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A randomized controlled trial of the effects of nurse case manager and community health worker team interventions in urban African-Americans with type 2 diabetes☆

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Abstract

The objective of the study was to determine the effectiveness and cost-effectiveness of primary care and community-oriented interventions in managing HbA_{1c}, blood pressure, and lipids, and reducing hospitalizations and emergency room visits over 2 years. We describe an ongoing, randomized controlled trial of 542 urban African-Americans with type 2 diabetes ages 25 years and older who are members of a university-affiliated managed-care organization in Baltimore, MD. The participants are 74% female, have a mean age of 58 years, and 35% have yearly incomes greater than US$7500. Participants were randomized to one of two intervention

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groups for a period of 2 years: (1) usual medical care plus minimal telephone intervention implemented by a trained lay health educator (control group) or (2) usual medical care plus intensive intervention implemented by a nurse case manager (NCM)/community health worker (CHW) team. The intensive NCM/CHW team executes individual plans of care using evidence-based algorithms that focus on traditional diabetes self-management, screening and management of diabetes-related complications, and social issues surrounding diabetes care. Face-to-face NCM visits are conducted in the clinic once per year and CHW visits are conducted in the participant's home one to three times per year, both with additional follow-up contacts as needed. Written and verbal feedback (when necessary) is provided to the participant's primary care physician. All participants are expected to attend a 24-month follow-up visit where data are collected by interviewers blinded to intervention assignment. As of May 1, 2003, recruitment is complete, interventions are being fully implemented, and 24-month follow-up visits are beginning. Baseline sociodemographic characteristics, health-care utilization, health behaviors, and clinical characteristics of the study population are reported. This study is designed to test the hypothesis that a primary-care-based NCM plus CHW team approach is an effective, practical, and economically feasible strategy for translating current knowledge about type 2 diabetes into high-quality health care for urban African-Americans.

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

1. Introduction

Although it is well established that African-Americans suffer disproportionately from diabetes and its complications, interventions culturally tailored for this population have been limited [1–6]. In a recent meta-analysis of randomized controlled trials evaluating educational and behavioral interventions in type 2 diabetes, very few studies reported including any African-American individuals, and only one study focused exclusively on African-Americans [7]. Several recent studies conducted among African-Americans have shown promising effects on diabetes self-care behaviors and parameters of diabetic control [8–10]. Nonetheless, more work is needed to determine how knowledge from previous large-scale studies will translate into optimal care for African-Americans.

We recently completed Project Sugar 1 (conducted from 1995 to 1999), a four-arm randomized controlled trial among African-Americans that evaluated nurse case manager, community health worker, and combined nurse case manager and community health worker team interventions to improve diabetic control [10]. We found that the nurse case manager/community health worker team intervention produced a 0.8% decline in HbA1c and moderate improvements in lipids and blood pressure, compared to usual care (control). Because this combined clinic and community-oriented approach seemed promising, but small numbers limited our statistical power, we devised a larger-scale study (Project Sugar 2) to evaluate the effectiveness of this approach in a more definitive fashion. Specifically, the new trial is designed to have a threefold larger sample size and to capture broader data on clinically relevant outcomes including health-care utilization and costs. As of May 1, 2003 recruitment is complete, interventions are ongoing, and 24-month follow-up visits are beginning. In this paper, we describe the recruitment yield, including comparisons of participants

and nonparticipants, the study design and interventions, and the baseline characteristics of the study participants.

2. Methods

2.1. Study setting

Project Sugar 2 is a randomized controlled trial funded by the National Institutes of Health (NIH) and set within a university-affiliated managed care organization (MCO). The MCO employs 100 primary care physicians in a staff-model practice at 19 sites, including five sites in the medically underserved areas of Baltimore City that were used for recruitment in this study. This network of community physicians provides care to 80,000 capitated patients under multiple contracts and to an additional 40,000 fee-for-service patients. One other university-affiliated primary care clinic was also included in recruitment.

This study utilizes several databases maintained by the MCO and the university-affiliated hospital. The members database contains demographic information: date of birth, sex, zip code, race, and insurance plan. The administrative medical claims and encounter databases include information regarding primary care visits, procedures and surgeries, emergency room visits, dates of service, and ICD-9 diagnosis codes. A database was also available to identify laboratory results with collection dates. The members, claims, and encounter databases were linked to laboratory data using hospital medical record numbers. We used this linked database to identify potential participants for the study, to compare data for participants and nonparticipants, and to triage patients for intervention based on suboptimal or poor laboratory values (e.g., HbA1c).

This study was approved through the Johns Hopkins Medicine Institutional Review Board in the Johns Hopkins School of Medicine. All participants gave written informed consent and understanding was tested formally by asking a series of questions. Recruitment was completed prior to activation of Health Information Portability and Accountability Act (HIPAA) regulations.

2.2. Population

Participants are 542 African-Americans with type 2 diabetes living in Baltimore City. Using administrative databases, we initially identified insured African-American patients, $\geq$25 years of age, with diagnosed diabetes (ICD-9=250) who were without significant comorbid conditions likely to lead to death within the next 3–5 years (cancer, AIDS, end-stage renal disease, active tuberculosis, alzheimer's disease, and congestive heart failure, using ICD-9 codes). We then screened these potential participants by telephone for our study eligibility criteria: African-American by self-report, type 2 diabetes (determined by self-report: age of diabetes onset >35 years and no insulin use at diagnosis), resident of inner city Baltimore, ages 25 years or older, receiving care at one of the six clinic sites, member of one of the MCO capitated or fee-for-service insurance plans, able to provide contact information for two family members or friends not living in the home, and no active participation in the MCO's other disease management programs. During the baseline visit, we screened for other exclusion criteria: unable or unwilling to give informed consent, unable to complete baseline assessment (interview, clinical measurements, venipuncture), likely to move from Baltimore City in the next 24 months, or having a severe psychiatric health condition that would limit participation in the intervention (e.g., schizophrenia).

2.3. Comparison of Project Sugar 2 participants and nonparticipants

Table 1 summarizes information comparing participants to nonparticipants using several data sources: (1) administrative and laboratory databases maintained by the MCO and (2) questionnaire data. Among the individuals we were able to contact by telephone, we asked those who refused to participate to answer a few sociodemographic questions. We compared three groups of nonparticipants to Project

Table 1
Comparison of Project Sugar 2 (PS2) participants and nonparticipants

	PS2 participants (*n*=542)	Nonparticipants		
		Participated in additional survey (*n*=401)	All eligible (*n*=413)	Eligibility unknown (*n*=861)
Managed care organization data				
Female	396 (73.1)	286 (71.3)	294 (71.2)	534 (62.0)*
Age (years)	57.6±11.2	64.6±12.0*	60.9±12.1*	54.4±16.7*
Insurance plan				
Capitated	384 (70.8)	247 (61.6)*	253 (61.3)*	436 (50.6)*
Fee-for-service	158 (29.2)	154 (38.4)	160 (38.7)	425 (49.4)
Clinical characteristics[b]				
HbA1c, %	8.1±1.9	7.7±1.8*	7.9±1.9	8.3±2.3
HDL cholesterol, mg/dl	50.5±15.1	53.2±14.8*	51.9±15.2	51.8±16.1
Serum creatinine, mg/dl	1.06±0.35	1.19±1.12*	1.10±0.60	1.12±1.10
Questionnaire data				
Difficulty managing diabetes (1–10), median[a]	5.0	2.0*	NA	NA
Education (years)	11.5±2.7	10.7±3.4*	NA	NA
Employment status[c]				
Retired/disabled	316 (58.3)	148 (71.8)*		
Employed (full or part-time)	176 (32.5)	45 (22.4)	NA	NA
Unemployed	25 (4.6)	3 (1.5)		
Homemaker/attending school	25 (4.6)	10 (4.9)		
Yearly household income <US$7500[c]	187 (34.5)	54 (33.8)	NA	NA
Reason for not participating[d]				
Not interested		210 (94.2)		
Satisfied with care		144 (64.6)		
Too busy	NA	67 (30.0)	NA	NA
Personal illness		29 (13.0)		
Too many appointments		23 (10.3)		

All results shown as *N* (%) or mean±S.D.
NA=not applicable.
[*] Indicates that when compared to Project Sugar 2 participants there was a statistically significant difference ($p<0.05$).
[a] Higher scores indicate more difficulty managing diabetes.
[b] Indicates that laboratory data from the managed care organization were not available (i.e., labs not performed) for 20–35% of participants and nonparticipants.
[c] Indicates that of the 223 individuals who answered refusal questionnaire over the telephone, 8% refused to give data for employment status and 52% refused to give data on income.
[d] Categories not mutually exclusive (total *n*=223).

Sugar 2 participants (note that numbers of individuals varied by data type and source). Initially, 2450 individuals were identified as being potentially eligible using administrative databases. Of these (categories not mutually exclusive), 401 refused (those who refused to undergo screening regardless of eligibility status), 413 were eligible but did not participate, and 861 others for whom we could not determine eligibility were evaluated, not including those individuals who refused (n=401) or who were not eligible (n=386).

Using administrative data, participants were significantly different from nonparticipants on nearly all sociodemographic outcomes (Table 1). A larger percentage of participants were female compared to nonparticipants. Participants were generally younger and were more likely to be enrolled in capitated health plans (plans that pay health organizations annual funds "per head" to cover health costs) than nonparticipants. In general, laboratory measurements (HbA1c, HDL cholesterol, and serum creatinine) were similar for participants and nonparticipants. The exceptions were that HbA1c was slightly higher in participants compared to nonparticipants who participated in the additional survey (8.1% vs. 7.7%, p=0.002) and HDL cholesterol was slightly lower in participants compared to nonparticipants who participated in the additional survey (50.5 vs. 53.2 mg/dl, p=0.02).

We compared several key characteristics between Project Sugar 2 participants (n=542) using questionnaire data from the baseline assessment and nonparticipants who answered a brief questionnaire (n=401). We did not have this information for other categories of nonparticipants. Compared to nonparticipants, more participants reported that, on a scale from one to ten, it was harder to manage their diabetes (median 5.0 vs. 2.0, p<0.05). Participants had a higher mean education level and were more likely to be employed than nonparticipants (p<0.05). There was no difference in household income levels between participants and nonparticipants.

The most common reasons for refusing to participate in the study (not mutually exclusive) were: not interested (94%), satisfied with current care (65%), too busy (30%), personal illness (13%), and too many appointments (10%). Others reasons for not participating (<10% of the population) were: disability, do not need help with diabetes, mistrust of the research institution, transportation problems, working, caring for children or older/ill adults, and participating in a different disease management program offered by the MCO. Before the study, we anticipated that a large number of individuals would not participate because of mistrust of the research institution; however, this was not among the top five concerns.

2.4. Design

We implemented a randomized controlled trial with two parallel arms (see Fig. 1). Participants (n=542) were randomly assigned to receive, in addition to their usual medical care, either a minimal intervention (consisting of occasional telephone calls and mailing of standard informational brochures) or an intensive intervention (consisting of ongoing, individually tailored efforts by a nurse case manager/community health worker team aimed at improving health behaviors of patients and preventive health practices by their physicians). At baseline and 24-month visits, a variety of health parameters are assessed including diabetic control (e.g., HbA1c), health-care utilization (e.g., emergency room (ER) visits, hospitalizations, surgical procedures), and direct health-care costs borne by the MCO. Randomization was stratified by three types of health plans and six clinic sites. Within each stratum, the randomization schedule was generated into blocks of sizes 2, 4, or 6 in random sequence using the Moses–Oakford algorithm [11] implemented in SAS. Assignment was carried out using sealed

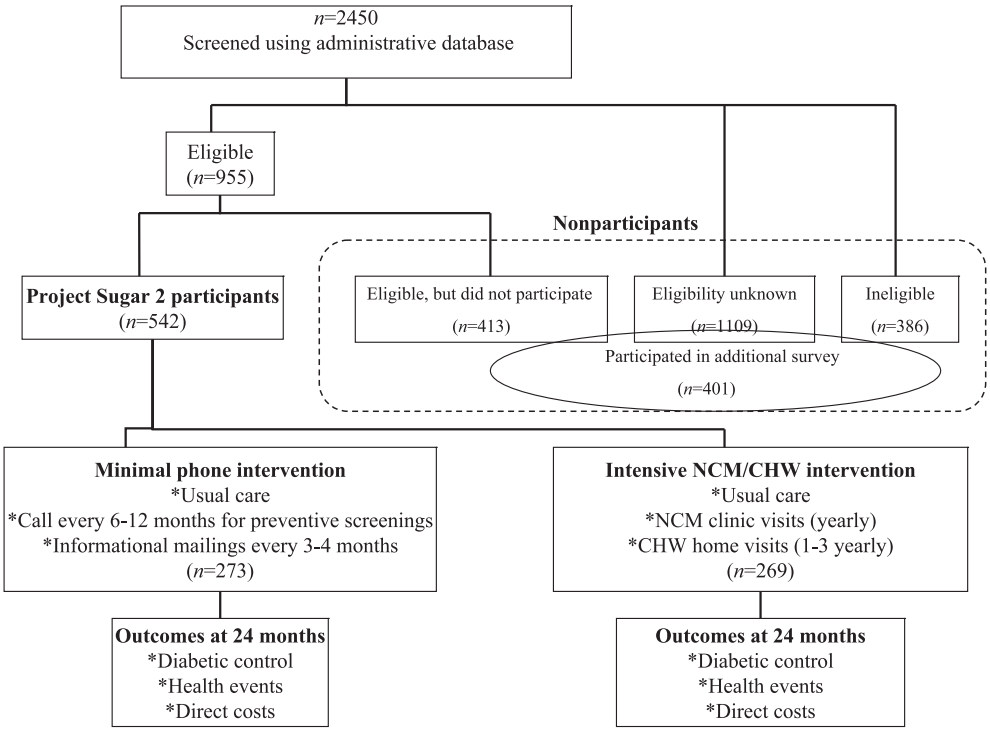

Fig. 1. Study design. NCM=nurse case manager, CHW=community health worker.

envelopes. After completion of informed consent and the initial baseline assessment, participants were randomized on a rolling basis between October 2000 and June 2002.

2.5. Interventions

The structure of the interventions is displayed in Table 2.

2.5.1. Minimal intervention

The minimal intervention is a phone-based intervention executed by a trained lay health educator. The lay health educator had no formal health-related experience prior to the study and participated in a 6-week training session that focused on project operations, teamwork, and general diabetes knowledge. The minimal intervention was designed with the following goals in mind: (1) to simulate the type of low-intensity intervention that might be adopted by the MCO (and other MCOs) in the absence of strong evidence favoring the Intensive Intervention; (2) to obviate ethical concerns about identifying individuals at high risk for complications without taking any additional action; and (3) to provide an incentive for enrollment and continued participation among those patients who had hoped to receive the intensive intervention. Minimal intervention participants (n=273) receive phone calls every 6–12 months to remind them of important preventive diabetes-related health care (i.e., HbA1c tests, primary care and specialty visits). A written summary of their health-care utilization, along with general recommendations (based on American Diabetes Association Clinical Practice Guidelines), are

Table 2
Structure of intensive versus minimal intervention

Feature	Intensive intervention	Minimal intervention
Personnel	1 NCM+3 CHWs	1 lay health educator
Total FTEs	4	0.5
Participant panel	269	273
Intake assessment and plan	Extensive	Minimal
Triggers	HbA1c>8.0% BP>130/80 LDL>100 Suboptimal monitoring Active foot problems Depressive symptoms Current smoking	No triggers
Intervention algorithms	Yes, individualized	Yes, generalized
Activities		
Clinic visits	Yes (NCM)	No algorithms.
Patient care	Yes (NCM)	Prompts for preventive
Home visits	Yes (CHW)	health-care utilization
Community events	Yes (CHW)	
Telephone calls	Yes (NCM+CHW)	Yes
Mailings[a]	Yes (NCM+CHW)	Yes
Feedback to primary care physician	Written, oral, email, pager	Written only
Duration	30 months	30 months

CHW=community health worker; FTE=full time equivalent.
[a] Newsletters, birthday cards.

sent to the participant's primary care provider. In addition, participants in this group receive diabetes-specific information via the mail (e.g., pamphlets and project newsletters). In general, this protocolized phone-based intervention is aimed at prompting participants to become more involved in their health care.

2.5.2. Intensive intervention

The intensive intervention employs the services of a nurse case manager (NCM) and community health worker (CHW) team.

2.5.2.1. Nurse case manager roles. The NCM is a registered nurse with a baccalaureate degree and relevant case management experience. After the 6-week training process, the NCM began to play several vital roles in the intervention. First, she trains and supervises the CHWs. Second, she oversees the completion of the intake assessment and plan for every patient in the panel (n=269). Finally, she directly conducts elements of the intervention that require nursing expertise (e.g., prompting the physician regarding suboptimal care patterns, offering to participate personally in the upward titration of insulin dose by arranging a series of visits with the patient). Typically, the NCM sees the patients in MCO clinic sites. The NCM communicates with the CHWs and visa versa regarding invention action plans and team strategies to enhance participants' diabetes care.

2.5.2.2. Community health worker roles. The CHWs are African-American women familiar with Baltimore City, without prior health-care training. In general, the CHWs working on the study have a high-school education, and prior work experience in semi-skilled positions (e.g., security guard). After the 6-week training process, the CHWs work as a team to provide interventions for the entire panel of 269 patients (each participant has a personal CHW, which could be any CHW from the team based on scheduling/logistical needs). Weekly meetings with the project director provide an opportunity to review participant tracking and problems faced by participants in adhering to care and treatment. These weekly meetings also reinforce initial training and assurance of CHWs' ease with implementing the treatment algorithms.

With close nursing supervision and daily contact, the CHWs play two vital roles in the intervention. First, they participate in the completion of an intake assessment and plan for every patient, with particular attention to problems not traditionally addressed by medical or nursing care (e.g., difficulty filling out medical forms because of low literacy; disorganized household interferes with regular medication adherence). Second, they intervene to overcome these problems (e.g., fill out forms and fax them to appropriate office; make several home visits to organize and monitor pill-taking behavior). Some CHW activities are conducted in the project office (e.g., telephone calls, form completion), some in the home (e.g., teaching a family member to perform glucose monitoring for a patient with poor eyesight and reviewing foods in kitchen cabinet and refrigerator), and some in the community (e.g., arranging field trips to the grocery store for education regarding healthy food choices or to a walking track to promote group exercise).

2.5.2.3. General approach. The intensive intervention is based on clinical algorithms developed from a comprehensive review of published clinical guidelines and recommendations and our experience from Project Sugar 1. The algorithms address the following areas: blood glucose control, blood pressure control, lipid control, depressive symptoms, smoking, foot screening, blood glucose monitoring, socioeconomic issues (e.g., employment, housing, insurance, caregiver concerns), alcohol use, and illicit drug use. Algorithms are designed to triage the level of control as optimal, suboptimal, poor, or very poor and direct the initiation of specific intervention action plans (IAPs). Higher risk participants (e.g., those in poor vs. optimal control) receive more aggressive (e.g., physician is paged vs. sent a written report; face-to-face meeting vs. telephone call) and more frequent follow-up (e.g., every week vs. every 2 weeks) to achieve better control. For example, with our depressive symptom algorithm, depressive symptoms are first assessed using the Primary Care Evaluation of Mental Disorders (Prime-MD) Patient Health Questionnaire (PHQ-9) [12]. If scores indicate no depressive symptoms, no action is taken and the patient is reassessed in 1 year. If scores indicate mild or moderate symptoms (and depression is diagnosed), the patient receives face-to-face education along with educational materials and is then reassessed in 1 year. If scores indicate major or severe depressive symptoms, a report is sent to the patient's primary care doctor and the patient receives face-to-face education along with educational materials. In this case, reassessment occurs sooner—at 3 months. If a participant indicates suicidal ideations, an at-risk protocol is implemented immediately where a physician on-call is paged.

Based on the algorithms (blood sugar, blood pressure, and lipids), IAPs are implemented by the NCM and CHWs. IAPs employ the Precede–Proceed model [13] to address the following areas: nutrition, physical activity, medication adherence, appointment adherence, and foot care. Overall, the Precede–Proceed model incorporates critical constructs from adult learning, social support, and behavior

modification theories and health services research such as predisposing, reinforcing, and enabling factors. The algorithms and IAPs serve as documentation tools, allowing for thorough and efficient tracking of the participants' progress.

After the NCM and CHW have completed the initial intervention visit for each participant, they meet to discuss and implement a plan of care. Subsequent intervention contacts are initiated by the NCM and/or the CHW as directed by participant needs, algorithms, or IAPs. The NCM conducts a minimum of one face-to-face clinic visit per participant each year. Each CHW conducts at least three contacts per participant yearly with at least one of those three being a face-to-face home visit. At the end the initial face-to-face contact and as needed thereafter, a written summary is sent to the participant's primary care provider. For quality control purposes, intervention charts are reviewed by the project director. Participants in this group also receive diabetes-specific information via the mail (e.g., pamphlets and project newsletters).

2.6. Data collection

2.6.1. Baseline assessment

The baseline assessment was conducted at the Johns Hopkins Outpatient Department General Clinical Research Center. During this visit, a questionnaire was administered and blood and urines samples were obtained for HbA1c, total and HDL cholesterol, serum creatinine, and urinary albumin. Information was collected on family history of diabetes, health-care utilization, diabetes-related health behaviors, currently prescribed medications, patient satisfaction with health care, medication adherence, and general health status. In addition, anthropometric and blood pressure measurements were obtained. On a random subsample of 132 (~25%) of randomized patients (regardless of intervention assignment), we assessed additional information on health behaviors and psychosocial factors such as diet, physical activity, depression, spirituality, diabetes knowledge and attitudes, and problem solving.

2.6.2. Interim health-care utilization telephone calls

Ten-minute telephone interviews are conducted at follow-up months 6, 18, and 30 on all participants. In these conversations, contact information and recent health-care utilization data are collected. These data are also collected in face-to-face interviews at baseline and follow-up visits. Thus, these key data, needed for assessment of health events and costs, are assessed at baseline, then at regular intervals throughout the 30 months of follow-up. At the time of the telephone interviews, we also ask participants about any health-care utilization (i.e., hospitalizations and ER visits) that may have occurred outside of the MCO network. In those instances, we contact the particular institutions/providers to confirm the event. We also obtain information about participant death from family members. If there is an indication that a participant is deceased, a death certificate is requested.

2.6.3. Twenty-four-month follow-up visit

Due to staff attrition, we were unable to conduct a 12-month follow-up visit, and we decided to focus our efforts on the intervention during that time. Therefore, our main follow-up occurs at 24 months (in progress). This visit is also conducted at the Johns Hopkins Outpatient Department General Clinical Research Center. During this visit, a questionnaire is administered by interviewers who are blinded to intervention assignment. In addition, anthropometric measurements, blood pressure, and blood and urines samples are obtained.

2.6.4. Economic data collection

The aim of data collection efforts related to economic variables is to assemble information required to determine direct medical costs, including those related to the interventions, from the perspective of the MCO. Labor costs can be derived directly from the personnel section project budget (e.g., NCM, CHW, lay health educator effort intervention costs), data collection effort (non-intervention costs), and direct medical costs that are contained within the administrative database with a few notable exceptions (prescription drugs, syringes, and glucose monitoring). Data for the economic evaluation will be generated from several sources; the resource types, data sources, and MCO-oriented cost assignments are summarized in Table 3.

2.6.5. Planned statistical analyses

Randomly assigned treatment group (intensive vs. minimal intervention) will be the main independent variable. Adherence to the assigned intervention (e.g., number of intervention visits kept) will be considered as a covariate in subsidiary, on-treatment analyses; however, the main analytic approach will

Table 3
Resources to be measured, sources of the data on resource utilization, and sources of costs to be assigned to the resources for Project Sugar 2 economic evaluation

Resource type	Source of data	Cost assignment
Intervention		
NCM or CHW time	Activity log	Actual salary or Bureau of Labor statistics
Phone calls	Activity log	Local rates or national averages
Mailings	Activity log	Local rates
Space	Floor plan	Local rates, national averages
Trainer effort	Activity log	Actual salary
Office visits	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Hospital outpatient encounter	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Ambulatory surgery center encounters	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Drugs (chronic therapy)	Patient interview	Drug Topics Redbook
Emergency room visits	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Home health provider	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Hospice services	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Hospitalization	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Nursing home stays	Administrative data, patient interview	MCO reimbursed amount and Medicare, Resource-Based Relative Value Scale
Mortality data	MD multiple cause of death file	Cost per life lost
Blood glucose monitor and strips	Patient interview	Redbook
Syringes	Patient interview	Redbook

NCM=nurse case manager, CHW=community health worker.

be based upon intention-to-treat, independent of subsequent adherence. There will be data regarding a wide array of dependent variables which fall into three broad categories: (1) dichotomous variables, such as achieved target HbA1c at 24 months: yes or no, or experienced a 0.4 mg/dl increase in serum creatinine indicative of renal function decline at 24 months: yes or no; (2) continuous variables, such as change in HbA1c, systolic blood pressure, or health status score from baseline to 24 months, as well as cumulative health-care costs over 24 months, and (3) time-to-event variables, such as death, hospital admission, or other diabetes-related health event at 24, 30, and 36 months.

Our approach will be to conduct the following analyses: unadjusted analyses of dichotomous data will employ contingency tables, with calculation of proportions and odds ratios. Multiple logistic regression will be used to perform simultaneous adjustment. Data on physiologic parameters and other continuous data will be analyzed using *t*-tests, analysis of variance, and linear regression. Analysis of health events will be handled using life table and person-year approaches (i.e., total events/total person-years of follow-up), with proportional hazard models and Poisson models serving as the corresponding regression techniques.

For power calculations based on our existing sample size, we chose 3-year hospital event rates as our main outcome (we will be able to track health events using administrative data). The rationale for this choice was based on (1) a study powered for this outcome would have even greater power to detect effects on continuous physiologic variables (e.g., HbA1c, blood pressure) and (2) the hospital event rates and the care they prompt, will drive costs. Assuming that 25% of adults with diabetes are hospitalized annually (from national survey data), 58% are expected to be hospitalized over 3 years. Then, with type 1 error set at 0.05 (two-tailed), we have 80% power to detect a 20% relative difference in hospitalization rates between the intervention groups.

3. Results

Baseline assessments were completed between October 2000 and June 2002, interventions started in November of 2000 and are ongoing, and 24-month follow-up visits started in November of 2002 and are ongoing. Baseline characteristics of the total study population and by randomization group are summarized in Table 4. Except for a difference in the number of individuals having at least one visit to the podiatrist (40% in minimal intervention group versus 50% in intensive intervention group, p=0.013), none of the characteristics were significantly different between the randomization groups.

Overall, participants were 73% female, with mean age 58 years, and about 35% had a yearly income less than US$7500. The majority of participants had capitated health insurance plans (72%). About one-third were married and one-third were employed full or part-time.

Many participated in diabetes-related preventive health care in the past 12 months (prebaseline): 33% had at least one visit to a nutritionist, 45% had at least one visit to a podiatrist, and 80% had at least one visit to an ophthalmologist. The mean number of visits to a primary care physician was 5. Thirty-nine percent reported having at least one emergency room visit and 23% reported at least one hospitalization. Very few participants had surgical/medical procedures indicative of diabetes complications; the most common procedure was laser eye surgery (8%).

The majority of participants had a glucose self-monitoring machine to check their glucose at home (85%). Of these, 40% reported monitoring every day. Participants were asked what level of blood sugar is perfect for them; the mean level reported was 123 mg/dl. About 30% reported being a current smoker.

Table 4
Baseline characteristics of the Project Sugar 2 study population by randomization group

	Randomization group		
	Minimal intervention (*n*=273)	Intensive intervention (*n*=269)	Total study group (*n*=542)
Sociodemographics			
Female	202 (74.0)	194 (72.1)	396 (73.1)
Age (years)	56.3±10.8	58.8±11.3	57.6±11.2
Yearly income<US$7500	97 (35.5)	90 (33.5)	187 (34.5)
Education (years)	11.5±2.8	11.5±2.5	11.5±2.7
Insurance plan			
Capitated	193 (70.7)	191 (71.0)	384 (70.8)
Fee-for-service	80 (29.3)	78 (29.0)	158 (29.2)
Marital status			
Married	84 (30.8)	93 (34.6)	177 (32.7)
Widowed/separated/divorced	124 (45.4)	122 (45.4)	246 (45.3)
Never been married	65 (23.8)	54 (20.0)	119 (22.0)
Employment status			
Retired/disabled	148 (54.2)	168 (62.5)	316 (58.3)
Employed (full or part-time)	99 (36.3)	77 (28.6)	176 (32.5)
Unemployed	12 (4.4)	13 (4.8)	25 (4.6)
Homemaker/attending school	14 (5.1)	11 (4.1)	25 (4.6)
Health-care utilization[a]			
Patient rating of overall health care (1–10), median	9.0	9.0	9.0
≥1 visit to nutritionist	81 (29.7)	96 (35.7)	177 (32.7)
≥1 visit to ophthalmologist	224 (82.1)	211 (78.4)	435 (80.3)
≥1 visit to podiatrist[b]	108 (39.6)	135 (50.2)	243 (44.8)
# of visits to primary care physician	5.3±4.7	5.1±4.2	5.2±4.4
≥1 emergency room visit	106 (38.8)	106 (39.4)	212 (39.1)
≥1 overnight hospital stay	63 (23.1)	64 (23.8)	127 (23.4)
Laser eye surgery	23 (8.4)	18 (6.7)	41 (7.6)
Heart bypass surgery	0 (0.0)	3 (1.1)	3 (0.6)
Angioplasty, heart	1 (0.4)	3 (1.1)	4 (0.7)
Angioplasty, peripheral	2 (0.7)	2 (0.7)	4 (0.7)
Amputation	4 (1.5)	5 (1.9)	9 (1.7)
Kidney dialysis	0 (0.0)	0 (0.0)	0 (0.0)
Health behaviors			
Has machine to check glucose at home	225 (82.4)	233 (86.6)	458 (84.5)
Glucose monitoring frequency			
Every day	83 (36.7)	101 (43.4)	184 (40.1)
Once or several times/week	95 (42.1)	94 (40.3)	189 (41.2)
Never	48 (21.2)	38 (16.3)	86 (18.7)
Perfect blood sugar level (mean, mg/dl)	122±36.7	123±29.1	123±33.1
Smoking			
Never	111 (40.7)	92 (34.2)	203 (37.5)
Former	88 (32.2)	91 (33.8)	179 (33.0)
Current	74 (27.1)	86 (32.0)	160 (29.5)

Table 4 (*continued*)

	Randomization group		
	Minimal intervention (*n*=273)	Intensive intervention (*n*=269)	Total study group (*n*=542)
Clinical characteristics			
First degree relative with diabetes	148 (54.2)	136 (50.6)	284 (52.4)
BMI, kg/m^2	34.9±8.6	34.0±8.2	34.5±8.4
Systolic blood pressure (mm Hg)	137±20	137±21	137±21
Diastolic blood pressure (mm Hg)	80±11	80±11	80±11
HbA1c, %	8.0±2.2	7.9±2.2	7.9±2.2
HDL cholesterol, mg/dl	51.3±15.0	51.1±14.9	51.2±15.0

All results shown as *N* (%) or mean±S.D.

BMI=body mass index, HDL=high density lipoprotein.

[a] Performed in the past 12 months (pre-baseline).

[b] Indicates statistically significant difference between the groups ($p<0.05$). The only statistically significant difference between the groups was for the number of visits to a podiatrist.

Many participants (52%) had a first-degree relative with diabetes. The mean body mass index (BMI) in the sample was about 35, which would be considered extremely obese according to NIH guidelines (69% had a BMI ≥30 kg/m^2). Although the mean systolic and diastolic blood pressure were 137 and 80 mm Hg, respectively, 72% had values ≥130/80 mm Hg). The mean HbA1c was 7.9% (43% with values <7%), and the mean HDL cholesterol was 51.2 mg/dl. Women had a higher mean HDL cholesterol level than men (53 vs. 46 mg/dl, respectively).

4. Discussion

Thus far, we have demonstrated that conducting a randomized trial within the context of a MCO is feasible. Specific aspects of the study that contributed to the feasibility included limiting data collection to one baseline visit and obtaining nonfasting samples, which enabled us to schedule baseline visits at various times during the day. In addition, we developed a partnership with the MCO; we included several individuals from the organization as part of our investigative team and worked together to plan all aspects of the study.

External validity of the trial seems reasonable. Slightly more females, younger persons, and persons having higher education levels and capitated health plans were enrolled. Our data also indicate that more persons who felt that it was hard to manage their diabetes enrolled in the study, probably hoping to utilize the services of the NCM and the CHW. Nonetheless, participants and nonparticipants were similar with respect to clinical variables, suggesting that we did not enroll a healthier study population. The fact that at the start of recruitment we focused on enrolling patients with capitated health plans, which included patients receiving Medicaid who are generally a younger group, probably explains why our participants are slightly younger than nonparticipants. To determine if age influenced differences in the other parameters (i.e., education, clinical characteristics, etc.) between participants and nonparticipants, we conducted age-adjusted analyses (data not shown). Age seemed to account for differences in education and HDL cholesterol between participants and nonparticipants.

If our hypotheses are correct and consistent with our previous study, the intensive NCM/CHW team intervention should produce significant improvements in diabetic control (HbA1c, lipids, blood pressure) and reductions in health events (emergency room visits and hospitalizations) in a cost-effective manner. This combined clinic and community-oriented approach may be an attractive model for providing specialized care for African-Americans with type 2 diabetes and can be incorporated into various disease management programs within MCOs.

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