Diabetes and Metabolism

The Cholesterol, Hypertension, And Glucose Education (CHANGE) study: Results from a randomized controlled trial in African Americans with diabetes

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Background Cardiovascular disease (CVD) and diabetes account for one-third of the mortality difference between African American and white patients. We evaluated the effect of a CVD risk reduction intervention in African Americans with diabetes.

Methods We randomized 359 African Americans with type 2 diabetes to receive usual care or a nurse telephone intervention. The 12-month intervention provided monthly self-management support and quarterly medication management facilitation. Coprimary outcomes were changes in systolic blood pressure (SBP), hemoglobin A1c (HbA1c), and low-density lipoprotein cholesterol (LDL-C) over 12 months. We estimated between-intervention group differences over time using linear mixed-effects models. The secondary outcome was self-reported medication adherence.

Results The sample was 72% female; 49% had low health literacy, and 37% had annual income <$10,000. Model-based estimates for mean baseline SBP, HbA1c, and LDL-C were 136.8 mm Hg (95% CI 135.0-138.6), 8.0% (95% CI 7.8-8.2), and 99.1 mg/dL (95% CI 94.7-103.5), respectively. Intervention patients received 9.9 (SD 3.0) intervention calls on average. Primary providers replied to 76% of nurse medication management facilitation contacts, 18% of these resulted in medication changes. There were no between-group differences over time for SBP (P = .11), HbA1c (P = .66), or LDL-C (P = .79). Intervention patients were more likely than those receiving usual care to report improved medication adherence (odds ratio 4.4, 95% CI 1.8-10.6, P = .0008), but adherent patients did not exhibit relative improvement in primary outcomes.

Conclusions This intervention improved self-reported medication adherence but not CVD risk factor control among African Americans with diabetes. Further research is needed to determine how to maximally impact CVD risk factors in African American patients. (Am Heart J 2013;166:179-186.e2.)

Background

Individuals with type 2 diabetes have increased risk for cardiovascular disease (CVD), resulting in higher mortality, morbidity, and costs.[1-3] Achieving simultaneous control of multiple CVD risk factors such as diabetes, hypertension, and hyperlipidemia reduces complications among patients with diabetes.[4-6] African Americans are approximately twice as likely as white patients to have ≥3 CVD risk factors[7,8] and to experience higher rates of coronary events, stroke, and mortality.[9-11] Together, CVD and diabetes account for more than one-third of racial disparities in mortality,[12] so addressing disparities in CVD risk factor control among patients with diabetes is essential.[13,14]

Failure to achieve chronic disease treatment goals arises from both patient treatment nonadherence and inadequate treatment intensification.[15,16] Interventions that target multiple CVD risk factors by addressing nonadherence and treatment intensification could therefore be particularly impactful.[17] Our prior work indicates that chronic disease self-management interventions may be especially effective among African Americans.[18] In light of racial disparities in CVD outcomes,[9-11] novel strategies

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targeting nonadherence and treatment intensification across multiple CVD risk factors in African Americans are needed.

We evaluated the impact of a telephone-delivered disease management intervention on CVD risk factors in African Americans with diabetes. The intervention was delivered remotely by research nurses following a model used successfully in prior studies.[19,20] This intervention incorporated patient self-management support to target nonadherence and medication management facilitation to address inadequate treatment intensification.

Methods

The CHANGE study (ClinicalTrials.gov Identifier: NCT00815789) randomized African American patients with type 2 diabetes to (1) usual care or (2) a nurse-administered telephone intervention incorporating CVD risk factor self-management education and medication management facilitation. Participants received care at 2 clinics in Durham, NC, where primary care providers (PCPs) including physicians, nurse practitioners, physician assistants, and residents serve significant numbers of African American patients. This study was approved by the Duke University Institutional Review Board.

Inclusion criteria were as follows: age ≥18 years; self-reported black/African American race; ≥1 PCP visit in the past year, a type 2 diabetes *International Classification of Diseases, Ninth Revision* code (250.x0/250.x2) within 3 years, and ≥1 hemoglobin A1c (HbA1c) measurement in the past year. Individuals were excluded for diagnosis of dementia, psychosis, or metastatic cancer; receipt of dialysis; recent (3 months) hospitalization for stroke, myocardial infarction, or coronary revascularization; pregnancy, expected pregnancy, or breast-feeding; nursing home residence; lack of telephone access; severely impaired speech/vision; or not speaking English.

Eligible patients received a letter from investigators and their PCP requesting study participation. A research assistant then arranged a meeting where participants provided informed consent, underwent a baseline interview, and received cardiovascular education pamphlets tailored to African Americans with diabetes. Participants were randomized to receive the intervention or usual care. Randomization used a computer-generated block-randomization sequence stratified by clinic site; a blinded staff member sealed randomization assignments within sequentially numbered, opaque, identical envelopes, and a research assistant revealed group assignments to participants.

Intervention overview

The CHANGE study intervention included self-management education and medication management facilitation components. Both intervention components were delivered by nurse interventionists centered outside the study sites, who communicated remotely with patients and PCPs following a model used in prior studies.[19,20] Nurses delivered self-management education modules via monthly telephone calls during the 12-month study period, and medication management facilitation occurred quarterly via electronic nurse-PCP communication.

Intervention materials were designed for low-income/low-health-literacy patients,[21] and all materials were reviewed by clinic directors. During the intervention development, all research staff underwent interactive training with the Duke Community Health Network focusing on cultural sensitivity and awareness of issues facing African Americans in our community.[21] Along with cultural sensitivity training, the 2 nurse interventionists (both white women) received intensive training in motivational interviewing. The intervention is described briefly below and in detail elsewhere.[21].

Self-management education modules

Nurses delivered self-management education modules during monthly telephone encounters according to a schedule (see online Appendix A for additional information regarding the self-management education intervention and module schedule). The self-management material addressed 3 separate domains: (1) disease management (including knowledge, self-monitoring, and medication use), (2) psychosocial determinants of disease control (including depression, memory, and social support), and (3) tailored behavior change (customized based on patient assessment, could include diet, exercise, smoking cessation, and others).

Module delivery used software that provided scripts to guide the interaction and record patient responses. This scripting ensured that the intervention was standardized according to patients' responses. The nurse began behavior change modules by identifying the patient's current stage of change according to the transtheoretical model.[22] Subsequent material was based on that stage and aimed to motivate positive behavior change.

Medication management facilitation

Nurse-PCP contacts occurred via secure electronic communication after completion of monthly telephone encounters at 3, 6, and 9 months. Nurses contacted PCPs with a summary of the patient's self-reported medication adherence, discrepancies with prescribed medication regimens, home monitoring information for blood sugar and blood pressure (BP), and the patient's willingness to change therapy (see online Appendix B for nurse-PCP contact template). If appropriate, nurses encouraged PCPs to make medication changes based on this summary, which they offered to facilitate by communicating with the participant and arranging follow-up laboratory studies; however, nurses did not recommend specific medication changes to PCPs. Each nurse-PCP contact generated a note in the electronic medical record (EMR), which summarized the contact. If a 3-, 6-, or 9-month patient telephone encounter could not be completed, nurses did not initiate the scheduled PCP contact for that period.

Study measures

We collected baseline data on patient demographics, comorbidities, medications, CVD risk factors, and upcoming appointment dates. At the baseline interview, patients completed a survey assessing health behaviors, health literacy,[23] and self-reported medication adherence.[24] This survey was repeated by telephone 12 months after enrollment. We collected vitals, insurance status, and comorbidities from a review of EMR data before the study and again after the 12-month patient interview.

Primary outcomes

Coprimary study outcomes were systolic BP (SBP), HbA1c, and low-density lipoprotein cholesterol (LDL-C). These

outcomes were not assessed at research visits but were ascertained based on routine clinic measurements from the Duke EMR. We included all available measurements for each primary outcome within a window before and after the 12-month intervention period; SBP was collected for the period 30 days before baseline through 30 days after study end, HbA1c was collected for the period 90 days before baseline through 90 days after study end, and LDL-C was collected for the period 90 days before baseline through 180 days after study end. If multiple BP readings were taken the same day, we used their mean, so patients had at most 1 daily measurement.

Secondary outcome

We measured self-reported medication adherence as an a priori secondary outcome using the Morisky Self-reported Medication-Taking Scale.[24] Patients responded to the following 4 statements: (1) "I sometimes forget to take my blood pressure medicine;" (2) "I am sometimes careless about taking my blood pressure medicine;" (3) "When I feel better, I sometimes stop taking my blood pressure medicine;" and (4) "If I feel worse when I take the blood pressure medicine, sometimes I stop taking it." Patients responding "strongly agree," "agree," "don't know," or "refuse" to any question were classified as nonadherent.[25]

Sample size estimation

Sample size estimation was based on detecting a 5-mm Hg difference in SBP (SD 11.0 mm Hg) between intervention and usual care groups at 12 months, a 0.5% (SD 1.1%) difference in HbA1c, and a 20-mg/dL (SD 43.5 mg/dL) difference in LDL-C. Assuming a 2-sided type I error of 0.05 and an attrition rate of 10%, we planned to enroll 200 patients in total to detect these differences with 80% power. Our sample size target was subsequently increased after we obtained additional funding.

Analyses

The primary study outcomes (SBP, HbA1c, LDL-C) were ascertained through EMR clinic data pulls. Patients in this study therefore had varying numbers of clinic-based outcome assessments captured at differing times. To describe average trends over time, we generated penalized splines for each of the 3 clinical outcomes over the 12-month study period. All outcomes indicated linear trends over time, so linear mixed-effects models were fit for each outcome. We included the following fixed effects in these models: (1) time, coded continuously as the number of days from baseline; (2) intervention group; (3) the interaction of time and intervention group; and (4) clinic site. Models for these outcomes also included patient-level random effects for intercept and linear time and the correlation between intercept and slope. The procedure MIXED in SAS v9.2 (Cary, NC) was used to fit all linear mixed-effects models and estimate treatment group differences at 12 months. Sensitivity analyses examined the impact of patients with higher values being measured more frequently during their regular clinical care (ie, outcome-dependent follow-up).[26,27] Post hoc analyses examined treatment group differences for patients with baseline HbA1c >9.0% as compared with other patients.

To evaluate our secondary outcome, we used conditional logistic regression (PROC LOGISTIC in SAS v9.2) to evaluate for a between-treatment group difference in change of medication adherence status from baseline to 12 months. We first excluded observations in which medication adherence status did not change across the 2 time points, then ran our model on the remaining observations. The 12-month medication adherence status was included as the dependent variable, and our independent variables included randomization arm and clinic site.

In addition, we examined the intervention effect for patients with improved adherence compared with those without improved adherence. We first estimated individual-level slopes from the SBP, HbA1c, and LDL-C mixed-effects models described above, then fit regression models with the individual-level slopes as the outcome and predictors including individual-level intercept (ie, baseline), intervention group, improved adherence (yes/no), and the interaction of intervention group with improved adherence.

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Results

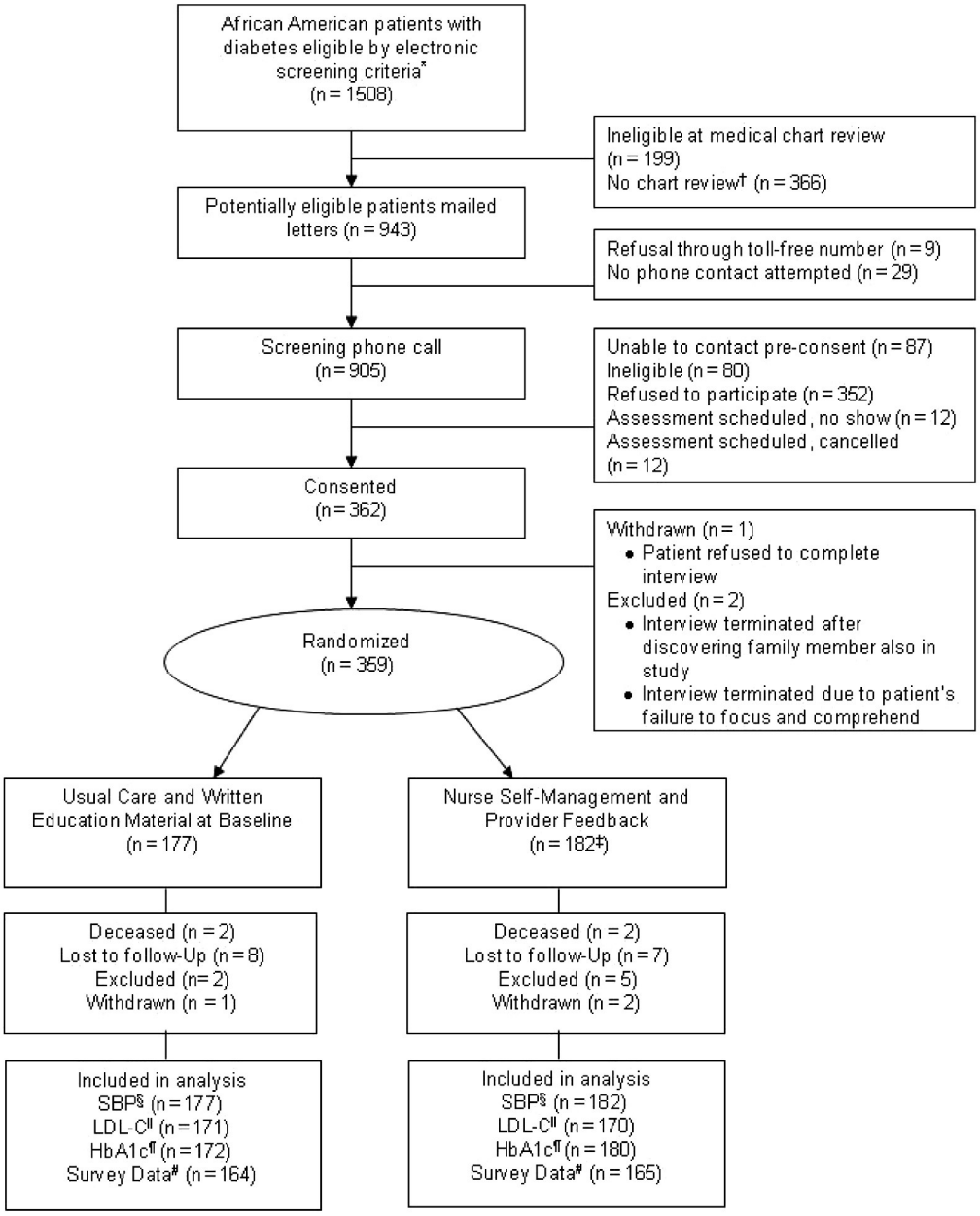
Baseline characteristics

We randomized 359 patients to usual care (n = 177) or intervention groups (n = 182) (Figure 1). Compared with 870 potentially eligible participants who were not included, randomized patients were more often female (73% vs 66%; P = .02) but did not differ in age; hypertension, coronary artery disease, chronic kidney disease, or congestive heart failure prevalence; or HbA1c, BP, or LDL-C. Table I shows the characteristics of included patients by intervention group and is notable for the 49% of patients with inadequate literacy and 37% with annual income <$10,000.

Intervention implementation

On average (SD), intervention patients received 9.9 (3.0) of the 12 scheduled self-management intervention calls. Each intervention call averaged (SD) 17.1 (7.3) minutes. After the completion of patient intervention telephone encounters at 3, 6, and 9 months, nurses contacted PCPs to relay summary information and facilitate any medication changes. Among intervention patients, nurses initiated 436 PCP contacts (110 PCP contacts could not be initiated because of patient dropout or failure to complete the preceding intervention telephone encounter). Primary care providers replied to 76% (332/436) of the contacts, and of these replies, 18% (59/332) resulted in medication change recommendations. Ninety-two percent (329/359) of patients completed the 12-month follow-up call within 455 days after the baseline interview.

Figure 1



Abbreviations: CHANGE = Cholesterol, Hypertension, and Glucose Education, CONSORT = Consolidated Standards Of Reporting Trials, SBP = systolic blood pressure, HbA1c = hemoglobin A1c, and LDL-C = low-density lipoprotein cholesterol

*Electronic screening criteria: Type 2 diabetes (ICD9 code of 250.x0 or 250.x2 in preceding 3 years); black race; ≥ 1 primary care visit at participating clinic in preceding year; age ≥ 18; ≥ 1 blood pressure and ≥ 1 HbA1c measurement recorded in past year.

†Not identified on randomly sorted upcoming appointment list (either no appointment during time period, or more people than needed available at same time period)

‡Three of these 182 participants were randomized to the Usual Care and Written Education Material at Baseline arm, but erroneously received the Nurse Self- Management and Provider Feedback intervention.

§Time period for SBP data: 30 days prior to baseline interview through 30 days after 12 month interview

‖Time period for LDL data: 90 days prior to baseline interview through 180 days after 12 month interview

¶Time period for HbA1c data: 90 days prior to baseline interview through 90 days after 12 month interview

#Time period for survey data: 455 days after baseline interview

CHANGE study CONSORT diagram.

Table I. Baseline characteristics of study participants by intervention arm

Baseline characteristics*	Usual care (n = 177)	Intervention (n = 182)
Demographics†		
Age (y), mean (SD)	57 (12)	56 (12)
Female	75%	69%
Married	32%	35%
Completed <12 y of schooling	30%	30%
Low health literacy (REALM ≤60)	49%	48%
Employed	37%	40%
Income <$10,000 per year	40%	35%
Current smoker	14%	19%
Insurance		
Private insurance/managed care	33%	40%
Medicare	41%	41%
Medicaid	18%	15%
Uninsured/Worker's compensation	8%	4%
Medical history‡		
Hypertension	96%	94%
Coronary artery disease	30%	31%
Chronic kidney disease	16%	11%
Congestive heart failure	16%	18%
Atrial fibrillation	8%	8%
Medication use‡		
No. of diabetes agents, mean (SD)	1.7 (0.9)	1.6 (0.9)
Patients using insulin	52%	51%
No. of antihypertensive agents, mean (SD)	2.9 (1.6)	2.6 (1.5)
No. of cholesterol-lowering agents, mean (SD)	0.9 (0.6)	0.8 (0.6)

REALM, Rapid Estimate of Adult Literacy in Medicine.
*Variables with missing values (usual care/self-management intervention): low health literacy (9/8); employed (2/0); and income <10,000 per year (6/6).
† All values self-reported (except insurance).
‡ Values obtained from EMRs.

Intervention effect

Figure 2 shows model-based estimated trajectories for each outcome by intervention group over the study period. Sensitivity analyses did not indicate bias caused by informative outcome-dependent follow-up (results not shown). The model-based estimate for baseline SBP was 136.8 (95% CI 135.0-138.6) for both groups, as we assumed a common intercept for both at baseline. Patients had a mean of 8.3 BP measurements over the study period. There was no significant between-group difference in model-estimated SBP over time (treatment-by-time $P = .11$) or at 12 months (3.0 mm Hg higher in the intervention group; 95% CI −0.6 to 6.6) (Table II).

The model-estimated baseline HbA1c value was 8.0% (95% CI 7.8-8.2); baseline HbA1c was measured a median of 31 days before study start (interquartile range [IQR] 0-59). Patients in both groups had a mean of 3.6 HbA1c measurements during the study window, with end point values measured a median of 31 days after study end (IQR 13-63). There was no significant between-group difference in model-estimated HbA1c over time (treatment-by-time $P = .66$) or at 12 months (0.1% lower in the intervention group; 95% CI −0.4 to 0.2). Post hoc analyses showed that HbA1c improved over time for patients with HbA1c >9.0% at baseline, but this improvement was similar to usual care (3-way interaction of high prior HbA1c-by-group-by-time $P = .14$).

The model-estimated baseline LDL-C value was 99.1 (95% CI 94.7-103.5) for both groups; baseline LDL-C was measured a median of 26 days before study start (IQR 0-49). Both groups had a mean of 2.1 measurements during the study window, with end point values measured a median of 84 days after study end (IQR 35-123). There was no significant between-group difference in model-estimated LDL-C over time (treatment-by-time $P = .79$) or at 12 months (1.0 mg/dL higher in the intervention group; 95% CI −6.5 to 8.5).

Adherence analysis

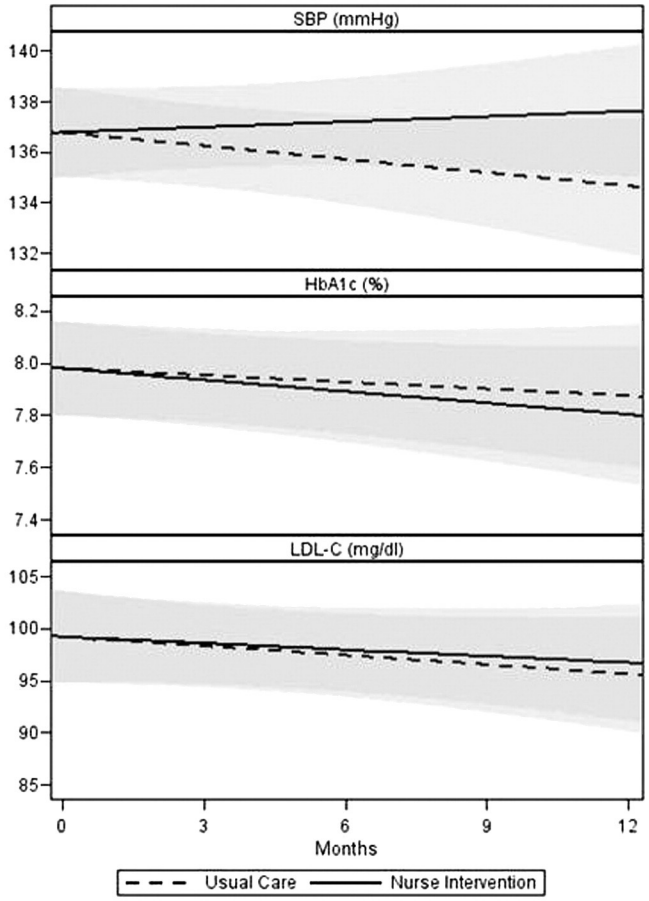
Compared with the usual care group, intervention group patients reporting medication nonadherence at enrollment were more likely to report medication adherence at study end. The conditional odds ratio for improved adherence among intervention versus usual care patients was 4.4 (95% CI 1.8-10.6, $P = .0008$). The results of the mixed-effects regression models on the individual-level slopes did not show a differential intervention effect on clinical outcomes for those with improved adherence compared with those without (intervention-by-adherence $P = .38$ and .15 for HbA1c and LDL-C, respectively). Systolic BP was not included in this analysis because the individual-level trajectories for this outcome were prohibitively variable over time.

Discussion

We enrolled a large group of African Americans with diabetes, limited financial resources, and high prevalence of low health literacy for a trial of a nurse-delivered intervention combining patient self-management education and facilitation of medication management. Despite frequent contact with patients/PCPs and good intervention participation, we observed no significant intervention effect on SBP, HbA1c, or LDL-C compared with usual care. Although intervention group patients were significantly more likely than the usual care group to report improved medication adherence from enrollment to study end, this improved adherence did not translate to lower HbA1c or LDL-C. Likewise, no differential intervention effect on HbA1c was seen for those with HbA1c >9.0% at baseline, although the sample size for the 3-way interaction in this post hoc analysis was limited.

Other self-management education interventions have targeted diabetes and other CVD risk factors with mixed results. Norris et al[28] reported results from 31 self-management trials that suggested early benefits in glycemic control decline over greater periods of follow-up. More recently, a meta-analysis of individual patient

Figure 2



Abbreviations: SBP = systolic blood pressure, HbA1c = hemoglobin A1c, and LDL-C = low-density lipoprotein cholesterol
* Treatment-by-time *P*-values = .11, .66, .79 for SBP, HbA1c, and LDL-C, respectively

Usual care and intervention model-based trajectories for SBP, HbA1c, and LDL-C with 95% confidence bands*.

Table II. Intervention effects* on SBP, HbA1c, and LDL-C at 12 months

Outcome	Usual care (SE)	Nurse intervention (SE)	Between-group difference (95% CI)
SBP (mm Hg)			
Baseline	136.8 (0.9)	136.8 (0.9)	
12 mo	134.7 (1.4)	137.6 (1.3)	3.0 (–0.6 to 6.6)
HbA1c (%)			
Baseline	8.0 (0.1)	8.0 (0.1)	
12 mo	7.9 (0.1)	7.8 (0.1)	–0.1 (–0.4 to 0.2)
LDL-C (mg/dL)			
Baseline	99.1 (2.2)	99.1 (2.2)	
12 mo	95.5 (2.8)	96.5 (2.8)	1.0 (–6.5 to 8.5)

* All outcome values represent mixed-effects model estimates.

education among patients with diabetes found evidence for modest benefit in the subgroup with HbA1c >8.0%, but no significant impact overall.[29] Although racial disparities in CVD outcomes and risk factor control are widely recognized,[8-12] relatively few studies have evaluated interventions addressing these disparities in African Americans. A systematic review of culturally targeted health education for minorities with type 2 diabetes found modest effects on HbA1c at 3 and 6 months; however, these differences were not significant 1 year after intervention initiation.[30]. We previously reported that a hypertension management strategy similar in structure to the CHANGE intervention benefitted African American subgroups,[18,31] but our current findings are more consistent with the systematic review.

Our study had multiple strengths. First, we were able to recruit a large African American sample with low health literacy and limited financial resources. Retention was

92%, which suggests a positive interaction between patients and nurse interventionists. Participants completed a high percentage of the telephone-delivered intervention modules. Furthermore, our approach did impact self-reported adherence relative to usual care, although this did not translate to improved CVD risk factor control.

There are several potential explanations for why this intervention did not affect CVD risk factor control, despite the fact that self-reported medication adherence improved. Our population's CVD risk factors were relatively well controlled at baseline, which may have limited our ability to detect the clinical impact of improved medication adherence. It is also possible that some patients in the intervention arm did not report medication nonadherence out of reluctance to disappoint study staff, such that that the intervention impacted adherence to a lesser extent than suggested by our analysis. The intervention's dose of self-management education may not have been sufficient to affect CVD risk factor control in this low-income, low-health-literacy population of African Americans; other investigators have cited this issue in similar studies.[32]

With respect to medication management, our quarterly contact with PCPs may have been insufficient to impact CVD risk factor control, even with the observed improvement in self-reported medication adherence. Furthermore, PCP contact was remote and was not conducted by clinic nurses with previously established relationships with those providers. We chose a centralized model for the nurse intervention because (1) using experienced nurse interventionists to deliver self-management interventions has been effective in several of our group's prior studies[19,20] and because (2) we were concerned about high clinic nurse turnover at the study's sites, so we felt that using experienced nurse interventionists would be more feasible and effective. Our results suggest that PCPs may have been less willing to adjust therapy with research nurses; we saw that although PCPs replied to 76% of nurse contacts, only 18% of these replies resulted in medication change recommendations from providers. However, this apparently low rate of treatment intensification must be interpreted cautiously because the percentage of these contacts that "should" have resulted in intensification is not yet clear. In addition, decisions not to intensify therapy within the context of a disease management intervention may actually often be appropriate,[33] particularly among patients with reasonable CVD risk factor control. Further investigation to clarify why medications were not intensified more frequently in the intervention group will be important. Inclusion of strategies to assure appropriate treatment intensification is likely important for interventions targeting CVD risk reduction among low-income, low-health-literacy African American populations.

Finally, our use of routine clinic measurements for outcome ascertainment may have impacted our results. For example, in evaluating SBP, we included all available BP data from Duke-affiliated clinics, regardless of specialty. Variability in routine clinic BP measurement has been increasingly recognized,[34] so although Duke-affiliated clinics have standard procedures for BP measurement, it is possible that all available clinic data may have introduced error into our analysis. In addition, the baseline and end point primary outcome values for this analysis were model derived. This issue may be particularly relevant for HbA1c and LDL-C, where baseline and end point values were based on measurements obtained longer before study start and after study end than for BP. Using model-derived outcome estimates may have biased our results toward the null, although we think it unlikely that any clinical benefit from the intervention would have dissipated by the time of end point measurement, especially for HbA1c (end point data measurement median was 31 days after study end for HbA1c, 84 for LDL-C). Although we do not know the extent to which our reliance on routine clinic measurements contributed to the study's negative result, this remains a noteworthy limitation of the study.

Substantial racial disparities in CVD prevalence and outcomes continue to exist. Despite prior data suggesting benefit with similar interventions, this nurse-administered, telephone-delivered self-management support and medication management facilitation intervention did not improve CVD risk factor control among African Americans. Although our intervention impacted self-reported medication adherence relative to usual care, this did not translate to improvement in CVD risk factors. Our findings suggest that disparities in CVD prevalence and outcomes may be difficult to address with low-dose clinic or telephone-based interventions and may, instead, require more intensive approaches.

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Appendix A. CHANGE study self-management education intervention and self-management module schedule

The self-management education intervention for the CHANGE study consisted of brief monthly telephone calls occurring for 12 months. A unique aspect of the intervention is that it was tailored to patients' needs; although some modules were activated at every encounter, others modules were only activated at specific encounters depending on patient characteristics. For example, the weight loss module was only activated for patients with a baseline body mass index >25 kg/m^2. The full schedule of self-management modules is listed in the Supplementary Table.

The intervention incorporated tailored information and feedback depending on the participants' baseline information and responses to scripted questions. Nurses began each module by identifying the patient's current stage of change according to the transtheoretical model. Subsequent material was then based on the stage of change and aimed at motivating the patient toward behavior change. This tailoring created flexibility for the intervention to address issues that were specifically relevant to a particular subject.

Supplementary Table. Full schedule of modules for the CHANGE self-management education intervention

Monthly encounter	Self-management modules covered during encounter
Encounter 1	Medication, adverse effects, memory, knowledge, depression
Encounter 2	Medication, adverse effects, risk communication, hypoglycemia
Encounter 3	Medication, adverse effects, diet, weight, self-monitoring
Encounter 4	Medication, adverse effects, exercise, stress, weight
Encounter 5	Medication, adverse effects, patient-provider interaction,* social support, exercise
Encounter 6	Medication, adverse effects, tobacco, alcohol, diet, self-monitoring
Encounter 7	Medication, adverse effects, memory, depression, tobacco
Encounter 8	Medication, adverse effects, hypoglycemia
Encounter 9	Medication, adverse effects, diet, weight, self-monitoring
Encounter 10	Medication, adverse effects, exercise, stress
Encounter 11	Medication, adverse effects, Pt-Pr interaction, social support
Encounter 12	Medication, adverse effects, tobacco, alcohol, knowledge

*Patient-provider interaction covers tools for patients to communicate effectively with their primary care provider.

Appendix B. CHANGE study template for nurse-primary care provider electronic communication (completed at 3, 6, and 9 months)

Dear Provider,
Attached is the quarterly summary sheet for your patient participating in the CHANGE study. Your patient's current diabetes control and other cardiovascular risk factors are summarized here. We work with the patients on improving adherence, diet and lifestyle, through monthly telephone contacts with our registered nurse. We can help facilitate medication changes if you decide these are appropriate.
In response we ask that you please:

1. Review the attached summary including the most recent information for disease and risk factor control.
2.) Respond to us by e-mail, and let us know:
   (a) If you want to continue the patient's current medication regimen.
   Or
   (b) If you would like to make any cardiovascular medication changes. Include the medication change information on your return e-mail to us. We will call the patient to let them know of any medication changes and document these changes in the electronic health record.
3.) If you would like the patient to come in for additional laboratory or clinic nurse blood pressure checks before his/her next appointment with you, please provide specific instructions in your email to us and we will facilitate this.

Thank you,
CHANGE Study Nurses

Date:
Patient's name/age:
History no.:

Contact information: Home phone Cell phone
Pharmacy: Location:
Telephone no.:

Behavior module(s) delivered at nurse's contact with patient:

Issues discussed with modules:

Current cardiovascular medications per browser, reviewed verbally with patient on (date):
Diabetes Meds

HTN Meds

Cholesterol Meds

Medication allergies:
Current medication adherence, adverse effects, or other issues:

Cardiovascular risk summary

Date	HbA1c	LDL	BP
xx/xx/xxxx	x.x%	xxx	xxx/xx
xx/xx/xxxx	x.x%	xxx	xxx/xx
xx/xx/xxxx	x.x%	xxx	xxx/xx

Most recent Self-monitoring

Date	FBG	Other BG values	Home BP	Comments

The patient is to make changes in medications to improve disease control.
*(Nurse to enter **"willing or not willing"** above).*
Missed appointment(s): Upcoming appointment: with:
Other information:

PROVIDER RECOMMENDATIONS

1. Medication change: YES NO
If yes, order (name of medication, dose, and frequency):
2. Request labs, BP check, or other needs prior to next clinic visit:

ACTIONS (completed by study nurses based on provider recommendations):

1. Medication change: YES NO
If yes, order for change (name of medication, dose, and frequency) per physician's request:
2. Labs, BP check, or other needs, prior to next visit: