ORIGINAL REPORTS: OTHER CARDIOVASCULAR DISEASE RISK FACTORS

SUSTAINABILITY OF A MULTIPLE RISK FACTOR INTERVENTION ON CARDIOVASCULAR DISEASE IN HIGH-RISK AFRICAN AMERICAN FAMILIES

Objectives: To determine the long-term effect of a community-based risk reduction intervention at five years after completion of a one-year randomized clinical trial and to determine the sustainability of the beneficial effects seen one year after the intervention.

Methods: 30- to 59- year-old African American siblings of probands with premature coronary heart disease (CHD) were randomized for care of multiple CHD risk factors to either one year of community-based care (CBC) provided by a nurse practitioner/community health worker team or enhanced usual care (EUC). At five years, 307 (84.6%) of the siblings returned for reevaluation.

Main Outcome Measures: Changes in and achievement of goal levels of low-density lipoprotein cholesterol (LDL-C), systolic and diastolic blood pressure (SBP and DBP, respectively), and smoking cessation at five years.

Results: No significant differences were seen between groups in mean LDL-C, SBP, and DBP or in the overall percentages achieving goal LDL-C, blood pressure, or smoking status. Changes after completion of the intervention suggest that the CBC group lost the beneficial effects for mean LDL-C and for percentage at goal LDL-C, while the EUC group continued to improve. CBC was associated with greater sustainability and less refractoriness of one-year results for LDL-C and blood pressure goals.

Conclusions: Although no group differences were found in mean risk factor levels at five years, data indicate that CBC is both feasible and associated with earlier sustainability of positive risk factor changes compared with EUC. (*Ethn Dis.* 2008;18:169–175)

Key Words: Risk Factors, Hypertension, Cardiovascular Disease, Community Participation, Prevention, Sustainability, African Americans Crystal W. Cene, MD; Lisa R. Yanek, MPH; Taryn F. Moy, MS; David M. Levine, MD; Lewis C. Becker, MD; Diane M. Becker, ScD

INTRODUCTION

A family history of premature coronary heart disease (CHD), a diagnosis made before 60 years of age, increases the risk of CHD in first-degree relatives.¹ Compared to the general population, siblings of probands have a risk that is up to 12 times higher, likely due to the interaction between genes and shared environment.^{2,3} For African Americans, a family history of premature CHD increases the disease risk fivefold.⁴ Untreated and poorly controlled known risk factors are more prevalent in African Americans with a family history of premature CHD.⁵

Community-based care (CBC) models using nurses and community health workers have been effective at reducing risk in high-risk African Americans in the general population.^{6,7} The Johns Hopkins Family Heart Study was a 1-year randomized trial to test the effectiveness of a community-based model of care, using nurse practitioners and community health workers compared with enhanced usual care (EUC). Known barriers to care were addressed in both groups.⁸ Results showed that CBC was twice as likely to achieve goal levels of low-density lipoprotein cholesterol (LDL-C) and blood pressure and was significantly more

Address correspondence and reprint requests to: Diane Becker; Division of General Internal Medicine; Johns Hopkins Medical Institutions; 1830 E Monument St, Room 8028; Baltimore, MD 21287; 410-955-7781; 410-955-0321 (fax); dbecker607@aol.com Our objectives were to evaluate the long-term effect of community-based care and enhanced usual care models at five years and to determine the sustainability of the beneficial effects seen at one year.

effective at reducing global CHD risk as compared with EUC, independent of other variables.⁸

Clinical trials designed to modify cardiovascular risk factors have been largely successful, with intervention groups experiencing greater short-term reductions in levels of risk factors than non-intervention groups.^{9–11} However, the long-term sustainability of the effects of these interventions remains unknown. Our objectives were to evaluate the long-term effect of CBC and EUC models at five years and to determine the sustainability of the beneficial effects seen at one year.

METHODS

Subjects and Design

Subjects were African American men and women who participated in the Johns Hopkins Family Heart Study.⁸ We recruited siblings from probands <60 years of age identified in 10 Baltimore hospitals during hospitalization for a CHD event from July 1998 through January 2001. Eligible siblings were between 30–

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59 years of age with no known history of CHD (verified by the primary care physician), no chronic glucocorticosteroid therapy, no autoimmune disease, no current cancer therapy, and no immediate life threatening co-morbidity. Siblings with criterion risk factors were randomized by family to CBC or EUC. Siblings in both groups were reexamined one and five years after randomization.

Screening, Measurements, and Recommendations

Five-year screening methods were the same as baseline and one-year screening and have been previously published.8 Briefly, after providing written informed consent, all siblings in both the CBC and EUC groups had a physical examination and medical history taken by a cardiologist. We measured resting blood pressure at four times over the day and took the average of four measurements using methods described by the American Heart Association.¹² Body mass index (BMI) was calculated from weight divided by the square of height. After subjects had fasted for 12 hours, we obtained blood for measurement of serum total cholesterol, high-density lipoprotein cholesterol (HDL-C), triglyceride, and glucose levels in the Johns Hopkins Hospital Chemistry Laboratory. LDL-C levels were estimated by using the Friedewald equation.¹³ We performed a physician-supervised maximal effort treadmill test that used a modified Bruce protocol. Maximal effort was used to estimate the metabolic equivalent level to represent physical fitness.

We used interviewer-administered questionnaires to elicit data on sex, race, education and co-morbidities. Current cigarette smoking was assessed by selfreport of any smoking within the past month and was biochemically validated by using expired carbon monoxide levels. Participants were instructed to bring all medication containers to their visit, and we recorded data on medication type, indication, frequency, and dosage directly from the bottles. All screening measurements at baseline, one year, and five years were completed by research assistants, nurses, and cardiologists who were not involved in the intervention. Randomization was performed by the research staff at the end of the screening day by opening a sealed envelope containing the computer-generated randomization.

All siblings and providers in both the CBC and EUC groups were given individually tailored recommendations based on national guidelines and specific to the individual's risk factor status.⁶ Risk factor-triggered educational messages were based on the following guidelines: Second Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II);¹⁴ the Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure;¹⁵ and smoking cessation guidelines issued by the Agency for Healthcare Research and Quality.¹⁶

For LDL-C and blood pressure, the goals of therapy were <130 mg/dL and <140/90 mm Hg, respectively. For smokers, the goal was total abstinence, and we recommended nicotine replacement and/or bupropion as an adjunct to standard behavioral methods.

Randomization

Criterion risk factors included current smoking, a fasting LDL-C \geq 130 mg/dL, or an average systolic blood pressure (SBP) \geq 140 mm Hg or a diastolic blood pressure (DBP) \geq 90 mm Hg. All eligible siblings in the same family were randomized together to either CBC or EUC using a computerized randomization schema. Siblings with no criterion risk factors were given recommendations on healthy lifestyle and did not enter the trial.

CBC Intervention

Siblings randomized to CBC received care at one nonclinical site in the community.⁸ At each visit, the nurse practitioner performed a physical assessment, evaluated patients for pharmacotherapy, and monitored adherence. The community health worker saw siblings for all smoking cessation and exercise counseling. We gave all siblings a pharmacy charge service card that allowed them to obtain their risk factor therapy prescriptions free of charge at any pharmacy. Primary care physicians were asked not to offer care for criterion risk factors or to change related therapy. After the one-year intervention was completed, siblings in the CBC group had care of their CHD risk factors resumed by their primary care physician.

EUC Intervention

Siblings randomized to EUC received the same screening and measurements as those in the CBC group, but this information was sent to their primary care physician. The physician provided them with usual care, including scheduling office visits, providing education, pharmacotherapy, and adherence monitoring. The EUC participants also received the same risk-specific materials as those in the CBC group. Their physicians also received these materials and recommendations for risk factor management based on national guidelines and specific to the individual's risk factor status.8 Siblings were informed about the pharmacy charge service card and instructed to ask their provider for it. The physician was mailed the pharmacy charge service card to give to siblings for free pharmacotherapy for risk factors. EUC participants were not seen by the nurse practitioner, nor did they receive education and counseling by the community health worker.

Primary Outcome Measurements

Changes and achievement of goal levels of LDL-C, SBP and DBP, and smoking cessation were the primary outcomes. To further examine sustainability we examined the achievement of goal levels of risk factors both at one and five years by individuals in both groups. We divided participants into four sustainability groups defined as 1) sustainers, who achieved their risk factor goal at both one and five years; 2) early adopters, who reached goal at one year but were unable to maintain the goal at five years; 3) late adopters, who achieved goal levels at five years but not at one year, or 4) refractory, who did not achieve goal levels at either one or five years.

Statistical Methods

We used intention-to-treat analyses, such that baseline values were used for any missing follow-up values. We examined continuous variables for normality using the Kolmogorov-Smirnov D statistic and baseline characteristics of the groups were compared using unpaired t tests. Between-group changes were evaluated by using analysis of covariance models of postintervention levels of continuous variables adjusted for baseline levels and contingency table arrays with the χ^2 statistic for categorical variables. Multiple regression models were used to examine attainment of risk factor goals adjusted for covariates and baseline risk factor levels. We examined the effect of the interventions by using the postintervention values adjusted for the baseline values.¹⁷ All regression models were adjusted for
 Table 1. Baseline sociodemographic and co-morbidity characteristics by intervention group

Characteristic	Community-Based Care n=196	Enhanced Usual Care <i>n</i> =167	P value
Mean age ± SD, years	47.6±6.7	47.9±5.7	.62
Mean education \pm SD, years	12.5 ± 2.4	13.0±2.4	.02
Female sex, %	61	66	.36
Health insurance, %	80	80	.92
Employed, %	80	77	.54
Regular primary care provider, %	73	74	.75
Diabetic, %	18	12	.11
Hypertensive, %	63	55	.11
Current smokers, %	37	43	.21
LDL-C ≥130 mg/dL, %	60	62	.77
Mean BMI \pm SD, kg/m ²	31.9±6.2	31.0±6.7	.21
Mean MET level \pm SD	9.2±2.9	9.5±3.0	.32

SD = standard deviation, LDL-C = low-density lipoprotein cholesterol, BMI = body mass index, MET = metabolic equivalent.

nonindependence of families by using generalized estimating equations.¹⁸

RESULTS

Sample Baseline Characteristics

We enrolled 363 African American siblings identified from 194 probands. The mean age was 47.8 ± 6.3 years, and 63% were women. There were 196 siblings representing 102 families in the CBC group and 167 siblings representing 92 families in the EUC group; 105 siblings had no criterion risk factors. The EUC group had a slightly higher educational level (Table 1). The percentage of siblings with baseline hypertension and hyperlipidemia was high, although the percentage on attendant medications was low (Table 3). Of the total sample, 40% were current smokers.

Comparisons of Interventions

Five years after baseline screening, 307 (84.6%) returned for followup. Reasons for the loss to follow-up were death (n=9; 4 CBC, 5 EUC), incident CHD event (n=7; 5 CBC, 2 EUC), refusal (n=14; 6 CBC, 8 EUC), and scheduling problems (n=26; 16 CBC, 10 EUC). Loss to followup was 15.8% and 15% in the CBC and EUC groups, respectively. Those who returned for followup were not statistically signifi-

Table 2.	Risk factors	by group at	baseline and	at one-year	and five-	year followup
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		CBC Group n=196			EUC Group <i>n</i> = 167			
Risk factor	Baseline	1 year	5 year	Baseline	1 year	5 year	P‡	P§
LDL-C, mg/dL	139±39	118±40	125±41*†	136±41	131±38	126±43*	.42	.01
SBP, mm Hg	139±16	130±14	140±17†	137±16	134±17	138±17†	.89	.02
DBP, mm Hg	89±10	84±9	87±9*†	86±11	85 ± 10	86±10	.28	.10
BMI, kg/m ²	32±6	32±6	32±6	31±7	31±7	32±7*†	.17	.28
MET level	9.2±3	_	8.9± 3	9.6±3	_	$9.1 \pm 3^*$.84	-

Values are mean ± 1 SD; CBC, community-based care; EUC, enhanced usual care; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure; DBP, diastolic blood pressure; BMI, body mass index; MET, metabolic equivalent.

* Within-groups *P* value < .05 baseline to five year.

† Within-groups P value <.05 one year to five year.

[‡] Between groups ANCOVA from baseline to five years, using the postintervention values adjusted for baseline.

§ Between groups ANCOVA from 1 year to 5 years, using the post-intervention values adjusted for baseline.

– MET level was not assessed at 1 year.

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	0	BC Grou n=196	đ	With diff (P v	in-group erence 'alue)	Ξ.	JC Group n=167		Within- differ (P va	group ence lue)	Between groups P+ Race-	Betweel groups P± 1_5
Characteristic	Baseline	1 year	5 year	Δ base to 5 years	Δ 1 year to 5 years	Baseline	1 year	5 year	Δ base to 5 years Δ	1 year to 5 years	5 years	years
3P <140/90 mm Hg, %	37	71	56	<.0001	.0004	44	60	53	.04	.16	.39	.94
3P medication use, %	35	52	55	<.0001	.37	32	41	50	<.0001	.0035	.57	.40
_DL-C <130mg/dL, %	39	67	57	<.0001	.01	38	47	54	<.0001	.078	.61	.23
Lipid-lowering medication	4	36	35	<.0001	69.	ω	16	22	<.0001	.02	.51	.60
Not currently smoking, %	63	69	67	.02	.44	57	59	62	.04	.25	.87	.39
Overweight, %	89	89	06	.18	.32	83	83	83	1.00	1.00	.19	.28
Obese, 🖉	59	58	62	.28	.12	53	52	56	.21	.058	.68	.60

cantly different from nonparticipants in demographics or baseline risk factor levels, although smokers and diabetics were slightly less likely to complete followup (P=.04 for smokers and P=.06 for diabetics).

There were no significant baseline or five-year differences between the CBC and EUC groups in the primary outcomes (Tables 2 and 3). Both groups achieved similar LDL-C levels at five years. The percentage of participants who achieved LDL-C <130 mg/ dL increased significantly from baseline to five years in both groups (Table 3). However, no difference was seen between groups in the percentage achieving LDL-C goal. At baseline, few participants were on lipid-lowering medications. Pharmacologic regimens increased significantly at five years within both groups.

Overall, the mean SBP levels in both groups did not significantly change from baseline to five years (Table 2). DBP was significantly lower at five years in the CBC group but did not change in the EUC group. The percentage of participants achieving goal blood pressure of <140/90 mm Hg was significantly higher in the CBC and EUC groups, but no significant difference was seen between the groups in the percentage achieving goal at five years. Approximately one third of participants in both groups reported being on antihypertensive medications at baseline, and this percentage increased significantly to approximately one half in both groups over the course of followup (Table 3). There were statistically significant increases in the percentages of participants who quit smoking in both CBC (14%) and EUC (17%) groups, with no difference between groups.

The percentage of participants who maintained goal LDL-C levels decreased from one to five years in the CBC group but increased in the EUC group. There was a statistically insignificant decrease in the percentage of CBC participants who were on lipid-lowering therapy

	LDL-C G	ioal (<130 <i>n</i> =218	mg/dL)*	BP Goal	mm Hg)*	
	CBC <i>n</i> =115	EUC n=103	Р	CBC n=124	EUC n=94	Р
Sustainers, % Goal at 1 and 5 years	23	12	.02	19	16	.52
Early adopters, % Goal at 1 year but not at 5 years	28	9	<.001	40	17	<.001
Late adopters, % Goal at 5 years but not at 1 year	14	19	.27	10	12	.63
Refractory, % Not at goal at 1 or 5 years	35	60	<.001	31	55	<.001

Table 4. Sustainability groups for LDL-C and blood pressure by intervention group

from one to five years, while the percentage of EUC participants increased significantly (Table 3).

The percentages of participants who maintained a BP of <140/90 mm Hg after completion of the intervention decreased significantly in both the CBC (-15%) and EUC groups (-7%). There was no significant change in the percentage of CBC participants taking blood pressure medications after completion of the intervention, but there was a significant increase in EUC participants. There were no significant differences within or between groups for smoking (Table 3).

Participants in CBC were twice as likely as those in EUC to be LDL-C goal sustainers (P=0.02) and slightly but not significantly more likely to be blood pressure goal sustainers. Participants who never achieved LDL-C goal at either one or five years (refractory) were 1.5 times more likely to be in the EUC group. Similarly those who were refractory for blood pressure goals were almost 1.5 times more likely to be in the EUC group than in the CBC group (Table 4).

Multivariable Analyses

Being at goal level of LDL-C at one year was associated with almost triple the odds of being at goal level at five years, and the use of lipid lowering medications at five years increased the odds of being at the five-year LDL-C goal by almost sixfold, independent of other covariates (Table 5). The relative odds of achieving blood pressure goal of <140/90 mm Hg at five years was more than two times higher in those who also achieved goal blood pressure at one year and who were on antihypertensive medications at five years, compared to those who were not using medications (Table 5). Men had significantly lower odds of achieving nonsmoking status (Table 5).

DISCUSSION

This study highlights the importance of examining the effect of a community-based risk factor intervention over time. While short-term change is commonly observed, longerterm change has been more elusive. To some extent this finding may be a function of the way studies are analyzed, using aggregate mean data to represent overall group responses. Most importantly, in our study, while mean levels of risk factors were not different at five years between the CBC intervention and EUC, there were notable differences in the percentage of participants who reached goal levels at one year and sustained that effect, suggesting that the CBC resulted in earlier control of risk factors for a subgroup of people within the overall group. Furthermore, fewer people in the CBC group compared to EUC were refractory, or failed to achieve goal levels at both measurement times.

Our study complements the work of other studies targeting multiple risk factor interventions for CHD.^{10,11,19–22} Our finding of significant reductions in risk factor levels within groups, but a

 Table 5. Multiple logistic regression analyses* predicting achievement of risk factor goals at five-year followup among those with

 the risk factor at baseline

	Regression 1: LDL-C Goal (<130 mg/dL) n=209		Regression 2: BP Goal (<140/90 mm Hg) <i>n</i> =206		Regression (Not Cu	n 3: Smoking Goal rrently Smoking) <i>n</i> =134
Independent Variables	Relative Odds	95% Confidence Intervals	Relative Odds	95% Confidence Intervals	Relative Odds	95% Confidence Intervals
Intervention Group†	.76	.35-1.62	1.14	.57-2.29	.43	.11–1.71
Medication Use [†]	5.86	2.83-12.11	2.26	.85-5.99	_	-
Male sext	.61	.29-1.31	.79	.39–1.58	.19	.0663
Diabetes†	.88	.35-2.22	1.27	.61-2.62	.33	.06-1.90
Goal at 1 year	2.78	1.33-5.83	2.38	1.20-4.72	.04	.0117

* Adjusted for age, educational level, body mass index, metabolic equivalent level, and nonindependence of families by using generalized estimating equations. † Variable coding: CBC group (vs EUC group); medication use (vs no medication use); men (vs women); diabetics (vs nondiabetics); goal at one year (vs not at goal at one year). ...community-based care resulted in earlier control of risk factors for a subgroup of people within the overall group.

lack of significant differences between intervention groups over time, is consistent with results of some studies^{23,24} and inconsistent with others.²⁵ However, all of these interventions lasted for at least four years, whereas our interest was in examining the effect of a shorter intervention to address barriers and empower patients and then transfer the care of the empowered patients back to the primary care provider. Thus, it is not surprising that as secular trends improved and there was increased adoption of risk factor therapies by providers and patients, particularly for hyperlipidemia, the EUC group would "catch up" with the CBC group.

Our results agree with those of other studies that show that after termination of an intervention, risk factor effects diminish over time.^{20,22,25,26} Notably, our analysis of sustainability stratified by intervention group highlights the danger of solely examining data in aggregate for each time period. Analyzing only the baseline to five-year between-group differences would suggest that the CBC intervention did not differ from EUC in achieving LDL-C and blood pressure goals. However, when we analyzed the data accounting for risk factor goal attainment over time, EUC was associated with significantly more refractoriness (ie, never achieving goal risk factor level at one or five years) than was CBC. CBC was associated with significantly more sustainability of LDL-C goals, and these beneficial changes occurred significantly earlier in CBC than in EUC for both LDL-C and blood pressure. Achieving risk factor control early reduces the time these high-risk individuals are exposed to atherogenic conditions. Thus, this analysis suggests that the CBC intervention may have advantages over EUC in attaining goal levels both in the shortand long-term.

Our results highlight the importance of early initiation of lipid-lowering and antihypertensive medication therapy. Medication use was the strongest predictor of achieving LDL-C and blood pressure goal at five years. Despite the significant increase in both groups in the percentage of participants on lipid lowering medications, <60% of our participants were at goal. However, our results compare favorably with those of other studies and population-level data, which have success rates <40% and substantial percentages of patients who fail to reach recommended targets, even after adjusting for other factors, including medication adherence.²⁷⁻³⁰

Our study has several strengths. We targeted high-risk African Americans, a traditionally under-served and understudied population with regard to longer-term risk reduction. We used a community partnership to design and implement a culturally tailored multiple risk factor intervention addressing clinically relevant outcomes. Our interventions were inclusive of both lifestyle and pharmacologic therapies. In a recent systematic review of interventions targeted to African American populations, Shaya et al. concluded that most existing programs tend to focus solely on lifestyle risk factors and participants' attitudes, with insufficient emphasis on clinical endpoints. Most are of relatively short duration and lack comprehensive community support, as well as a sustainability measurement.³¹

The primary limitation of our study is our inability to track exactly what occurred at the individual and provider levels from one to five years. As with many program-implementation effectiveness studies, we also do not know which specific operational intervention components produced the results we observed.

The results of this trial have clinical and research implications. This intervention trial was designed explicitly to eliminate major known barriers, and issues such as access, affordability of medications, educational resources, child-care needs, opportunities for exercise, and cultural competences of providers were all addressed in this intervention. Our results show that even with a comprehensive intervention we still struggle to engage most of the population to the extent necessary to achieve risk factor goals. We do show, however, that CBC, addressing known sociocultural and access barriers, produces a group with a higher probability of sustaining favorable risk factor changes.

Future areas of research should aim to better understand the barriers and facilitators of long-term sustainability of community-based interventions for cardiovascular risk reduction in high-risk African American populations from the perspectives of the patient, the healthcare provider, and the healthcare system.

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