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Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans☆

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Abstract

Background. African Americans suffer disproportionately from diabetes complications, but little research has focused on how to improve diabetic control in this population. There are also few or no data on a combined primary care and community-based intervention approach.

Methods. We randomly assigned 186 urban African Americans with type 2 diabetes (76% female, mean \pm SD age 59 \pm 9 years) to 1 of 4 parallel arms: (1) usual care only; (2) usual care + nurse case manager (NCM); (3) usual care + community health worker (CHW); (4) usual care + nurse case manager/community health worker team. Using the framework of the Precede–Proceed behavioral model, interventions included patient counseling regarding self-care practices and physician reminders.

Results. The 2-year follow-up visit was completed by 149 individuals (84%). Compared to the Usual care group, the NCM group and the CHW group had modest declines in HbA_{1c} over 2 years (0.3 and 0.3%, respectively), and the combined NCM/CHW group had a greater decline in HbA_{1c} (0.8%, $P = 0.137$). After adjustment for baseline differences and/or follow-up time, the combined NCM/CHW group showed improvements in triglycerides (-35.5 mg/dl; $P = 0.041$) and diastolic blood pressure, compared to the usual care group (-5.6 mmHg; $P = 0.042$).

Conclusions. Combined NCM/CHW interventions may improve diabetic control in urban African Americans with type 2 diabetes. Although results were clinically important, they did not reach statistical significance. This approach deserves further attention as a means to reduce the excess risk of diabetic complications in African Americans.

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Keywords: Behavioral interventions; African Americans; Type 2 diabetes; Nurse case-manager; Community health worker; Randomized controlled trial

Introduction

Type 2 diabetes is responsible for a tremendous public health burden and is associated with long-term complica-

tions that lead to serious illness and disability [1]. The burden of type 2 diabetes affects African Americans disproportionately. The prevalence and incidence of diabetes is higher in Blacks than in Whites [2–4]. Furthermore, the rates of diabetic retinopathy, diabetic nephropathy including ESRD, and lower extremity amputations are also substantially greater in Blacks compared to Whites [2]. Growing evidence suggests that the excess risk of complications in African Americans is modifiable, and that the disparity

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stems in large part from poorer control of major risk factors like glycemic control and blood pressure [5–7]. Control of these factors depends on the behaviors of patients (e.g., diet, physical activity) and physicians (e.g., treatment threshold and target), and on the structure of the health care system (e.g., access to care, continuity of care) [3,8–11].

Recent evidence from the Diabetes Control and Complications Trial (DCCT) [12] and the United Kingdom Prospective Diabetes Study (UKPDS) [13] suggests that achieving tight glycemic control can substantially reduce the risk of complications. Strong evidence also favors blood pressure control, regular foot care, and smoking cessation [13–15]. However, the manner by which such knowledge will be translated into clinical practice is still unclear. One approach has been the use of nurses in the clinical setting to supplement diabetes care by providing case management and education [16–24]. Another approach is the use of community health workers to serve as liaisons between the health care system and the family, in addition to providing diabetes education and social services [25–27]. While these two would appear complementary and potentially synergistic, they have not been tested together. Moreover, they have not been adapted for use in urban African American populations. Therefore, we conducted a randomized controlled trial to determine whether multifaceted, culturally sensitive, primary care-based behavioral interventions implemented by a nurse case manager (NCM) and/or a community health worker (CHW) could improve HbA_{1c}, a measure of long-term blood glucose control, and other indicators of diabetic control (i.e., lipids and blood pressure) in a sample of urban African Americans with type 2 diabetes.

Methods

Study setting and population

Project Sugar 1 was an NIH-funded, randomized controlled trial of primary care-based interventions. The study population consisted of 186 African American adults with type 2 diabetes living in East Baltimore, a predominately African American, inner-city community. Eligibility for the trial was determined by medical chart review and two screening visits. Age (35–75), African American ancestry, presence of type 2 diabetes (as indicated by physician diagnosis), and residence in one of seven East Baltimore zip codes were preliminary eligibility criteria. In addition, all participants attended either the Johns Hopkins Outpatient Center or the East Baltimore Medical Center for primary care within the previous year. Participants were excluded if they had comorbid conditions limiting probable life span to <4 years (e.g., cancer, AIDS) or indication of end-stage complications of diabetes (kidney dialysis or transplant, blindness, or lower extremity amputation). Informed consent to screen and to randomize was obtained from each participant. This study was approved through the Johns

Hopkins University School of Medicine Joint Committee on Clinical Investigation.

Of the approximately 3800 medical charts reviewed for preliminary eligibility criteria, 822 individuals were identified as having African American ancestry and type 2 diabetes. We then screened individuals by phone for other exclusion criteria (comorbidity, disability, residence) and invited them to schedule an initial screening visit at the Johns Hopkins Outpatient Department General Clinical Research Center. Using these methods, 156 individuals were deemed ineligible. The most common ineligibility criteria were diagnosis of diabetes not certain (24%) and residence outside of the catchment area (15%). We were unable to reach 161 individuals, 78 did not show for the screening visit, and 241 refused participation. These 480 individuals (58%) were considered “nonresponders.” In contrast, 186 individuals (23%) attended both of the required screening visits and were randomized into the study. Specifics of the recruitment process and comparisons of the *Project Sugar 1* participants to the nonresponders are reported elsewhere [28]. Comparisons of participants and nonresponders revealed that the group was similar with regard to age and sex, but HbA_{1c} was lower in participants than nonresponders.

Design

We conducted a randomized controlled trial with four parallel arms. The randomization schedule was formed into variable blocks (2 to 6) using the Moses–Oakford algorithm [29], after stratification by sex and clinic site. Assignment was implemented using sealed envelopes. After the two initial screening visits were completed, participants were randomized on a rolling basis between April 1995 and February 1997.

Interventions

Project Sugar 1 interventions were created using Precede–Proceed as a theoretical basis for the behavioral model [30]. Overall, the model incorporates critical constructs from adult learning, social support, and behavior modification theories and health services research such as predisposing, reinforcing, and enabling factors. Predisposing factors are those antecedents to behavior that provide the rationale or motivation for the behavior such as knowledge, beliefs, and attitudes, including self-efficacy, values, and motivation. They are further conceptualized as potential psychological barriers to entering into or remaining in care and to adhering to treatment recommendations. Enabling factors are those that allow a predisposition to be translated into behavior, such as assessing health care resources, or acquiring appropriate skills. Reinforcing factors such as family peer or health provider support are conceptualized as influential subsequent to a behavior.

There were four arms: (1) usual medical care (control); (2) usual medical care + NCM intervention; (3) usual

medical care + CHW intervention; (4) usual medical care + NCM + CHW (combined team intervention). Interventions began as soon as possible after randomization and continued up to the point of the 2-year outcome assessment visit.

Usual medical care only

Participants assigned to the usual medical care (control) group continued on-going care from their own health professionals. In addition, they received a quarterly newsletter, which contained information on various diabetes-related health topics and on-going trial communication (e.g., baseline demographic profile of all participants).

Nurse case manager intervention

The NCM was a registered nurse with a baccalaureate degree in training to be a certified diabetes educator. NCM interventions were 45-min face-to-face clinic visits and/or telephone contacts. The NCM coordinated care according to the American Diabetes Association (ADA) Clinical Practice Recommendations for all participants assigned to the nursing and the combined NCM/CHW group. She provided direct patient care, management, education, counseling, follow-up, referrals, and physician feedback and prompting, which included advising regimen changes and implementing changes under physician's orders. The goal was to conduct visits approximately three times per year, plus additional contacts as needed.

Community health worker intervention

The CHW was a local high school graduate who was enrolled in college part time, and had no formal training in health care before the study. CHW interventions were 45- to 60-min face-to-face home visits and/or telephone contacts. Unlike the NCM, the CHW did not directly implement therapeutic strategies (e.g., recommend change in medication doses). Rather, the CHW facilitated preventive care by offering to schedule appointments and visits, along with providing education. Her main responsibilities were to monitor participant and family behavior, reinforce adherence to treatment recommendations, mobilize social support, and provide physician feedback, which included reporting on identifiable problems such as high blood pressure readings or dietary habits. The goal was to conduct visits approximately three times per year, plus additional contacts as needed.

Combined NCM/CHW intervention

This intervention combined the individual activities of the NCM and CHW. In addition, the two interventionists conducted biweekly conferences to coordinate interventions and promote synergy. The goal was to conduct approximately three visits per year with the NCM and three visits per year with the CHW, plus additional contacts as needed.

General approach

Interventions focused on the following domains: diet, physical activity, foot care, vision care, blood glucose self-monitoring, blood pressure control, adherence to medication and appointments, referrals, and, where appropriate, smoking cessation. Participants were asked to prioritize three domains for initial attention. Interventionists determined the needs of each participant through an assessment of the baseline characteristics and the initial intervention visit [31]. Subsequently, interventions were tailored to the overlapping areas between participant priorities and the assessed needs. Interventionists attended weekly meetings initially with project investigators. Cases were presented at these meetings, and strategies to overcome barriers to care and adequate diabetes control on a case-by-case basis were discussed. Interventionists were required to keep documentation of baseline screening visit summary notes, telephone interactions with participants, health care providers and social workers, materials sent or given to participants, and weight and blood pressure values. Furthermore, clinical flowsheets and summaries of intervention visits, including telephone interventions, were summarized on physician update forms that were sent to primary care physicians.

Intervention participation

The numbers of face-to-face and telephone intervention visits before the 2-year follow-up visit by intervention group were summarized. In each intervention arm, the majority of individuals received at least one face-to-face intervention visit. Twenty-five percent in the NCM groups received at least three visits and 62% in CHW groups received at least three visits. Less than 5% in the NCM groups and <20% in the CHW groups received at least seven visits. Overall, more individuals were seen in the CHW groups, which may be related to the fact that the CHW saw the participants in the convenience of their homes. Many participants (~50%) also received at least one telephone intervention. Since it was not feasible to ensure that three intervention visits corresponded directly to the yearly follow-up visits, it was expected that individuals would complete six intervention visits before the 2-year follow-up. Our actual participation fell far short of that goal primarily because of insufficient staff support and participant noncompliance. Many times, participants failed to come into the clinic or were not home at the time of the community visit, despite the fact that visits were arranged at the participant's convenience and preappointment letter and telephone reminders were made. Telephone interventions were supplemented when participants could not be seen face-to-face. Specific priorities and needs addressed at the intervention visits are described elsewhere [31].

Data collection

Participants attended baseline screening visits and the 2-year follow-up visit at the Johns Hopkins Outpatient De-

partment General Clinical Research Center, where they underwent standardized interviews, physical assessment, and laboratory testing. All data were collected by technicians who were masked to intervention assignment.

Diabetic control in this study was defined as factors that influence the development of diabetes-related complications, namely, HbA_{1c} lipids, and blood pressure. The main outcome variable, HbA_{1c}, was measured using high-pressure liquid chromatography. HbA_{1c} is a measure which reflects the previous 2–3 months of blood glucose control. An alternative to looking just at blood glucose levels, which can fluctuate day to day, HbA_{1c} is a more stable measurement that is now used in standard practice [32]. Lipid profile (HDL and LDL cholesterol, and triglycerides) was measured after a 10- to 12-h fast. Blood pressure was assessed using a random-zero sphygmomanometer; the mean of three readings over one visit was used at baseline and follow-up.

Dietary practices were assessed using a food frequency questionnaire designed to guide cholesterol reduction in low-income individuals [33]. The questionnaire consists of 31 food frequency items and 11 food preparation questions. It identifies positive as well as problematic dietary behaviors, and measures potential barriers to dietary change [33]. Responses from individual questions compile into a total dietary risk assessment score that ranges from 0 to 84. Higher scores indicate less-optimal dietary practices such as higher fat and cholesterol intake and lower complex carbohydrate intake [33].

Physical activity was measured using a questionnaire about habitual physical activity during leisure time [34]. Scores range from 1 to 4, and higher scores indicate increased physical activity. Height was measured using a stadiometer with shoes off and weight using a balance beam scale with light clothing. Duration of diabetes was determined by interview; the age at diabetes diagnosis was subtracted from the age at baseline.

Statistical analysis

Frequency distributions, percentages, means, and standard deviations were tabulated overall and by randomization group. Triglycerides were log-transformed for analysis because the variable was highly skewed. However, log-transforming this variable did not produce any statistically significant differences in the effect sizes; therefore, the absolute changes were reported. ANOVA and X² tests were performed to assess comparability between the intervention groups at baseline.

Two sample *t* tests with unequal variance were used to test the effect of the interventions; whether the differences from baseline to 2-year follow-up were statistically different in each of the three intervention groups compared to controls. Because the time windows for the 2-year follow-up were wide (18–35 months), and outcome measures differed slightly (albeit insignificantly) across intervention groups at baseline, linear regression was used for adjustment. HbA_{1c},

blood pressure, HDL cholesterol, LDL cholesterol, and triglycerides were entered as dependent variables in separate models.

Because the endpoints required measurement of clinical parameters, these data were available only on those who completed the 2-year follow-up visit (84%). Without valid data on these parameters between baseline and 2-year follow-up, we were unable to use the last observation carried forward method. Therefore, among the 149 completers, we analyzed according to assigned group at randomization without regard to adherence to the intervention regimen.

For main clinical endpoints, we also conducted subsidiary analyses using alternative approaches such as on-treatment (only those who had at least 1 face-to-face intervention visit and completed 2-year follow-up), and factorial (NCM participants compared to all other participants not receiving the NCM intervention, and likewise, the CHW participants compared to all other participants not receiving the CHW intervention). Analyses were conducted using *STATA* statistical software [35]. Tests of significance were two-tailed.

Follow-up rates

By the time the 2-year visit was closed on August 31, 1999, 149 participants completed the visit, and 9 had participants died, yielding a follow-up rate of 84% (149/[186 – 9]). The most common reasons for not completing the visit were death, working during visit hours, and personal or family illnesses. The number of deaths did not differ between study groups (2 usual care, 2 NCM, 2 CHW, 3 combined NCM/CHW). This follow-up rate refers to completion of the 2-year follow-up visit and should not be confused with the intervention participation rate. Compared to completers (*n* = 149), noncompleters (*n* = 37) had lower household incomes and higher LDL cholesterol; the two groups were otherwise similar with regard to baseline characteristics.

Results

Baseline characteristics of study participants

Selected baseline characteristics of 149 participants who completed the 2-year follow-up are summarized by randomization group in Table 1. The population was predominately female with a mean age of 59 years, and most had less than a high school education. The majority of participants had extremely modest incomes, and many were dependent on medical assistance or lacked health insurance entirely.

The mean duration of diabetes was 9 years. Ninety-one percent of the participants reported taking diabetes medication; 46% of the sample used insulin, and 45% used oral hypoglycemic agents. Seventy-three percent took blood pressure medication, and 21% took cholesterol medication.

Table 1
Selected baseline characteristics of 149 *Project Sugar 1* participants who completed 2-year follow-up by randomization group

	Randomization group ^a				Total (N = 149)
	Usual care (N = 34)	NCM (N = 38)	CHW (N = 41)	NCM/CHW (N = 36)	
Female	25 (74)	29 (76)	32 (78)	28 (78)	114 (77)
Age (years)	57 ± 8	59 ± 11	59 ± 9	60 ± 7	59 ± 9
Education (years)	10 ± 3	10 ± 2	9 ± 3	10 ± 3	10 ± 3
Yearly income ≤\$7500	15 (44)	15 (42)	25 (61)	19 (53)	74 (50)
Receives medical assistance	17 (50)	13 (34)	19 (46)	13 (36)	62 (46)
Duration of diabetes (years)	9 ± 8	8 ± 8	8 ± 8	12 ± 8	9 ± 8
Uses insulin	17 (50)	17 (45)	16 (39)	19 (53)	69 (46)
Uses oral hypoglycemic agents	17 (50)	20 (54)	16 (39)	14 (39)	67 (45)
Uses blood pressure medication	21 (62)	32 (84)	28 (68)	28 (78)	109 (73)
Uses cholesterol medication	6 (18)	7 (18)	9 (22)	9 (25)	31 (21)
Dietary fat score	24 ± 7	26 ± 8	27 ± 8	24 ± 7	25 ± 8
Leisure-time physical activity index ^b	2.4 ± 0.5	2.7 ± 0.6	2.3 ± 0.6	2.3 ± 0.6	2.4 ± 0.6
Monitors every day	10 (30)	12 (32)	9 (22)	14 (39)	45 (30)
Smoking					
Never	15 (46)	20 (53)	16 (39)	15 (42)	66 (45)
Former	12 (36)	13 (34)	17 (41)	14 (39)	56 (38)
Current	6 (18)	5 (13)	8 (20)	7 (19)	26 (17)
BMI (kg/m ²)	34 ± 8	33 ± 8	33 ± 5	33 ± 7	33 ± 7
Systolic blood pressure (mmHg)	127 ± 20	125 ± 15	129 ± 20	129 ± 14	127 ± 17
Diastolic blood pressure (mmHg)	78 ± 11	75 ± 12	75 ± 11	76 ± 15	76 ± 12
HbA _{1c} (%)	8.5 ± 2.0	8.8 ± 2.2	8.4 ± 2.0	8.6 ± 1.9	8.6 ± 2.0
Total cholesterol (mg/dl)	209 ± 40	211 ± 46	217 ± 46	208 ± 41	211 ± 43
HDL cholesterol (mg/dl)	49 ± 12	49 ± 13	45 ± 12	47 ± 13	47 ± 13
LDL cholesterol (mg/dl)	135 ± 33	138 ± 39	149 ± 43	132 ± 36	139 ± 38
Triglycerides (mg/dl)	125 ± 71	117 ± 52	117 ± 49	147 ± 106	126 ± 72
Face-to-face intervention visits ^c	N/A	2 ± 1	3 ± 2	2 ± 2, NCM 3 ± 2, CHW	—
Phone interventions ^c	N/A	2 ± 2	1 ± 2	3 ± 4	—

Note. All results shown as N (percentages) or mean ± standard deviation.

^a NCM, nurse case manager intervention; CHW, community health worker intervention; NCM/CHW, nurse case manager/community health worker combined intervention.

^b Statistically significant differences between the groups ($P < 0.05$). Besides physical activity index, there were no significant differences between trial groups.

^c Intervention visits that occurred after baseline and before the 2-year follow-up.

About one-third of individuals reported monitoring every day. Only 18% were current smokers.

The mean body mass index (BMI) (33 kg/m²) was well within the range of obesity, and approximately 32% of the participants had a BMI over 35 kg/m². Mean systolic and diastolic blood pressure were 127 and 76, respectively, with 26% of participants having blood pressures greater than 140/90 mmHg [36]. Other than total cholesterol, the mean lipid profile measures (HDL cholesterol, LDL cholesterol, and triglycerides) were in the normal range. Fifty-eight percent of participants had LDL cholesterol greater than 130 mg/dl [37]. The mean HbA_{1c} was 8.6%. Fifty-four percent of participants had HbA_{1c} levels greater than 8.0%, falling in the unacceptable range according to American Diabetes Association (ADA) recommendations [37].

The groups differed only in their baseline leisure time physical activity index, with the NCM individual group having a slightly higher index than the rest of the groups ($P < 0.05$). Otherwise, the baseline characteristics were similar across all trial groups.

Diabetic control

Fig. 1 shows the effect of the intervention on parameters of diabetic control over 2 years. For the main outcome, HbA_{1c} (Fig. 1a), the NCM and the CHW individual interventions had similar effects (-0.31 ± 0.49 vs $-0.30 \pm 0.48\%$, respectively). The combined group showed an $0.80 \pm 0.52\%$ decline in HbA_{1c} compared to controls. The NCM and CHW individual group had small increases in HDL cholesterol (Fig. 1b); however, the combined group had a slight decrease. All intervention groups appeared to show adverse effects on LDL cholesterol (Fig. 1c), because the control group dropped by 16.7 ± 5.5 mg/dl. The combined NCM/CHW group had the smallest increase compared to controls. The largest effect on triglycerides (Fig. 1d) was seen in the combined NCM/CHW group. The NCM group had the greatest increase in systolic blood pressure (Fig. 1e); the CHW group and the combined NCM/CHW interventions had decreased effects. The NCM intervention had virtually no effect on diastolic blood pressure (Fig. 1f).

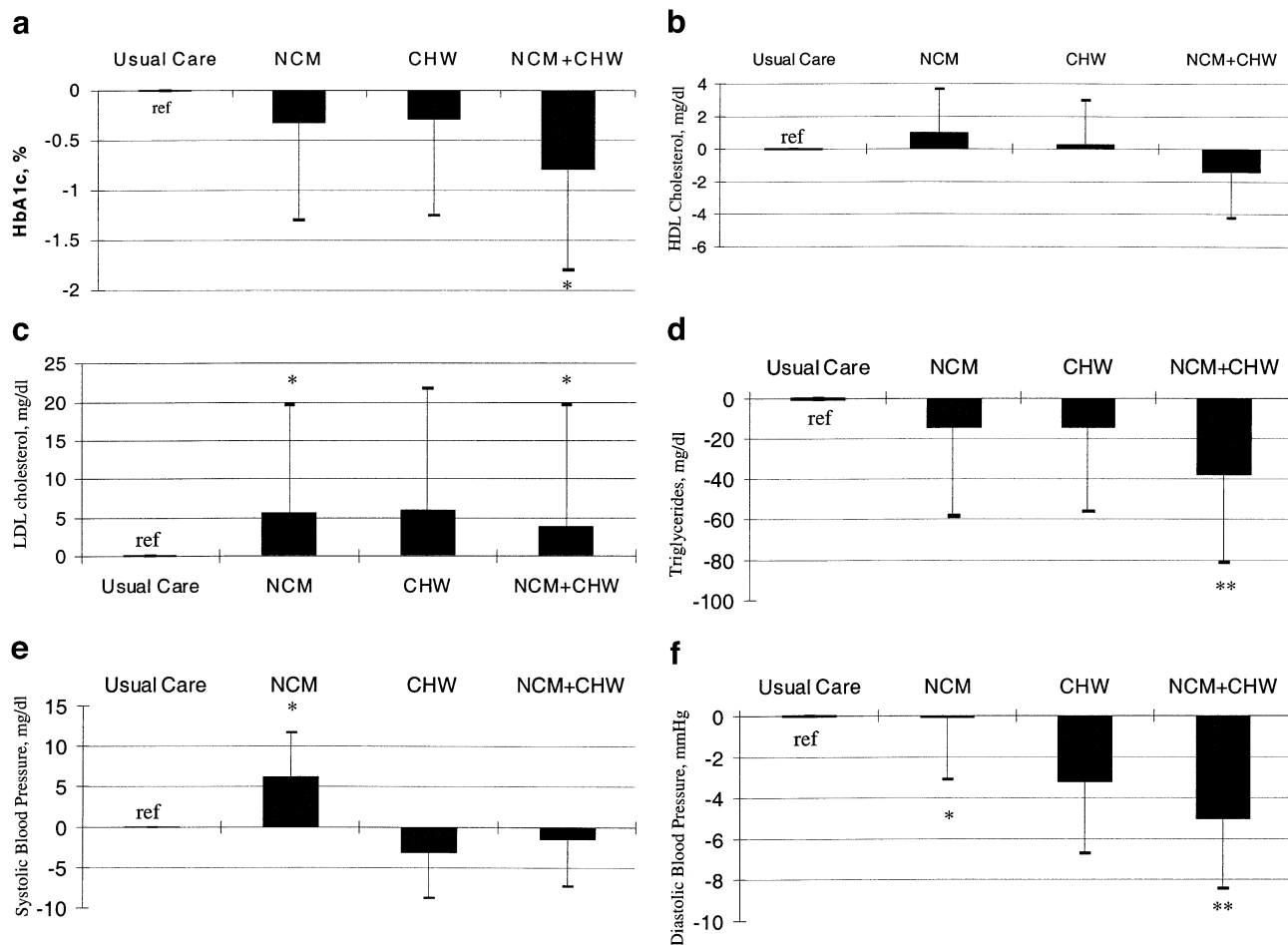


Fig. 1. Effect of interventions on diabetic control in 149 African Americans with type 2 diabetes. Effect is defined as the difference in parameter change (2-year baseline) in each of the three intervention groups compared to controls (intervention controls). Bars indicate the standard error for each change. None of these results were statistically significant in the main analysis. * $P < 0.05$ for within-group change from baseline. (a) HbA_{1c}; (b) HDL cholesterol; (c) LDL cholesterol; (d) triglycerides; (e) systolic blood pressure; (f) diastolic blood pressure. ** $P < 0.05$ in multivariate regression analyses adjusting for follow-up time and baseline characteristics for between-group comparisons of the change from baseline.

However, the CHW intervention and the combined NCM/CHW intervention had a substantial effect on DBP (-3.2 ± 3.5 and -5.0 ± 3.4 mmHg, respectively).

Analyses examining the effect of the interventions after adjusting for the baseline levels of the parameters of diabetic control and follow-up time (indicated by the number of days from randomization) were conducted. Adjusted effect sizes showed trends similar to those of the unadjusted results. The effect size for triglycerides in the combined group (-35.5 mg/dl) was statistically significant after adjusting for follow-up time ($P = 0.041$). After adjustment, the NCM group had a decrease in diastolic blood pressure compared to controls. The combined group had a statistically significant effect on diastolic blood pressure after adjusting for baseline levels (-5.6 mmHg; $P = 0.042$). Other than the effect on triglycerides and diastolic blood pressure in the combined NCM/CHW group, no statistically significant effects were shown after adjustment.

Other subsidiary analyses were conducted to further examine the effect of the interventions on parameters of dia-

betic control. In the on-treatment analysis, results were very similar to those of the main analyses. We did see larger effects for those individuals who received more intervention visits, but these results were not statistically significant. In the factorial design analysis for both main and on-treatment, the NCM and CHW had similar effects. The NCM had slightly larger declines in total cholesterol and the CHW had slightly larger declines in systolic and diastolic blood pressure. No statistically significant effects were found.

Diabetes-related health behaviors

Effects of the intervention on diabetes-related health behaviors and intermediate factors are shown in Table 2. The CHW intervention had the largest effect on dietary risk scores with a 3.45-unit decline compared to controls. The NCM intervention produced a smaller increase in physical activity compared to controls. Both the CHW and the combined NCM/CHW intervention groups produced a larger increase in physical activity compared to controls. These

Table 2
Effect of 2-year interventions on diabetes-related health behaviors and BMI by intervention group

	Intervention group ^a		
	NCM (N = 38)	CHW (N = 41)	NCM/CHW (N = 36)
Dietary risk score	-2.40 ± 1.99	-3.45 ± 1.87	-2.13 ± 1.92
Leisure-time physical activity index	-0.14 ± 0.18 ^b	+0.26 ± 0.18 ^b	+0.34 ± 0.18 ^b
Body mass index (BMI) (kg/m ²)	+0.42 ± 0.46	+0.57 ± 0.47	+0.82 ± 0.55

Note. Effect is defined as the difference in parameter change from (2-year baseline) in each of the three intervention groups compared to controls (intervention controls). None of these results were statistically significant in the main analysis. All results shown as mean ± standard error.

^a NCM, nurse case manager intervention, CHW, community health worker intervention; NCM/CHW, nurse case manager/community health worker combined intervention.

^b Within-group change from baseline ($P < 0.05$).

within group increases were statistically significant ($P < 0.05$). All intervention groups had increases in BMI compared to controls. The NCM group had the smallest increase, followed by the CHW group, and the combined group had the largest increase compared to controls. Besides the within-group changes, there were no statistically significant between-group differences.

Conclusions

These results suggest that combined NCM/CHW interventions in primary care may produce significant improvements in HbA_{1c}, lipids, and blood pressure. In this intervention group, declines in diastolic blood pressure and triglycerides were statistically significant, and declines in HbA_{1c} were clinically important, although they did not reach statistical significance. Overall, the combined NCM/CHW intervention produced greater effects than the NCM or the CHW intervention alone, and to our surprise, the NCM and CHW individual groups produced similar effects. These conclusions are supported by a randomized controlled trial design with uniformly good follow-up rates ($\geq 80\%$).

Four possible limitations deserve comment. First, the number of participants that could feasibly be recruited into the study was small. This limited our statistical power to detect effects over time, as well as our ability to conduct stratified analyses. Because between-group differences did not reach statistical significance, post hoc power calculations were conducted to determine the minimal detectable difference between the intervention groups and controls that the study could detect at 80% power [29]. For HbA_{1c}, we had 80% power to detect a 1.2% difference. The combined NCM/CHW group produced a difference of 0.8%. Minimal detectable differences for the other parameters of diabetic control were far larger than the actual effects seen in the study, except for triglycerides (effect -37.3 mg/dl), which came close to the minimal detectable difference of 47 mg/dl.

Second, because only 23% of those eligible chose to participate, volunteer bias is a possible threat to external validity. In our investigation of external validity, we found

that nonrespondents were similar to participants with respect to age and sex, but glycemic control was better in *Project Sugar 1* participants [28]. In addition, we focused exclusively on people who were already receiving health-care, so our CHW results may not be generalizable to the general population of African Americans with diabetes. However, it should be noted that the effects of the CHW interventions may be even greater than those seen in this study if we apply this model in a population with no health care. Furthermore, since we aimed to measure effectiveness in this study, generalizability may be an issue; however, it poses no threat to internal validity.

Third, several factors related to our follow-up warrant concern. Windows for the follow-up visits were wide, our intervention participation was suboptimal, and the interventionists may have experienced a learning curve during the course of the study. Nonetheless, follow-up was similar across the randomization groups, and considerable effort was made to follow-up both adherent and nonadherent individuals. Additionally, efforts were made to account for some of these issues in the statistical analysis.

Finally, we lacked the resources to track changes in medication and incident diabetes complications. We did have some data on medication adherence, but adherence was uniformly high, so we had some question about its validity.

Previous literature on behavioral interventions to improve diabetes care have been the subject of several review articles and meta-analyses, including one by our own group [38–41]. Compared to previous literature, our study has many strengths. First, the randomized design is the best design to assess the effectiveness of the interventions. Many previous studies have evaluated behavioral interventions using before vs after designs, which may have problems with confounding by secular trends. Second, the sample size of 186 participants in this study surpassed the typical sample sizes (range 18 to 854 participants; median = 70), although many of these studies had only two study groups [41]. Third, fewer than 30% of the studies in the current literature reported using a theoretical/behavioral model, whereas *Project Sugar 1* used a theoretical model in the development of the interventions and as a framework for

interventions throughout the study. Fourth, previous studies have not attempted a medical and public health approach by combining a nurse case manager and community health worker into an integrated intervention in a primary care setting. Fifth, although the 2-year follow-up was not long enough to assess hard clinical endpoints such as micro- and macrovascular complications, it surpassed the 1-year or less follow-up duration in most educational/behavioral intervention trials [41]. Sixth, unlike most studies in the area, *Project Sugar 1* evaluated cardiovascular-related variables in addition to the traditional blood sugar measurements. Finally, this study adapted culturally sensitive interventions for African Americans, an approach not reported in most of the current literature.

Several studies have examined the effect of education provided by a nurse or nurse case management on diabetes outcomes [16–18,21,24]. More recently, Weinberger et al. [21] evaluated nurse-coordinated interventions, which showed a 19 mg/dl difference in fasting blood glucose at the 1-year follow-up between the intervention group and controls. A difference of 0.60% was shown between the groups for glycohemoglobin. Both results were statistically significant. It is unknown how many African Americans were included in the study, although greater than 60% of participants were Caucasian. Likewise, Aubert et al. [24] conducted a randomized controlled trial which found that using a nurse case manager within a health maintenance organization reduced HbA_{1c} by 1.0% over 1 year compared to a usual care group. The majority, 83%, of participants were White and it is unknown how many were African American.

Several studies have also examined the effect of community health workers on diabetes outcomes [25,26]. Corkery et al. [25] observed improved completion rates of a diabetes education program when bicultural, bilingual, Hispanic American community health workers operated in clinics by reinforcing self-care instructions and reminding participants of upcoming appointments. Similarly, a randomized trial by Hopper et al. [26] was conducted in a predominately low-income African American population. This study demonstrated a 5 mg/dl decrease in fasting blood sugar when comparing those diabetic patients offered home health aides to those receiving routine care only. No studies used a combined nurse case manager/community health worker approach.

One other notable study was a randomized controlled trial of weight reduction and exercise for diabetes management in older African American subjects [42]. This study evaluated interventions conducted by a registered dietician/exercise physiologist team and utilized culturally appropriate materials for African Americans. There was a 2.4% difference in HbA_{1c} over 6 months between the intervention group and controls. Although this study does not provide evidence for the nurse case manager/community health worker approach, it does demonstrate the effectiveness of culturally relevant interventions.

We were disappointed that our intervention groups had a

slight weight gain over 2 years compared to controls, despite efforts of interventionists to promote weight loss by diet and exercise. We speculate that this increase may be related to increased adherence to previously prescribed antidiabetic medications associated with weight gain (e.g., insulin, sulphonylureas) or prescription of additional antidiabetic medications associated with weight gain. Unfortunately, we lacked adequate data on medication use at 2 years to confirm this speculation.

One surprise surfaced from our results: the community health worker and the nurse case manager individual groups produced similar effects. We hypothesized that the aggressive nurse case management style would yield larger effects than the community health worker. Nonetheless, changes in the NCM and CHW were comparable across a range of diabetic parameters. In fact, the CHW group displayed greater improvements in dietary risk scores and leisure time physical activity than the NCM group. One explanation for this similarity may be the differential intervention participation: intervention participation was much higher in the community health worker groups, with only 25% of participants in the NCM groups receiving at least three visits compared to 62% of the participants in the CHW groups.

As expected, the combined NCM/CHW group displayed the largest effect for all parameters except HDL cholesterol and systolic blood pressure. These results suggest that community health workers may be an essential component to the diabetes care team. In other analyses of our intervention data, we found that at 77% of visits, interventionists were called upon to address needs well beyond traditional diabetes care, including finances, family responsibilities, insurance, and other health concerns [31]. Community health workers can provide comprehensive care regarding social and some medical needs at a less expensive cost. This would suggest that for best results, a NCM/CHW team may be most effective, and when resources are scarce, community health workers may be a suitable alternative for effective case management. Nevertheless, we cannot rule out the possibility that the larger effects shown for the combined NCM/CHW group may also be explained by the increased number of intervention visits relative to the individual groups, no matter which interventionist conducted them. It is also possible that the NCM's participation and practices in the combined group may have affected the practices by the CHW in the CHW individual group and vice versa.

Our results have several implications. First, participation has shown that randomized controlled trials are feasible and acceptable for an urban, low socioeconomic status, African American population, a group that has been labeled as "hard to reach." Second, this study has important implications for the feasible implementation of NCMs and CHWs into the primary care setting to produce improvements in diabetic control, and reduce the excess burden of diabetes-related complications in African Americans. A multidisciplinary approach may be needed to address the complex diabetes-related needs in this population. Furthermore, this strategy

of behavioral interventions may be applied as a model to modify risk factors for other chronic diseases in minority populations. Further research in this area should be conducted to confirm the physiologic benefits of interventions, to determine the effects of interventions on health events, and to estimate their cost-effectiveness.

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