

Outcomes of National Community Organization Cardiovascular Prevention Programs for High-Risk Women

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Abstract The purpose of this study was to reduce cardiovascular disease (CVD) risk in women by implementing a cardiovascular prevention health promotion program in faith- and community-based sites. The primary outcomes were reducing obesity and increasing physical activity. A longitudinal cohort of high-risk (age > 40, ethnic minority) women ($n=1,052$) was enrolled at 32 sites across the USA. The pre- or post-educational intervention consisted of eight biweekly counseling sessions conducted over 4 months each addressing one of six of the major CVD risk factors (smoking, diabetes, hypertension, cholesterol, obe-

sity, and physical inactivity) as well as signs and symptoms of a heart attack and stroke; plus 4–6 maintenance sessions over three additional months. A multifaceted approach delivered by lay and medically trained personnel involving medical screenings, health behavior counseling, risk behavior modification, and stage of change were determined at baseline and end of counseling or maintenance. Following list-wise deletion, data were analyzed on 423 women who completed all follow-up time-points. Overall, significant improvement was attained in most of 28 secondary outcomes but not in the primary outcomes. Knowledge and awareness of heart disease as the leading killer or women, all of the signs and symptoms of a heart attack, calling 911, and CVD risk factors increased significantly ($p < 0.05$) by 8.8%, 13.6%, 5.8%, and 10%, respectively. There was a 10% ($p < 0.05$) increase in participants attaining control for hypertension (blood pressure < 140/90) coupled with a significant reduction in mean blood pressure in the entire cohort. Knowledge of effective CVD risk modification strategies for all CVD risk factors increased significantly ($p < 0.05$), except for obesity. In addition, there were significant ($p < 0.05$) increases in forward movement in stage of change for each CVD risk factor (range +10% to +39%). Thus, a heart disease prevention intervention built around a model of community engagement, advocacy, self-efficacy, resource knowledge, and health promotion in faith- and community-based organizations is successful at improving cardiovascular knowledge and awareness outcomes in high-risk women. Limitations of our study include the high dropout rate, significant time demands on site coordinators, limited resources for program implementation, lack of morbidity and mortality endpoints, and failure to attain the primary outcomes of weight loss and physical activity. Future studies should not only assess the effect of community education interventions on lifestyle change and

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knowledge and awareness of participants but should also address program duration, cost, and resources required to attain improved outcomes.

Keywords Heart Disease · Women · Minority · Prevention · Community-Based · Faith-Based Organization · Education and Awareness

Introduction

Cardiovascular disease (CVD), including heart disease and stroke, is the leading cause of death for women in the USA [1]. Compared to men, women have higher CVD mortality, higher morbidity following a heart attack or stroke, lower awareness of CVD, and a higher prevalence of most major risk factors for CVD. Since 1984, the number of CVD deaths for females has exceeded those for males in the USA [2]. In 2002, about 60,000 more US women died of CVD than men [2], and 38% of women die within 1 year of having a heart attack compared to 25% of men who have heart attacks [1]. Yet, heart disease is largely preventable.

Some experts speculate that the difference in CVD outcomes and risk factor prevalence between women and men may be due, in part, to a lack of awareness among women and their physicians of the risks for CVD in women [3, 4]. A 2003 national survey conducted by the American Heart Association found that 35% of women cite breast cancer as their greatest health threat while only 13% of women believe that their greatest health threat is heart disease [5]. However, more women die of heart disease than of all cancers combined. Furthermore, although awareness over time has improved slightly, the majority of women fail to identify the risk factors for heart disease, such as high blood pressure and high cholesterol [5]. Yet, more women than men in the US have the five major risk factors for CVD: high blood pressure, high cholesterol, type 2 diabetes, physical inactivity, and obesity [2]. Thus, a key to prevention in women is increased awareness of risk.

The issues attributing to women's increased CVD risk pertain to factors that relate to more than knowledge and awareness of threat. Health professionals and women need education on heart disease risk and its symptomatology [4–7]. The most common heart attack symptoms in women differ from those in men, and women are more likely than men to experience “atypical” symptoms [8]. Ethnic minority women have greater lack of heart disease symptom awareness and of the risk factors that predominate in ethnic or racial minority groups than white women [4, 9]; therefore, greater education is needed in this area as well.

The need to improve preventive interventions and messaging is even greater for women over the age of 40,

particularly those in underrepresented groups [10]. A woman's risk of CVD starts to rise between the ages of 40 and 60; thus, behavioral modification programs that target women aged 40 years and older have the potential to prevent CVD and its risk factors including obesity, hypertension, high LDL cholesterol, and type 2 diabetes that often develop around the ages of 40 to 60 [10]. Thus, women aged >40 are a high-risk group. In addition, because African-American women have the highest age-adjusted heart disease and stroke death rates of any female race or ethnicity group in the USA [10], a higher prevalence of many major risk factors for CVD [2, 11, 12], and lower awareness of CVD threat, this group of women stand to gain significantly from modalities designed for prevention and risk reduction. Health disparities in racial or ethnic minority groups have inspired researchers and health practitioners to address the disproportionate high morbidity and mortality rates from CVD in these groups.

Targeted CVD behavioral modification interventions, including those in community settings and those incorporating counseling efforts, have been successful in modifying cardiovascular risk behaviors in women [13–17]. However, risk behavior modification that translates knowledge into practice is pivotal to achieving improved health outcomes. Particularly effective strategies for modifying CVD risk behaviors of women include attention to stage-of-change, physical activity, process variables, community participation or social networks, empowerment, and communitywide counseling program [15, 18–27]. The Centers for Disease Control and Prevention's Racial and Ethnic Approaches to Community Health (www.cdc.gov/reach) aims to address the Healthy People 2010 goal of eliminating health disparities among segments of the population, utilizing a model with demonstrated effectiveness for health promotion in a number of settings [28].

With this foundational evidence, the purpose of the present CVD prevention study was to design and implement a pre/post educational intervention with the primary goal of reducing CVD risk in high-risk women in community- and/or faith-based sites across the USA through a multifaceted approach involving medical screenings, health behavior counseling and risk behavior modification. The heart disease prevention activities were built around a model of community engagement, advocacy, self-efficacy, resource knowledge, and participant education. We hypothesized that a cardiovascular disease prevention program targeting high-risk women and implemented in local community networks would enhance knowledge and awareness of heart disease and its attendant risk factors, reduce cardiovascular risk, change attitudes, promote physical activity, and help women establish or maintain a healthy weight.

Methods

Performance Sites

This study was sponsored by the US Department of Human Health Services, Office on Women's Health (DHHS-OWH) through a competitive award mechanism. Four lead sites were selected. Each was either a national faith-based or national community organization having a network of at least 10 sites across the USA with large populations of high-risk women (defined as racial and ethnic minority women, aged 40 years and older) or partnered with a national faith-based or national community organization having such a network. Two of the lead sites were academic medical centers and two were nonacademic institutions. A brief description of each lead site is provided below. A listing of the 32 community- and faith-based affiliated partner sites is summarized in Table 1.

The Association of Black Cardiologists The Association of Black Cardiologists (ABC), a nonprofit organization founded in 1974, conducts continuing medical education for physicians, community-based interventions for patients, screenings for cardiovascular disease, and advocates for health policy to effect improvement in community well-being. For this study, ABC worked in partnership with the United Church of Jesus Christ.

The Black Women's Health Imperative The Black Women's Health Imperative (The Imperative), formerly the National Black Women's Health Project, a national nonprofit 501(c)(3) organization founded in 1983, advocates for women's health and leadership development and is devoted solely to ensuring optimum health of Black women and girls. Consistent with a self-help or care approach, the Imperative has a network of 40 affiliated organizations and community-based field offices across the country for actively engaging

Table 1 Community- and faith-based study sites

Study lead sites	ABC	The Imperative	RCSHD	UC Davis
Participating partner community and faith-based sites				
Baltimore, MD: Transformation Ministries of UCJC		Turner Chapel AME Church; Marietta, GA Sigma Mu Zeta–(Zeta Phi Beta); Marietta, GA	Seattle, WA: St. Andrew Kim Church	Eastern Shore, NY
Yemassee, SC: Family Worship Center (Apostolic)		Center for Black Women's Wellness; Atlanta, GA Atlanta Chapter Mocha Mom; Atlanta, GA	Lodge Grass, MT: Our Lady of Loretto Church	Fresno, CA
Lakeland, FL: Greater Faith Christian Center, 1st Pentecostal Apostolic Church, Inc		New Covenant AME Church; Charlotte, NC	Carthage, MO: Grace Episcopal Church	Phoenix, AZ
Yonkers, NY: United Church of Jesus Christ		Delta Zeta (Zeta Phi Beta); Charlotte, NC	Detroit, MI: Most Holy Redeemer	Prince Georges County, MD
Spring Lake, NC: The Soul Harvest Apostolic Church		Chicago Chapter, Mocha Moms; Chicago, IL Tau Xi Zeta (Zeta Phi Beta); Chicago, IL	St. Louis, MO: Centennial Christian Church	Sacramento, CA
Decatur, GA: Kingdom Building Worship Ministries		Mt. Calvary AME; Towson, MD	Buffalo, NY: Mt. Olive Baptist Church	Selma, AL
Orange, NJ: 1st United Tabernacle Church		Lambda Pi Zeta (Zeta Phi Beta); Carson, CA Auxiliary: Carson Zeta Amicae (Zeta Phi Beta); Carson, CA Grant AME Church; Los Angeles, CA	Atlanta, GA: Atlanta Intercultural Ministries, Inc.	Shelby County, TN
Randallstown, MD: Set the Captives Free		AME Union Church; Philadelphia, PA	Ypsilanti, MI: Brown Chapel A.M.E. Church	Windy City, IL
Columbia, SC: Rehoboth United Apostolic		Philadelphia Chapter, Mocha Moms	Cleveland, OH: La Sagrada Familia	–
Gwynn Oak, MD: Mount Olive Holy Evangelical		Beta Delta Zeta; Philadelphia, PA	–	–

N/A site dropped out or declined to participate, *UCJC* United Churches of Jesus Christ, *ABC* Association of Black Cardiologists, *The Imperative* Black Women's Health Imperative, *RCSHD* Research Center for Stroke and Heart Disease, *UC Davis* University of California, Davis Women's Cardiovascular Medicine Program, *AME* African Methodist Episcopal Church Connectional Health Commission, *CBWW* Center for Black Women's Wellness; *MM* Mocha Moms, Inc.; *ZETA* Zeta Phi Beta Sorority, Inc.

Black women in their personal health and wellness. For this study, the Imperative established partnerships with the African Methodist Episcopal Connectional Health Commission, Center for Black Women's Wellness, Mocha Moms, Inc., and Zeta Phi Beta Sorority, Inc.

Research Center for Stroke & Heart Disease The Research Center for Stroke & Heart Disease is a 501(c)(3) organization founded in 1997, a division of the Jacobs Neurological Institute at the State University of New York at Buffalo. The entirely grant funded organization was established to raise awareness of and prevent stroke and heart disease in communities. The Center designs, implements, and evaluates studies to educate individuals and motivate them to adopt practices effective in reducing risk factors. The Center employs several fulltime and part-time staff and contractors with expertise in health care management, epidemiology, communications, and computer programming. Staff engage in grant writing; study or project design, implementation, and evaluation; health research and epidemiological surveillance/profiling; data collection, management, and analysis; and disseminating results. The Center is the go-to organization for regional and statewide stroke and heart disease death and prevalence statistics and associated risk factors. For this study, the RCSHD partnered with a number of faith-based sites around the country selected on the basis of their CVD risk and ethnic and geographic diversity.

University of California, Davis Women's Cardiovascular Medicine Program The Women's Cardiovascular Medicine Program at the University of California, Davis was established in 1994 as one of the first women's heart programs in the country. The program is under the dual umbrella of the UC Davis Health System's Heart Center and the Department of Internal Medicine in the School of Medicine. The comprehensive and interdisciplinary program focuses on providing state-of-the-art cardiovascular health care and prevention for women through advocacy, clinical care, education, and community engagement. The program also fosters and conducts research that addresses women's heart health issues and gender differences in heart disease utilizing basic science, translational, and epidemiological approaches. For this study, the University of California, Davis partnered with The Links, Inc., a national nonprofit community organization of professional African-American women involved in volunteer community work to favorably influence life course in African-American communities.

Participants and Recruitment

This was a longitudinal pre- or post-educational health promotion intervention study conducted between September 2006 and May 2008. Participants were recruited as a

cohort between January 2007 and June 2007 from the participating faith-based groups and national community organization sites. Each lead site selected a minority population group of women based on the organization's history of prior collaboration, direct programmatic delivery with the selected organization or group, or national needs assessment focused on CVD risk, ethnic diversity, and geographic dispersion. Recruitment strategies included program and church announcements and advertisements, pastor speaking guides, flyers, organization chapter meetings, website announcements, word of mouth, and encouragement from other members. The study site leaders used their congregations, local social ties, and networks to recruit and retain women in the study. Study women were a part of the communities the organizations served or were affiliated with the local chapter, church, or community organization. The study population included high-risk women (racial and ethnic minority women aged 40 years and older); however, all high-risk women were eligible to participate in the program regardless of race, religion, or age. Participants were given incentives during the intervention to encourage continued participation (e.g., pedometers, heart healthy cookbooks, red dress pins, etc.). The Human Subjects Review Panels of each of the lead study site organization or institutions approved this study, and all participants provided informed consent.

Program Implementation and Study Design

Each lead site implemented one program in partnership with up to ten faith- and/or community-based partner sites across the USA. There were four phases to program implementation: Phase I—Program Planning, Development, and Recruitment; Phase II (4 months)—Counseling Sessions; Phase III (3 months)—Maintenance Sessions; and Phase IV—Program Evaluation/Write-Up. The total study performance period was 18 months. The total period of intervention was 7 months. Each phase of implementation is briefly summarized below.

Phase I—Program Planning, Development and Recruitment An orientation meeting was held in Washington, DC with the PIs of each lead site, senior-level project managers, and the Office on Women's Health project manager to clarify tasks and requirements, answer questions, and ensure uniform implementation of the program. Lead sites worked collectively on a standard survey assessment instrument used to collect data from all participants. The survey instrument assessed demographic, clinical parameter, health history, health behavior, and knowledge and awareness variables. Each lead site formed a multidisciplinary planning committee for consultation in designing the educational seminars, ensuring cultural appropriateness, and to assist with

identifying site leaders (typically a faith-based or community leader or a health professional affiliated with the individual sites). Site leaders were trained on the intervention via a required 1-day training course, developed and administered by the lead site. Site leaders were charged with recruiting participants from their organizations, churches, and local communities, enrolling participants and administering informed consent, and encouraging participant retention in the program. The program was delivered at each site by the site leaders and incorporated qualified cardiologists, endocrinologists, nurses, dietitians, physical exercise, and other health professionals in the development and/or implementation of the curriculum and small group discussions.

The lead sites assisted site leaders in compiling a local directory of cardiovascular resources (cardiologists, dietitians, diabetes experts, weight loss and exercise programs, public health screening, and diagnosis information) available in the community of each site, including health-care alternatives for the uninsured and underinsured women. Each lead site prepared a site leader manual and toolkit to implement the cardiovascular program in their community. Lead sites established a website or enhanced an existing organization's website to provide cardiovascular support and information online unique to their geographical location and population group. Websites were linked to the DHHS/OWH "For Your Heart" website (<http://www.4women.gov/hhs>) and to the National Heart Lung and Blood Institute's "Heart Truth" campaign website (<http://www.nhlbi.nih.gov/health/hearttruth/>). Additional materials used to promote the program, provide additional cardiovascular disease information, and highlight progress made by individual sites and participants included a print and/or web-based newsletter distributed to all partnering sites and participants.

Phase II—Counseling Sessions Each faith- or community-based site conducted eight biweekly group counseling sessions over a period of 4 months. The sessions lasted 90–120 min each and were located at the faith- or community-based site or at other appropriate clinical facilities in the community. Each session addressed one of the six major risk factors for CVD (smoking, diabetes, hypertension, cholesterol, obesity, and physical inactivity), ways to modify risk, and the benefits associated with risk modification. In addition, stress prevention and the signs or symptoms of heart attack and stroke in women were addressed during at least one of the eight group counseling sessions. Sessions included interactive and clinical lectures, health demonstrations, video presentations, personal testimonies, and other heart healthy activities. Additional activities during counseling sessions included pre- and post-knowledge tests, medical screenings, and low to

moderate physical activity (dancing, walking, chair exercises, yoga, or aerobics). Participants were encouraged and organized to also meet in groups at least once a week to engage in some form of moderate intensity physical activity. Each counseling session also included small group discussion focused on encouraging participants to incorporate weight control strategies and physical activity into their daily lives. Participants were encouraged to use self-monitoring tools (logs, journaling, health passports) and establish lifestyle change goals. Participant attendance at each session was encouraged by the site leader, group members, and/or a buddy system and varied from 100% to approximately 50–75% depending on the session and time of year.

Before the first counseling session (baseline), participants were screened for all six major CVD risk factors and assessed their CVD risk profile and stage of change via a pretest with a self- or interviewer-administered survey. During the last counseling session, participants performed the same screenings and assessments as at baseline using a post-test identical to the baseline survey. Screenings included height, weight, body mass index (BMI), systolic and diastolic blood pressure, and fasting blood tests for total cholesterol and blood glucose. Community partners (city and county health departments, community health clinics, recharge labs) assisted each site with the screenings.

Phase III—Maintenance Sessions The maintenance sessions directly followed the group counseling sessions and lasted for an additional 3 months. The purpose of maintenance was to provide program participants additional time in counseling, motivate participants to meet personal goals established at the onset of the program, and help "maintain" healthy lifestyle practices achieved during the counseling sessions. Site leaders and participants decided themselves on the number, frequency, and format of the maintenance sessions which included any or all of the following activities: additional group counseling seminars, screenings, testimonials, personal counseling, field trips (fitness centers, grocery stores, restaurants to practice selecting healthy foods), etc. Each session typically lasted 90–120 min and included a physical activity and a small group discussion component. During maintenance participants were encouraged to continue to organize and to meet in smaller groups at least once a week to engage in some form of physical activity. Participant attendance was encouraged as for counseling sessions and varied from 100% to approximately 50–100% depending on the time of year.

At the end of the maintenance sessions, participants were screened again for all six major CVD risk factors and self-assessed their own personal CVD risk profile and stage of change. Participants performed the same screenings and

assessments as at end of counseling using a post-test identical to the end of counseling and baseline survey.

Phase IV—Program Evaluation Data were also obtained from self-monitoring materials and from feedback and evaluation forms.

Outcome Variables and Metrics

A total of 28 outcomes or sub-outcomes were evaluated. The primary outcomes (reducing obesity and increasing physical activity) and major secondary outcomes for the study are summarized in Table 2. In selecting program outcomes, emphasis was placed on aligning objectives and targets with those of Healthy People 2010 (<http://www.health.gov/healthypeople>). Knowledge and awareness about heart disease and its symptoms, knowledge of cardiovascular health status and cardiovascular risk factors, knowledge of effective interventions for risk factor modification, and clinical parameters were all assessed. Each lead site designed a local database for the purpose of collecting and entering participant data from its affiliated

Table 2 Primary and secondary outcomes assessed in response to the cardiovascular disease prevention intervention

Primary outcome measures

Decrease the proportion of women who are obese (BMI \geq 30 kg/m²)

Increase the proportion of women who engage regularly (at least 30 min/day) in moderate physical activity (outside of program sessions)

Secondary outcome measures

Decrease the proportion of women who smoke cigarettes

Increase the proportion of women with diabetes at baseline whose diabetes is under control (FBS \leq 125 mg/dl)

Increase the proportion of women with high blood pressure at baseline whose blood pressure is under control (SBP \leq 140 mmHg, DBP \leq 90 mmHg); (SBP \leq 120 mmHg, DBP \leq 80 mmHg)

Decrease the proportion of women with high total blood cholesterol (>240 mmHg; >200 mmHg)

Increase the proportion of women who are aware that heart disease is the #1 killer of women

Increase the proportion of women who are aware of the early warning symptoms and signs of a heart attack and the importance of accessing rapid emergency care by calling 911

Increase the proportion of women who know all of the major risk factors for CVD (overweight, physical inactivity, smoking, diabetes, blood pressure, cholesterol)

Increase the proportion of women who know how to modify the major risk factors for CVD (overweight, physical inactivity, smoking, diabetes, blood pressure, cholesterol)

For each CVD clinical risk factor (overweight, physical inactivity, smoking, diabetes, blood pressure, cholesterol), move 50% of women forward at least one Stage of Change

sites. Data confidentiality was kept through the use of unique numeric identifiers.

Data Coordinating Center, Data Management, and Data Analysis

The RCSHD performed all data and statistical analyses for this study on data collected at each of the study time points (baseline, end of counseling session, and end of maintenance) using a predefined data dictionary. Data were analyzed using SPSS (version 15.0 for Windows; SPSS Inc., Chicago, IL). The program evaluation was established to demonstrate, at minimum, the primary and secondary outcome measures and the overall effectiveness of the program. For all analyses, a list-wise deletion was performed and only participants with data at all three data collection periods were included in the longitudinal analyses ($n=423$). The number of women, for whom there was a complete dataset, the number for whom there was not, and the percentage of women with incomplete data, is provided in Table 5.

For normally distributed variables, arithmetic means and SDs were calculated. For categorical variables, frequencies, and proportions were calculated. The three time points were treated as a within-participants factor (effect over time). Survey answers were recoded to reflect presence or absence of knowledge/health state/behavior (e.g., 0—does not know all symptoms for heart attack, 1—knows all symptoms for heart attack). Frequency tables were generated for demographic, clinical, and knowledge variables as well as subgroups (age, race or ethnicity, education, site, etc.), and the proportion of participants in each knowledge, health state, or behavior was calculated. Difference in proportions across time were calculated for end of counseling and baseline, end of maintenance and baseline, end of maintenance, and end of counseling. Due to the repeated design of the study, difference scores were subjected to a two-tailed paired t test to assess for significant differences from zero. For stages of change, differences in proportion across time were directly calculated. For each participant, forward movement was coded as +1 and lack of forward movement was coded as 0. Coding reflected a count of the number of participants with forward movement between two study time periods. For each time period, the proportion of participants was calculated and analysis performed by assessing “differences in proportions” for a health behavior (e.g., increase in the proportion of women moving forward one or more stages of change for a health behavior). For interval scaled questions, when participant answers were provided on Likert scales, the mean values were subjected to repeated measures ANOVA. The Bonferroni correction was used for multiple comparisons. All statistical significance tests were at $\alpha=0.05$ level.

(B) knowledge and awareness was lowest for two of the five outcomes (all symptoms of MI, and all symptoms of MI + calling 911 (9.1% and 9.8%, respectively), and highest for the three remaining outcomes. There were significant ($p < 0.05$) gains in knowledge for all outcomes at the end of the counseling sessions (plus 8.8%, 13.6%, 5.8%, 12.4%, and 10%) for knowledge of heart disease as the leading killer of women, all symptoms of a heart attack, calling 911, all

symptoms for heart attack + calling 911, and all CVD risk factors, respectively (Fig. 2). The gains persisted into the end of maintenance for all outcomes. However, during maintenance, knowledge and awareness increased further and significantly ($p < 0.05$) for the three of the knowledge and awareness outcomes: heart disease as the leading killer, all symptoms of MI, and all symptoms of MI+ calling 911 by an additional 1.5%, 7.6%, and 8.3%, respectively (Table 5).

Table 3 Demographics of the study population at baseline

Characteristic	Lead study site				
	Total cohort, % enrollees	ABC	The Imperative	RCSHD	UC Davis
Demographics, no.	(<i>n</i> =1,052)	254 (24%)	226 (21.5%)	246 (23.4%)	326 (29.9%)
Age, years					
<40	13.1	22.4	19.9	12.2	8.6
40–60	51.4	42.4	54.4	60.2	50.5
>60	25.5	18.4	19.9	28.3	33.6
Race					
Caucasian (non-Hispanic)	3.8	0.3	0.0	15.2	0.3
Black (non-Hispanic)	72.7	75.7	90.7	30.9	92.1
Asian/Pacific Islander	1.9	0.3	0.0	7.8	0.0
American Indians/Alaska natives	2.7	1.3	0.4	9.3	0.0
Other	6.9	0.7	0.4	26.8	0.0
Unknown/Missing	11.6	21.4	8.0	10.0	6.4
Ethnicity					
Hispanic	14.7	4.3	3.9	46.4	1.0
Non-Hispanic	84.0	91.4	94.4	53.2	96.9
Education					
Some high school or less	8.9	8.2	1.8	21.6	4.0
High school graduate	10.5	11.8	8.3	16.7	4.9
Some college, vocational, or technical school	23.2	28.6	24.8	22.7	17.4
College graduate	21.1	15.8	26.1	15.6	27.0
Post-graduate	22.2	9.9	28.3	11.5	38.2
Unknown/missing	13.8	25.0	9.73	10.8	7.3
Health insurance status					
Medicaid or state	6.2	7.6	4.0	8.9	4.3
Medicare	14.7	14.1	11.1	16.7	15.9
HMO or other commercial	49.0	36.2	62.0	33.5	64.8
Disability	1.6	2.3	1.8	1.1	1.2
Private pay	9.2	8.2	7.1	8.6	12.2
None	12.4	12.2	10.2	26.8	2.5
Other	6.7	4.9	7.1	9.7	5.5
Unknown/missing	1.2	2.6	0.4	1.5	0.0
Socioeconomic status (income/year)					
Up to \$19,999	9.9	10.2	7.5	20.8	2.5
\$20,000–39,999	16.1	18.8	16.4	20.8	9.5
\$40,000–74,999	21.7	18.8	25.7	17.1	25.4
≥\$75,000	21.7	10.5	27.9	6.7	40.1
Unknown/missing	21.9	34.9	13.3	23.4	14.4

Table 4 Baseline cardiovascular risk profile of the study population

Characteristic (risk variable)	Baseline (n=1052) % Enrollees
Diabetes mellitus (self-report)	15.5
Pre-diabetes	17.7
FBS \geq 126 mg/dl	8.7
Hypertension (self report)	42.0
SBP \geq 140 or DBP \geq 90, mmHg	33.8
SBP \geq 120 or DBP \geq 80, mmHg	73.2
Pre-hypertensive (self-report)	20.4
Prescribed medication for HBP (self-report)	40.9
Hypercholesterolemia	
TC $>$ 240 mg/dl	5.8
TC $>$ 200 mg/dl	25.3
Obesity	
BMI \geq 30 kg/m ²	38.4
Mean BMI (kg/m ²)	32.2
Physical activity (self-report)—days/week	
\leq 2 days	30.6
3–4 days	24.7
\geq 5 days	28.6
Smoking (self-report)	
Everyday	4.0
Some days	1.5
Family History (self-report; early onset CVD in mother, sister, brother, or father)	40.5
Heart disease (self-report)	
CHF	2.6
CAD	3.0
Myocardial Infarction	2.8
Angina	3.8
Stroke (self report)	2.5

HBP high blood pressure, *FBS* fasting blood sugar, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *TC* total cholesterol, *HDL* high density lipoprotein cholesterol, *BMI* body mass index, *CHF* congestive heart failure, *CHD* coronary heart disease, *CAD* coronary artery disease, *CVD* cardiovascular disease

Effect of the Intervention on Risk Factor Control

At baseline, there was substantial variation in the degree of control of each of the six major CVD risk factors: diabetes, hypertension, obesity, smoking, cholesterol, and physical activity (Fig. 3). At baseline, a greater percentage of participants had their diabetes, hypertension, and obesity controlled (67%, 52%, and 57%, respectively), than smoking or cholesterol. As a result of the counseling intervention, and compared to baseline, there was a significant ($p<0.05$) 10% increase in the percent of participants who attained improved control for hypertension (blood pressure $<$ 140/90 mmHg). This improvement

was not due to chance as statistical significance was confirmed following correction for multiple comparisons (Bonferroni). Interestingly, following the maintenance phase, the proportion of women who engaged regularly, preferably daily, in moderate physical activity for at least 30 minutes per day dropped by 7.4% ($p<0.005$ following Bonferroni correction).

However, compared to baseline, there were no significant increases in control for any of the other risk factors by the end of counseling or the end of maintenance, although there were declines in the percentage of smokers and those with high cholesterol.

Effect of the Intervention on Knowledge of CVD Risk Modification

We evaluated the participant's knowledge of CVD risk factor modification strategies for hypertension, cholesterol, smoking, diabetes, physical activity, and obesity (Fig. 4). Baseline knowledge of CVD risk modification strategies was, overall, high for each risk factor. Knowledge of modification strategies was lowest for cholesterol and highest for obesity (53% and 93%, respectively). Compared to baseline, knowledge of effective CVD risk modification strategies for all CVD risk factors increased significantly ($p<0.05$) following the counseling phase, except for obesity. The changes in knowledge that were attained at the end of counseling continued during the maintenance phase for hypertension and physical activity were maintained for the other risk factors and were unchanged from baseline for obesity.

Effect of the Intervention on Readiness for Cardiovascular Risk Behavior Change

The proportion of women who moved forward one or more stages of change for a given health behavior was assessed for diet, weight, physical activity, smoking, blood pressure, cholesterol, and diabetes. Compared to baseline, and corrected for multiple comparisons, there was a significant ($p<0.05$) increase in forward movement in stage of change between baseline and end of counseling in the study participants (Fig. 5). The increase in forward movement for stage change varied from +24% to +37% for six of the risk factors (diet, weight management, physical activity, blood pressure, cholesterol, and diabetes). Although the increase in forward movement was the lowest (10% increase) for smoking, the change was statistically significant compared to baseline. The forward movement in stage of change continued during the study maintenance phase and was significant compared to baseline for diet, physical activity, and diabetes, reached a plateau for weight and smoking, and significantly decreased during maintenance

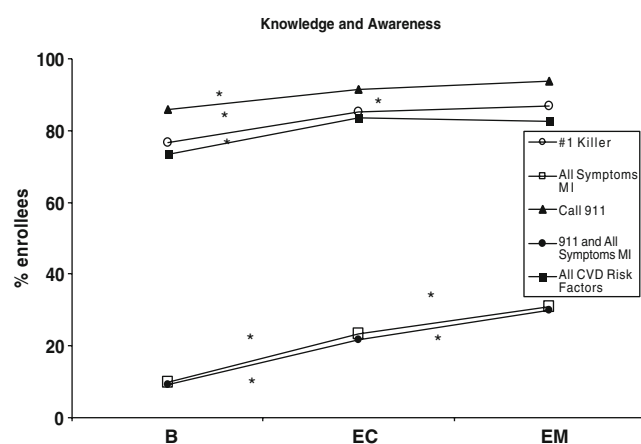


Fig. 2 Effects of the intervention on knowledge and awareness of heart disease for participants who completed all assessments. Cardiovascular outcomes (proportion of women) at baseline (B), end of counseling (EC), and end of maintenance (EM) for women enrolled in the study. All comparisons are paired (pre- or post-intervention) for women with data at all three time points. Knowledge and awareness outcomes were assessed as follows: heart disease as the #1 killer of women; all symptoms of a myocardial infarction (MI); calling 911; all symptoms of MI and calling 911; and all of the major cardiovascular disease (CVD) risk factors (diabetes, high blood pressure, high cholesterol obesity, physical inactivity, and smoking). Statistically significant changes (* $p < 0.05$) for comparisons of B to EC and EC to EM are noted

for blood pressure and cholesterol. Compared to baseline, the greatest relative increase for stage change at each of the intervention time points occurred for physical activity with 37% and 39% of participants moving forward at least one stage of change by end of counseling and end of maintenance, respectively.

Effect of the Intervention on Clinical Variables

The effect of the community-based cardiovascular disease prevention intervention was assessed for a number of clinical parameters: weight, BMI, SBP, DBP, fasting total cholesterol, and fasting blood glucose (Fig. 6). At baseline, the mean weight and BMI of study participants was 189.3 lbs and 32.1 kg/m², respectively. Therefore, this was an obese cohort. The mean systolic and diastolic blood pressure of study participants was 130.6 and 79.6 mmHg, respectively. Mean fasting total cholesterol and blood glucose were 190.2 and 101 mg/dl, respectively. During the intervention, there was a small improvement in all clinical parameters, though the changes were not statistically significant following the counseling or maintenance phases, with one exception: compared to baseline, there was a significant ($p < 0.05$) reduction in systolic blood pressure to a mean systolic pressure of 127.9 mmHg at the end of the maintenance phase.

Table 5 Participant follow-up for study outcomes

	Women with follow-up	Women without follow-up	Missing at follow-up (%)
Knowledge and awareness			
#1 Killer	423	614	59.2
All symptoms MI	265	772	74.4
Call 911	395	642	61.9
911 and all symptoms MI	241	796	76.8
All CVD risk factors	332	705	68.0
Risk factor control			
DM control	396	641	61.8
HTN control (<140/90)	219	818	78.9
HTN control (<120/80)	219	818	78.9
Obesity control	397	640	61.7
Physical activity	461	576	55.5
Smoking control	94	943	90.9
Cholesterol (>240)	388	649	62.6
Cholesterol (>200)	388	649	62.6
Risk factor knowledge			
HTN	386	651	62.8
DM	419	618	59.6
Smoking	356	681	65.7
Cholesterol	416	621	59.9
Physical activity	403	634	61.1
Obesity	422	615	59.3

Discussion

The goal of this study was to implement and evaluate outcomes for CVD risk knowledge and awareness, health state for clinical CVD risk factors, and behavior change in high-risk ethnic minority women during a total 7-month faith- and/or community-based CVD prevention intervention consisting of counseling and maintenance periods. Our results show that the program, delivered by both lay faith- and community-based site leaders and health professionals, was overall very effective in achieving the proposed goals. Study participants made improvements in essentially every secondary outcome of the study, with over half of outcomes showing statistically significant gains compared to baseline. Although most of the gains were attained at the conclusion at the 4-month counseling phase, additional gains were realized in the subsequent 3-month maintenance phase.

In terms of the specific study outcomes, the program was very successful in increasing knowledge and awareness of all of the heart disease awareness outcomes and in increasing knowledge and awareness of successful cardiovascular risk factor modification interventions for nearly all of the cardiovascular risk factors. It was also very effective

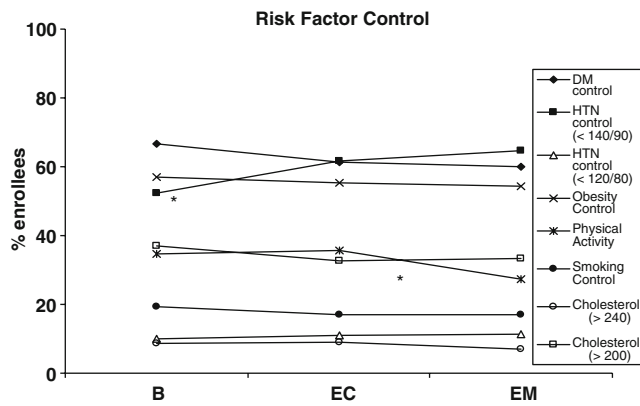


Fig. 3 Effects of the intervention on control of cardiovascular risk factors for participants who completed all assessments. Cardiovascular outcomes (proportion of women) at baseline (B), end of counseling (EC), and end of maintenance (EM) for women enrolled in the study. All comparisons are paired (pre- or post-intervention) for women with data at all three time points. Control of cardiovascular risk factors were assessed for each of the following: diabetes (diabetics with fasting glucose ≤ 125 mg/dl), hypertension (HTN; hypertensives with blood pressure $<140/90$ mmHg; blood pressure $<120/80$ mmHg), high total cholesterol (TC) (TC >240 mg/dl and TC >200 mg/dl), obesity (BMI <30 kg/m²), physical activity (regular, preferably daily, moderate physical activity for at least 30 min/day), and smoking (current smokers). Statistically significant changes ($*p<0.05$) for comparisons of B to EC and EC to EM are noted

in helping participants move forward at least one stage of change for nearly all cardiovascular risk factors. In terms of risk factor control, the program was most successful in attaining control of systolic hypertension over a 7-month

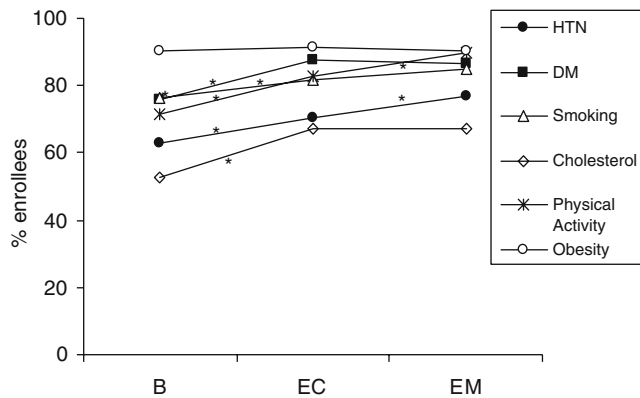


Fig. 4 Effects of the intervention on knowledge of cardiovascular risk modification for participants who completed all assessments. Cardiovascular outcomes (proportion of women) at baseline (B), end of counseling (EC), and end of maintenance (EM) for women enrolled in the study. All comparisons are paired (pre- or post-intervention) for women with data at all three time points. Knowledge of effective cardiovascular risk modification interventions (e.g., utility of decreased sodium intake for blood pressure control, utility of decreased fat intake for control of high cholesterol, etc.) were assessed for each of the following risk factors: diabetes (DM), hypertension (HTN), high cholesterol, obesity, physical inactivity, and smoking. Statistically significant changes ($*p<0.05$) for comparisons of B to EC and EC to EM are noted

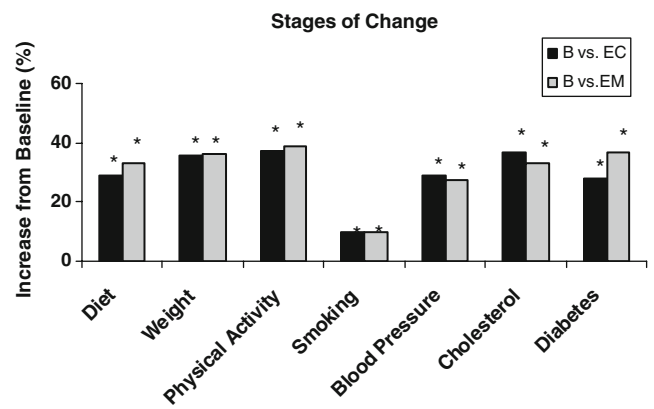


Fig. 5 Effects of the intervention on stages of change for cardiovascular risk factors for participants who completed all assessments. Proportion of women moving forward at least one stage of change (Prochaska’s stages of change model, see text) for each cardiovascular risk factor (diet, weight, physical activity, smoking, blood pressure, cholesterol, and diabetes) at end of counseling (EC) and end of maintenance (EM) compared to baseline (B) for women enrolled in the study. All comparisons are paired (pre- or post-intervention) for women with data at all three time points. Statistically significant changes ($*p<0.05$) for comparisons of B to EC and EC to EM are noted

intervention period. This may be a reflection of the fact that hypertension was the most prevalent cardiovascular risk factor in our study population (42%). It may also be that blood pressure was affected by exercise and nutrition to a greater extent over the time period covered by this intervention. The lack of significant change in some of the other clinical parameters (e.g., cholesterol, fasting blood

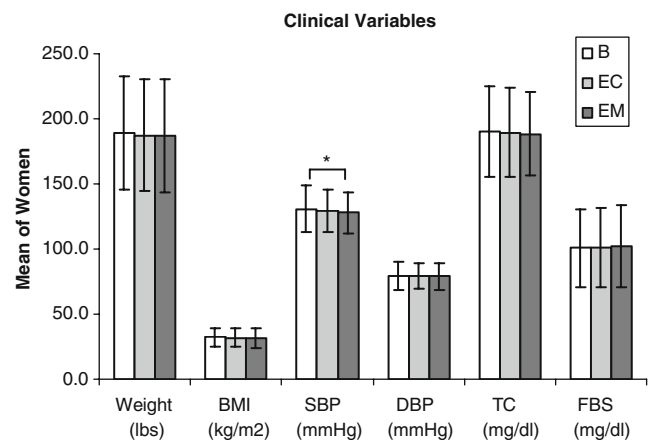


Fig. 6 Effects of the intervention on clinical parameters for participants who completed all assessments. Cardiovascular clinical outcomes at baseline (B), end of counseling (EC), and end of maintenance (EM) for women enrolled in the study. All comparisons are paired (pre- or post-intervention) for women with data at all three time points. Clinical parameters (means \pm SEM) were assessed for the following: weight (lbs), body mass index (BMI, kg/m²), diagnosis of diabetes (DM), systolic blood pressure (SBP, mmHg), diastolic blood pressure (DBP, mmHg), total cholesterol (TC, mg/dl), and fasting blood glucose (FBS, mg/dl). Statistically significant changes ($*p<0.05$) for comparisons of B to EC and EC to EM are noted

glucose) may, in part, have been due to the relatively large variation in values for these parameters in the study cohort.

The program was least successful in the primary outcomes of improving obesity and increasing physical activity in the study participants, though readiness to change increased significantly for these risk factors. The lack of effectiveness of the intervention in reducing obesity, and increasing physical activity, is in concert with the findings of many prior studies indicating that these two risk factors are not only difficult to modify but that behavior change may be related to a number of factors including stage of change, elapsed time in the action stages of change, effectiveness of motivational interviewing and behavior counseling techniques provided, use of self monitoring tools, information retention, and others [20, 29–36]. In addition, a longer period of community intervention and empowerment than provided here may be more effective for these two risk factors. In our study, it is interesting to note that participant's self assessment of their knowledge of successful obesity modification interventions did not increase. Perhaps the women felt that relative to other risk factors, there was greater presentation of new information for other risk factors. Regarding physical activity, the length of time and intensity of exercise increased by anecdotal reports from the participants, though frequency did not. Thus, future studies should look at not only frequency of exercise but also track time and intensity.

There were a number of limitations and challenges encountered and overcome during this study. They related primarily to participant retention, lead site coordinator time demands, and resources available. Although there was a relatively high dropout rate during the counseling phase (32.3%), the dropout rate was subsequently relatively low for participants who remained in the program (8.5%). In addition, overall, the program satisfaction was rated to be high by the study participants. Many of the women who participated and continued in the program did so out of their strong desire to be a part of a culturally relevant and supportive program. In addition, participation in the program provided participants with an opportunity to enhance their social network. The importance of social networks and social support structures in cardiovascular disease outcomes and cardiovascular risk behavior change has been previously reported [37, 38]. This program placed higher than anticipated time demands on site leaders and coordinators who were responsible for program implementation. Preprogram site leader training sessions, efforts to provide a standardized curriculum across sites, and well-defined program goals were important elements to ensuring successful outcomes across sites. Regarding program resources, funds were limited and all sites relied heavily on local networks and partnerships for additional support and for providing meeting facilities for participants. Future

interventions of this type should take into account these additional demands and provide funds and resources commensurate with the complexity of the type of faith- and community-based health behavior intervention delivered and the rigor of the desired outcomes goals.

Although the CVD prevention program intervention was overall very effective in attaining program outcomes, there were a number of important “lessons learned.” These are summarized as follows: (1) the program intervention implemented for this study required careful coordination between the program sponsor (DHHS-OWH), the lead sites, and the program implementation community- and/or faith-based sites. However, coordination and in-kind support was also required from partnering organizations and groups. It was, therefore, imperative that communication be seamless, and education reiterative, among all participating groups in order to ensure uniformity of implementation and a common understanding of the study goals and project outcomes. In addition, significant time and effort were required to build new collaborative community relationships, or adapt extant ones, with local partners, local community officials, and stakeholders in order to establish trust, ensure availability, build capacity, meet the needs of the program, and support program implementation. (2) The project's ambitious expectations to complete required program components within the limited timeframe was a major challenge. While adhering to program timelines, flexibility had to be built in to accommodate local and regional circumstances including summer months and vacations, weather, time commitment of site leaders, conflicting schedules of organizational partners, etc. (3) Utilizing the lead sites' and/or partnering organization's existing communication system to reach their constituents and members through organizational newsletters, flyers, emails, e-invites, letters, and church bulletins was an effective strategy for recruiting participants in the project. (4) Development of a standardized yet culturally appropriate, gender-specific health education curriculum, site leaders' guide, educational materials, and other culturally relevant materials and activities by each site were effective tools in generating small group discussions, subject participation in exercise sessions and program activities, and encouraged group cohesiveness and empowerment at each site. And (5) recruitment of site leaders who were peers to the study participants added to the effectiveness of the delivery of the curriculum and program because participants could better relate to them. Additionally, allowing the community- and faith-based groups to use their creativity and resources to develop maintenance sessions that focused on risk factors of cardiovascular disease was an effective strategy in participant retention and participation during this phase of the program. Additionally, this curricular flexibility afforded the community partners

the opportunity to create sessions that were tailored to their community, have a sense of ownership over their sessions, and encouraged group cohesiveness.

In summary, our study and results demonstrate that a heart disease prevention educational intervention program aimed at high-risk women and delivered in community- and/or faith-based sites can be highly effective in improving CVD outcomes for women. Our findings have implications for the broader use of these strategies and approach in cardiovascular disease prevention for high-risk women. In order to further increase efficacy, future efforts should be directed towards health promotion programs among high-risk women, not only those with established cardiovascular disease and those more motivated to participate in clinical trials targeting lifestyle change. Given that the primary outcomes of reducing weight and increasing physical activity were not attained, studies should also address whether a health promotion approach is sufficient to attain improved outcomes in weight management and in increasing physical activity in this population. Future studies should not only assess the effect in lifestyle change and knowledge awareness but also address program duration, cost, and resources as a function of improved outcomes. It is possible that with a longer duration program and additional resources, even greater improvements in outcomes could have been observed, particularly for clinical targets. It would also be of benefit to follow a high-risk cohort of women for a longer duration to determine whether outcomes gains can be maintained and further optimized. Thus, policy makers and funding agencies should consider faith-based and community intervention programs of this type in their priority initiatives. In addition, because of the success of the intervention delivered, it would be of interest to determine whether more complex risk factor patterns and new and emerging CVD risk factors, such as the metabolic syndrome, inflammatory markers, and subclinical disease markers, can be similarly and favorably modified.

In conclusion, we observed that when working with faith-based national and civic organizations targeting high-risk women of color, it is beneficial to align efforts with both the national faith-based and/or the local community organization to ensure that program implementation efforts are effective and successful. CVD interventions for women of color should be designed to enhance the strengths of community resources inclusive of community stakeholders and members of the target population during planning and implementation and identify race, culture, and gender as contributing factors to CVD. The interventions should also incorporate program components that encourage healthy social networks and empowerment. These strategies will help to ensure that high-risk women and those from underrepresented groups will derive a greater sense of accountability and self-worth from a program designed for

and by them. These are important tools in the fight against heart disease—the leading killer for all women.

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Appendix

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ABC: Rosalyn Scott, M.D., MSHA: principal investigator; Ann L. Taylor, M.D.: program clinical director; Akilah Heggs, MA: senior director, Community Programs; Jacqueline Lewis: program manager; Becky E. Leach: program coordinator and elder, United Churches of Jesus Christ; Carol Hall: data analyst.

The Imperative: Cheryl S. Taylor, PhD, MSN, RN—principal investigator; Shavon Arline, MPH—co-investigator/project director; Judith May, BS—program assistant; Camonia Long, MS—research assistant; Eleanor Hinton Hoytt—president and CEO; Valerie Rochester—director of programs. Partner sites: African Methodist Episcopal Church Health Commission, Dr. Miriam Burnett—medical director; Center for Black Women's Wellness, Jemea Dorsey—executive director; Mocha Moms Incorporated, Donna "Dee-Dee" Jackson—national president; Zeta Phi Beta Sorority Incorporated, Barbara Moore—international president; and Zeta Phi Beta Sorority, Incorporated, Dr. Constance Hendricks—director of national Zetas Helping Other People Excel.

RCSHD: Shannon S. Carrow, MS, Executive Director, Research Center for Stroke & Heart Disease, The Jacobs Neurological Institute, State University of New York at Buffalo: Primary Investigator; Kristen E. Martin, BA, Project Manager Research Center for Stroke & Heart

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