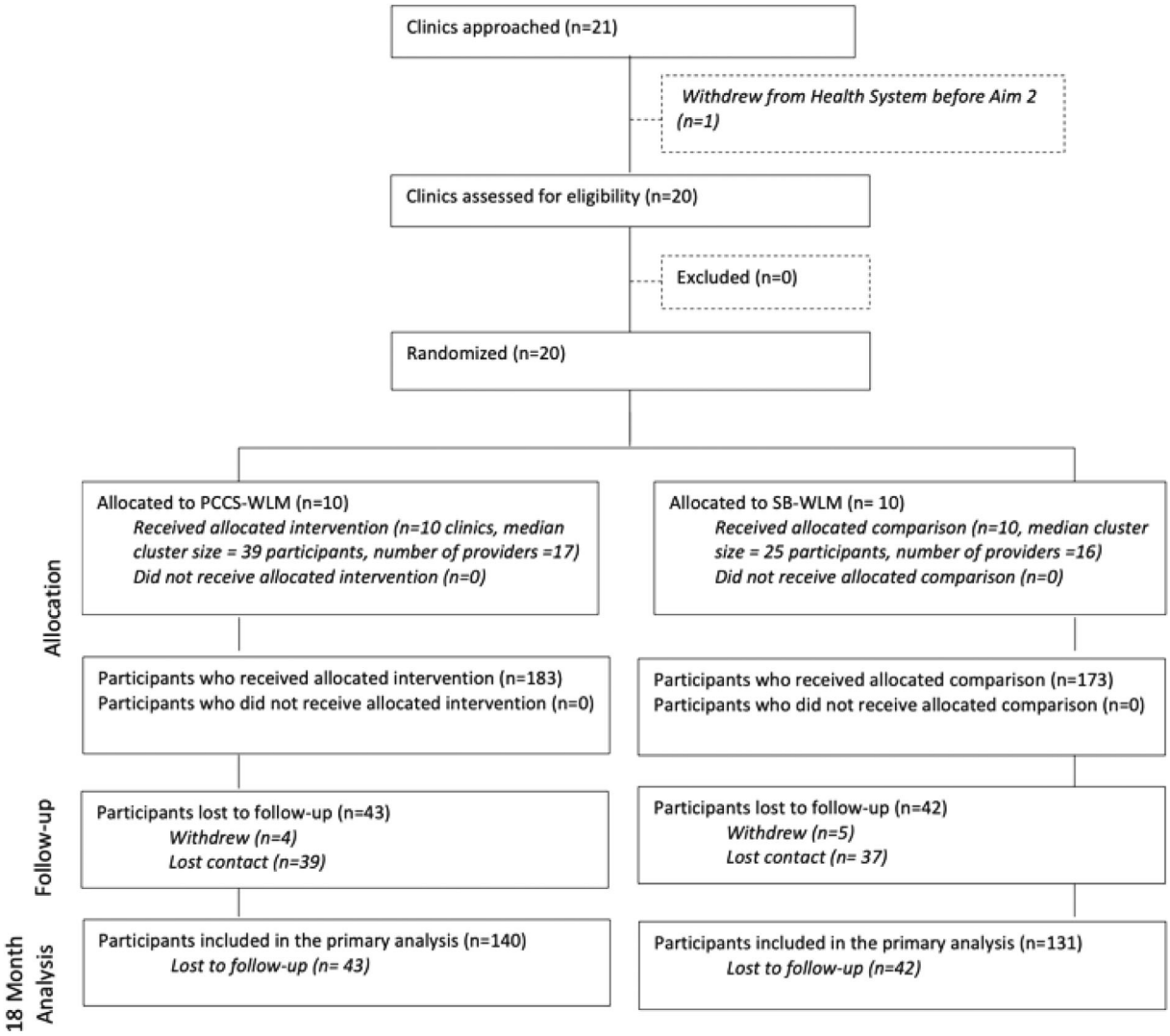


FIGURE 1 CONSORT diagram.

2.3.3 | WLM phase

During the 12 months immediately after completing the 6-month HSWL Program, participants had quarterly visits with their physician so that the physician could provide these participants with counselling and support, which was designed to help them continue to lose weight or maintain their weight loss. In this phase, two different 12-month WLM Programs that were implemented by physicians were compared—(1) the PCCS-WLM Program and (2) the SB-WLM Program. The 20 primary care clinics from which the patient participants in this study were recruited were randomly assigned to one of these two programs and the patient participants and their participating physicians were blinded as to which program their clinic had been assigned. Block randomization with a block size of 4 was conducted by a biostatistician using PROC PLAN in SAS version 9.4. Both programs consisted of quarterly participant-physician clinical encounters during which physicians in each program reviewed the participant's weight/BMI and implemented evidence-based provider behavioural counselling strategies for WLM. A summary form that includes the patient's weight loss goals and health-smart goals was provided to the physician before the first of four WLM visits with the patient. Participants were compensated $75 after completing the WLM programs.

Before beginning either of the physician-implemented WLM programs, the physicians received training on how to implement their assigned WLM program. All physicians, regardless of program assignment, received a 4-h training session which included a 3-h group, in-person training and a 1-h self-completed online training as well as three virtual booster training sessions at quarterly intervals. The Principal Investigator (PI) led the training for the 16 physicians who implemented the PCCS-WLM Program, and the Co-PI led the training for the 17 physicians who implemented the SB-WLM Program. The research team gave the providers the materials for the behavioural strategies implemented in both of the WLM conditions. Of the clinics randomized to the PCCS-WLM group, physicians were: 62.5% were female, 18.8% were African American and 74.9% were White. Of the

clinics randomized to the SB-WLM group, physicians were: 47.1% female, 23.5% African American and 70.6% White.

The onset of the COVID-19 pandemic paused the program for 3 weeks. It should be noted that the pandemic affected only the WLM phase for Waves 2 and 3. Participants in Wave 1 had already completed this phase and participants in all waves had completed the HSWL Program. During this pause, the investigators established safety protocols for all the participants and physicians. Notably, the WLM phase programs for participants in Waves 2 and 3 were changed from in-person delivery to telehealth visits. Instructions on how to use the telehealth services were provided to participants.

PCCS-WLM Program

This program was designed to enable physicians to: (a) talk with their Black women patients about their weight, weight loss goals, barriers to their weight loss goals, and strategies for overcoming their goal barriers; (b) deliver this talk in patient-centred, culturally sensitive ways (i.e., ways that enable Black women patients to feel comfortable with, trusting of, and respected by the physicians talking with them); (c) 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; (d) not forget the health-smart behaviours (healthy eating and drinking, physical activity and managing stress/anxiety and depression) learned in the HSWL Programs; (e) use behaviours and display attitudes in physician–patient interactions with Black women patients that are provider cultural sensitivity indicators in published literature,[21,22] but customized for use when counselling Black women patients with obesity (e.g., literature-based indicators for these women, such as being honest and direct, respectful of religious beliefs).[21] This program was developed based on qualitative focus group data conducted among Black women with obesity.[16]

The training of physicians to deliver the PCCS-WLM Program included engaging in the behaviours and strategies identified in these focus groups. Physicians were instructed on behaviours that promote comfort among Black women with obesity (e.g., being compassionate, sensitive and understanding; normalizing emotions, such as stress, that impact eating), behaviours that promote trust (e.g., connecting with patients; expressing caring; say that they want to earn their trust and care about their health), and behaviours that promote the feeling of being respected (e.g., addressing the patient as "Ms"; make eye contact; ask about patients' feelings/emotional health).

To ensure fidelity of the physician-implemented PCCS-WLM, medical students and CHWs conducted external quality control monitoring during the training and during the actual clinical encounters with their patients who were study participants. Within a week of the observation, the person who conducted the external quality control monitoring with each physician met with that physician via Zoom to provide feedback on what the physician did well and areas of needed improvement. The physician was provided copies of the feedback. Only one physician needed additional training on one aspect of the physician-implemented—training that was individually provided.

SB-WLM Program

This program was designed to enable physicians to (a) implement motivational interviewing approaches when talking with their patients about their weight loss goals and behavioural strategies to achieve these goals, (b) become knowledgeable about empirically supported behavioural change principles that have been used to help patients maintain weight loss in previous interventions, (c) communicate how to use these empirically supported behavioural change principles to have patients initiate or maintain their self-selected health-smart goals related to weight loss and/or WLM 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 health-smart behaviour goal. This program was based on standard behavioural treatment approaches for weight loss management programs.[12,23]

2.4 | Statistical analyses

The sample size needed was calculated using the method proposed by Donner and Klar.[24] Based on this calculation, a sample size of 500 would be needed to detect an effect size of 0.39 with 80% power and a 5% significance level to detect a 5-pound (2.27 kg) change in weight from 6 to 18 months. Assuming a 25% dropout rate per clinic, it was determined that 680 participants would be enrolled.

An intent-to-treat analysis was used. Missing weight data were multiply imputed for the full sample of participants who provided weight data at baseline. The imputation model reflects all participants and not just those participants who returned after baseline data were collected. One hundred imputed data sets were generated. The results from the 100-imputed pooled data set using Rubin's method were used to address each hypothesis and research question.[25]

The analysis to address Hypothesis 1 was conducted using a paired samples *t*-test. The dependent variable was weight in pounds. To determine the significance of the number of participants who achieved +5% weight loss from baseline to 6 months, a confidence interval (CI) of the proportion was used. A dichotomized dependent variable was used where 0 indicated that the participant did not achieve +5% weight loss and 1 indicated that the participant achieved +5% weight loss.

The analysis to address Hypothesis 2 was conducted using a multilevel logistic regression with participants nested within the clinic. A dichotomized dependent variable was used where 0 indicated that the participant gained more than 1 pound (0.45 kg) between 6 and 18 months (i.e., did not maintain weight loss) and 1 indicated that the participant gained less than 1 pound (0.45 kg) or continued to lose weight between 6 and 18 months (i.e., maintained weight loss). This criterion was used because there is no universally recognized definition of WLM and 1 pound (0.45 kg) would represent 100% WLM (accounting for minor fluctuations in water weight). Similar studies were considered successful if participants retained 80% or more of initial weight loss.[26–28] The independent variable was the WLM group (i.e., the PCCS-WLM group or the SB-WLM group). The analysis to

address the second research question used a 95% CI of the mean to examine the difference in weight in pounds between the PCCS-WLM and SB-WLM groups.

3 | RESULTS

3.1 | Description of the study sample

Data on the participants' characteristics at baseline are presented below in Table 1. There were no baseline group differences between the PCCS-WLM group and the SB-WLM group with regard to age, education and income. The observed intra-cluster correlation coefficient (ICC) in the analysis population was 0.03 for the full occasion by group model across all occasions. The ICC for baseline was 0.02, 6 months was 0.00, and 18 months was 0.01.

TABLE 1 Participant characteristics at baseline

	SB-WLM ($n = 332$)	PCCS-WLM ($n = 351$)
Age (years)	51.52 (SD = 12.06)	52.46 (SD = 12.32)
Range	21–82	22–88
Education (%)		
Less than high school	4.8	3.7
High school	25.3	30.2
More than high school	55.1	57.8
Missing	14.8	8.3
Income (%)		
$39 999 or lower	47.6	47.5
$40 000+	34.0	37.1
Missing	18.4	15.4
Employment (%)		
Part-time	8.7	6.8
Full-time	37.5	43.6
Unemployed but looking for a job	5.4	5.6
Do no work (e.g., retired, disabled)	35.8	36.2
Missing	14.5	8.3
Number of adults in household (%)		
1	31.2	34.2
2	36.4	35.6
3	13.0	17.4
4	3.3	3.1
5	1.8	1.1
6+	0	0.3
Missing	14.2	8.3

Abbreviations: PCCS-WLM, Patient-Centered Culturally Sensitive Weight Loss Maintenance; SB-WLM, Standard Behavioural Weight Loss Maintenance.

Hypothesis 1. Mean weight for all participants decreased from 240.1 pounds (SEM = 1.83, kg = 108.9) to 237.4 pounds (SEM = 1.99, kg = 107.7) from baseline to 6 months. The change of 2.7 pounds (SEM = 0.88, kg = 1.2) was a decrease of 1.1% and was statistically significant, $t(184) = 3.03$, $p < .01$, 95% CI [0.93, 4.40].

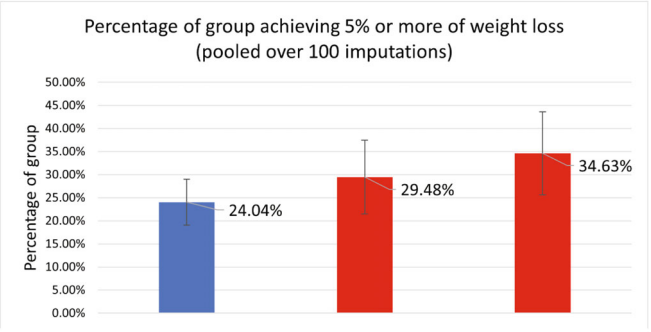
3.2 | Research Question 1

Twenty-four percent of the participants lost +5% of their baseline body weight by 6 months (SEM = 0.002). The number of participants who achieved +5% weight loss by 6 months was significantly different than 0, 95% CI [0.48, 0.64]. In addition, 29.5% of the participants in the SB-WLM Program and 34.6% in the PCCS-WLM Program had lost +5% of their baseline body weight at 12 months after their initial weight loss during the 6-month HSWL Program. The number of participants who achieved +5% weight loss by 18 months was statistically different than 0, 95% CI [0.29, 0.30] for participants in the SB-WLM Program and 95% CI [0.34, 0.35] for participants in the PCCS-WLM Program.

Hypothesis 2. Although the PCCS-WLM group had about 1.59 times (Exp[B] = 1.59) higher odds of achieving WLM compared to the SB-WLM group from month 6 to month 18, this difference was not significant, $B = 0.47$, standard error = 0.30, $p = .125$, 95% CI [−0.22, 1.15]. See Figure 2.

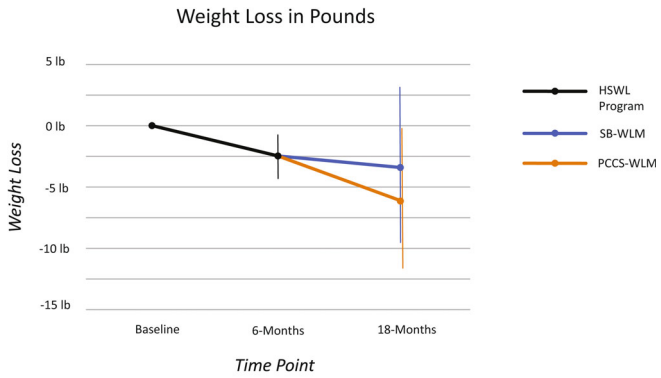
3.3 | Research Question 2

The PCCS-WLM group had a significantly lower weight at 18 months than the SB-WLM group ($p < .05$). At 18 months, the mean weight for the PCCS-WLM group was 231.9 pounds (SEM = 2.96, kg = 105.2)



Note: SB-WLM: standard behavioral weight loss maintenance program; PCCS-WLM: patient-centered, culturally sensitive weight loss maintenance program. Results reflect data from 100-imputed pooled data set using Rubin's method.

FIGURE 2 Percent of participants achieving ≥5% weight loss by occasion.



Note: lb = pounds; SB-WLM: standard behavioral weight loss maintenance program; PCCS-WLM: patient-centered, culturally sensitive weight loss maintenance program.

FIGURE 3 Participant weight loss by occasion.

and for the SB-WLM group was 239.4 (SEM = 3.22, kg = 108.6). There was a non-significant difference in mean weight between the PCCS-WLM (235.4 pounds, SEM = 2.63, kg = 106.8) and the SB-WLM (239.5, SEM = 2.84, kg = 108.6) groups at 6 months. See Figure 3.

4 | DISCUSSION

The present study is one of two known clinical trials that have tested the comparative effectiveness of the long-term impacts of two evidence-based lifestyle interventions designed to promote and maintain weight loss among Black women with obesity—a disease that disproportionately impacts these women. This study fills a major gap in existing obesity literature as it addresses the call for such interventions to occur in primary care settings—sites likely used by most individuals, including those who have low incomes.

A key finding in this study was that there was significant weight loss among the participating Black women patients following the CHW-delivered HSWL Program. This finding suggests that CHWs can effectively implement the HSWL Program within community-based primary care sites (i.e., sites based in the community that are outside a hospital setting) and that such implementation can promote weight loss. This finding is novel because although the HSWL Program has previously been shown to be effective in promoting weight loss among a sample composed of primarily Black women,[18] it has not been tested when implemented by CHWs in a community-based primary care site with a sample composed of Black women with obesity. This finding supports a call in the Affordable Care Act for the integration of CHWs in primary care clinics.[13]

Another key finding was that both physician-implemented WLM programs were effective in maintaining weight loss among Black women patients. The physician-implemented SB-WLM Program resulted in approximately 29% of the patients in this program losing +5% of their baseline body weight and the physician-implemented PCCS-WLM Program resulted in approximately 35% of participants in the program losing +5% of their body weight. Together these findings suggest that primary care physicians can be trained to effectively implement WLM interventions for their Black women patients with obesity.

The additional finding that the PCCS-WLM group had a significantly lower weight at month 18 than the SB-WLM group despite no significant differences in weight before implementation of these WLM interventions (i.e., Research Question 2) suggests that the PCCS-WLM Program may have some advantage over the SB-WLM Program in producing weight loss among Black women with obesity. This finding lends support to national calls for patient-centred culturally sensitive health care to help reduce health disparities such as obesity disparities that disproportionately affect Black women.[15,29] This finding is also consistent with the findings from the test of the Patient-Centred Culturally Sensitive Health Care Model, which showed that perceived provider cultural sensitivity directly predicted dietary adherence among African American patients.[29]

4.1 | Study limitations

Although this study has several methodological strengths and important findings, it has two notable limitations. One limitation is that of the 683 Black women patients who enrolled in this study and provided baseline data, only 81.8% participated in the study (i.e., attended any of the intervention sessions in the study). In clinical intervention trials that solely enrolled Black women, dropout rates have ranged from 8% to 43%.[30,31] Some of the reasons given by the women patients in the present study for not participating in the study after enrolment were having moved, not having a babysitter, and having gotten a new job that prevented study participation. Notably, very few of the enrolled women patients (less than 2%) said that they were no longer interested in participating and the remaining women were unable to be reached for further participation. For these reasons, we recommend future weight loss intervention studies include a run-in period so that participants could demonstrate their commitment to the research study, and the ability to complete key aspects of the intervention. Despite the high dropout rate, all participants who provided baseline data were included in the analyses.

The second study limitation is the unknown impact of the COVID-19 pandemic on the effectiveness of the investigated weight loss interventions. It is known from the booster training with the physicians in the present study that because of COVID-19, approximately half of the patients regained some of their lost weight due to not exercising with their friends and/or not going to the food store to buy fruits and vegetables to protect themselves. This pandemic also necessitated changing from in-person delivery of physician-implemented WLM visits to offering telehealth visits. For safety reasons, at the beginning of the pandemic, the WLM visits with the physicians were delayed for 3 weeks while procedures were established to protect patients and providers who wanted to participate in the WLM sessions in person. The patients who chose to participate in the WLM sessions via telehealth had to be coached by the healthcare staff on how to use this modality.

4.2 | Study strengths

The present study had notable strengths. First, a large sample of Black women patients with obesity participated—a group with the highest prevalence of obesity in the United States, but that has been underrepresented in obesity-focused clinical trials. Despite the 1993 National Institutes of Health Revitalization Act, ethnic/racial minorities are still underrepresented in clinical trials.[32,33] The second strength of this study was the long-term (18 months) intervention tested and its included focus on WLM. This is particularly important given much research indicating that weight regains typically occurs following weight loss for 1–5 years.[34] The third strength is that the intervention met the need for an effective systems approach to treating obesity in primary care clinics that include both primary care providers and primary care support (i.e., participation of CHWs in the treatment of obesity).

The present intervention is novel in that it involved a sample of Black women patients with obesity at primary care clinics as intervention recipients, CHWs as weight loss interventionists, and the physicians of the intervention recipients as WLM interventionists. Fourth, this study demonstrated that CHWs can be effective obesity research and intervention partners within primary healthcare sites. These professionals successfully implemented the HSWL Program—a program that produced significant weight loss among the participating Black women patients. Because the Centers for Medicare and Medicaid waives the co-payment for behavioural counselling sessions such as those that constitute the HSWL Program, Medicare and Medicaid patients with diagnosed obesity will have free access to this treatment.

5 | CONCLUSION

This study provides support for using the evidence-based, multi-component, behaviour-focused HSWL Program to treat obesity within primary care clinics and for involving CHWs in the implementation of this program. It is likely that the costs of hiring CHWs to conduct this program will be offset by reducing the downstream high cost of untreated obesity and related diseases such as diabetes, hypertension, heart disease and some cancers. In addition, implementing the HSWL Program through CHWs is a scalable solution—the number of CHWs in the United States is increasing.[35]

The findings of the present study also suggest that primary care physicians can play an important role in promoting WLM among their Black women patients with obesity. However, execution of this role by these providers requires receiving practical training in demonstrating patient-centred culturally sensitive behaviours that are desired by Black women patients with obesity. Finally, the findings of the present study also provide support for further research to evaluate the impact of the PCCS-WLM Program. However, before such research, attention needs to be given to the barriers to study participation. Assessment of these barriers and identification of strategies to overcome them are important steps in obesity intervention research involving Black women patients—a group disproportionately impacted by obesity.

AUTHOR CONTRIBUTIONS

Study concept and design: Carolyn M. Tucker, Stephen D. Anton and Nipa R. Shah. *Funding acquisition*: Carolyn M. Tucker and Stephen D. Anton. *Writing of the original draft*: Carolyn M. Tucker, Stephene D. Anton, Lori A. Bilello and Michael Marsiske. *Writing editors*: Anne Mathews, Fern Webb, Frederic Desmond and Kirsten G. Klein. *Data analyses*: Michael Marsiske, Guillermo M. Wippold, Shiva P. Gautam and Meagan A. Henry.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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