EVALUATING A PROBLEM-BASED EMPOWERMENT PROGRAM FOR AFRICAN AMERICANS WITH DIABETES: RESULTS OF A RANDOMIZED CONTROLLED TRIAL

Robert M. Anderson, EdD; Martha M. Funnell, MS, RN, CDE; Robin Nwankwo, RD, MPH; Mary Lou Gillard, MS, RN, CDE; Mary Oh, BS; J. Thomas Fitzgerald, PhD

Objective: The objective of this study was to evaluate the impact of a problem-based empowerment patient education program specifically tailored for urban African Americans with type 2 diabetes.

Research Design and Methods: The study used a randomized controlled trial (RCT) pre-test/post-test design with repeated measures. Patients were randomly assigned to either a six-week intervention group or a six-week wait-listed control group. After completing the six sessions, patients were invited to participate in one of two follow-up conditions; attend a monthly support group or receive a monthly phone call from a nurse. Assessment measures included HbA1C, lipids, blood pressure, weight, self-management behavior and psychosocial adaptation.

Results: Both control and intervention patients showed a broad array of small-to-modest positive changes during the six-week RCT. These gains were maintained or improved upon during the one-year follow-up period. For patients in the two follow-up conditions, a positive correlation was seen between the number of follow-up contacts and their one-year HbA1C values.

Conclusions: We believe that results of this study can be attributed to volunteer bias, study effects (ie, providing study data on several occasions to patients and their physicians during the one-year study period), and impact of the interventions. However, the study design does not allow us to examine the relative impact of these three factors on the patient improvements seen over the one-year study period. (*Ethn Dis*. 2005;15:671–678)

Key Words: African Americans, Diabetes, Empowerment, Patient Educator

From The Michigan Diabetes Research and Training Center (MMF), and the Department of Medical Education (RMA, RN, MLG, JTF, MO), The University of Michigan Medical School, Ann Arbor, Michigan.

Address correspondence and reprint requests to Robert M Anderson, EdD; G1111 Towsley Center, Box 0201, University of Michigan; Ann Arbor; MI 48109-0201; 734-763-1153; 734-936-1641 (fax); boba@umich.edu

INTRODUCTION

Diabetes in African Americans

African Americans are two times more likely to have diabetes than their Caucasian counterparts. Approximately 2.7 million African Americans are diagnosed with diabetes.[1] One in four African-American women age 55 and older has diabetes.[2] Compared to Caucasian Americans, African Americans suffer greater diabetes-related complications with a higher incidence of kidney failure and eye disease.[3–5] Despite the importance of achieving tight glycemic control for improving long-term health outcomes, some studies have found African Americans with diabetes to exhibit poorer glycemic control than their Caucasian counterparts.[6,7] African Americans with diabetes are therefore prime candidates for participation in effective self-management interventions.

Recent meta-analyses have found self-management interventions to have a positive impact on diabetes-related health outcomes, specifically increasing diabetes-related knowledge and improving blood glucose monitoring, dietary habits, and glycemic control.[8–11] Among people with type 2 diabetes, however, gains are usually lost by six months without follow-up or on-going self-management support.[9] Self-management interventions specifically targeting African-American patients have also yielded promising findings.[12–15]

All of the effective interventions had behavior change as their goal and incorporated and emphasized behavioral strategies, rather than a traditional didactic approach. Effective educational strategies included the use of focus groups,[16] ethnic food recipes, and curricula and handouts that had been modified or developed to meet the specific needs of the target population.[17] Behavioral strategies shown to be effective included goal setting, controlling/avoiding triggers to eat, and portion-control and self-monitoring.[17] This study examines the impact of a problem-based empowerment intervention for African Americans with diabetes.

All of the effective interventions had behavior change as their goal and incorporated and emphasized behavioral strategies, rather than a traditional didactic approach.

RESEARCH DESIGN AND METHODS

Study Design

The study used a randomized control group pre-test/post-test design with repeated measures (see Figure 1). Patients were randomly assigned to either the intervention group or the wait-listed control group. Baseline data were collected from both groups at enrollment. For the intervention group, baseline data served as the pre-test measure; for the control group, the data collected at the end of the six-week control period also served as the pre-test data for their subsequent participation in the six weekly group sessions.

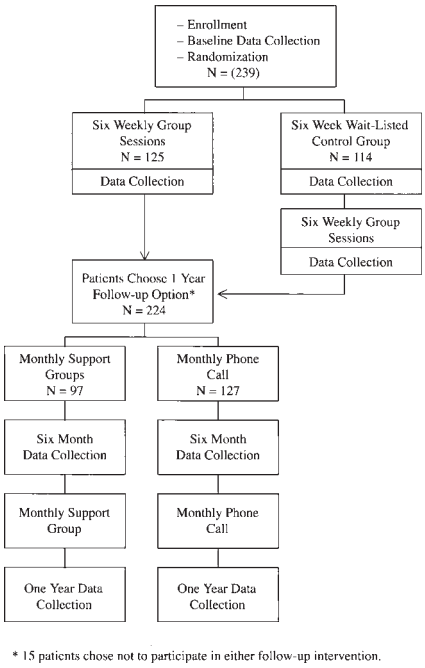

Fig 1. Research design

Table 1. Structure of weekly group sessions

Component 1: Reflecting on self-management experiments
At the end of each group session, patients were invited to identify a goal and action plan related to their self-management. These exercises were presented as one-week self-management experiments. They were viewed as experiments because a plan that did not work generated as much new knowledge as a plan that succeeded. At the beginning of the subsequent session, patients were invited to reflect on their experience of working on their self-selected goals and talk about what they had learned and how it could be applied in the future.

Component 2: Discussing the emotional experience of living with diabetes
Living with diabetes raises emotional issues related to relationships, work, family, economic circumstances, overall health, physical functioning, and other life dimensions. During each session patients were encouraged to discuss important events that had occurred since the previous meeting and to reflect on how these events had affected their self-management.

Component 3: Engaging in systematic problem-solving
The problem-solving component of the program was based on the recognition that patients are much more likely to be motivated to address their own issues and priorities than issues introduced by an educator. The problems raised during the group sessions included interacting with healthcare providers as well as self-management and psychosocial issues. Patients learned important problem solving skills by participating in systematic educator-guided problem solving discussions.

Component 4: Answering clinical questions
This component provided the opportunity for patients to inquire about diabetes self-management related issues. Because we had completely eliminated lectures, we kept careful records to ensure that all the diabetes-related topics required by the national diabetes education standards were covered during the six-week program. If a topic did not come up during sessions one through five the educators introduced it at session six.

Component 5: Culturally tailored education materials
In addition to ensuring cultural relevance by focusing on the concerns and priorities of the patients in the program, we used education materials that were developed with and for the target audience (eg, ethnic recipes, appropriate reading level).

The intervention consisted of six weekly two-hour group sessions. Patients assigned to the six-week intervention group participated in the six weekly sessions immediately after the collection of baseline data. Patients assigned to the control group participated in the six weekly sessions immediately after the six-week control period. After their six weeks of sessions all patients were offered the opportunity to join a monthly support group or receive a monthly phone call.

Data were collected at baseline and after the six-week group sessions, after the six-week control period, at six months, and at one year. Patients received a $50 cash stipend for completing the six-month and one-year study assessments.

Recruitment

The program was designed and marketed as a culturally specific program focused on the concerns and issues of urban African Americans with diabetes living in the metropolitan Detroit area. The city of Detroit has an estimated 50,000 citizens with diabetes. Recruitment strategies included displaying posters in community organizations with which we have collaborated in the past, eg, churches, senior citizen centers, and social service agencies. We also employed newspaper and radio advertisements, as well as word-of-mouth. Interested patients were invited to a group enrollment meeting where all of the details of the study and the intervention were explained and questions were answered. Each enrollment meeting had a 15-minute break allowing patients not interested in enrolling in the study to leave unobtrusively. After the break patients wishing to join the study completed the informed consent process, had blood drawn by a phlebotomist, and completed the written questionnaires. Patients were randomized to either the wait-listed control or intervention groups immediately after signing the informed consent forms.

Interventions

The interventions that are the focus of this study evolved from three areas of research conducted by the Michigan Diabetes Research and Training Center (MDRTC) over the past 20 years. These areas include the development and evaluation of: 1) effective methods and materials for use in diabetes education; 2) culturally specific educational materials and community-based programs for urban African Americans with diabetes; and 3) the empowerment approach to facilitating self-directed behavior change for persons with diabetes.

The structure and process employed in the design and conduct of the intervention reflects what has been learned from this research. The primary

Table 2. Empowerment behavior change model*

1. ''Tell me more about the problem. What did you do? What were the results?''
2. ''How do you feel about the results? How will you feel if things don't change?''
3. ''What are some potential options for addressing this problem? Which option is best suited to your situation? Are you willing to take steps to improve things for yourself?''
4. ''What are you going to do when you leave here? How will you decide if your plan worked?''

* Questions were not intended to be used exactly as worded. They are included here to convey the overall empowerment based problem-solving approach used in the classes. During the sessions the educators engaged in appropriate, natural (based on extent of relationship, education level, etc) dialogue with patients about all aspects of self-management behavior.

intervention was a program consisting of six two-hour group sessions held weekly in convenient community-based locations. The overall structure of those sessions is shown in Table 1.

At session 1, patients were given the results of their HbA1C, lipids, blood pressure, and weight evaluations, which had been conducted at baseline. The resulting values were presented in writing with handouts that provided basic information about normal values and five to eight behaviors that affect each of these laboratory parameters. Patients were given a few minutes to review their own data and then one of the two educators (all sessions were conducted by a nurse and a dietitian) asked, ''Are there any questions?'' In virtually every program the next two hours were spent answering patients' questions about the meaning of their values and their risk for short- and long-term complications. Patient-identified problems became the focus of guided problem-solving discussions. The problem-solving process was based on our empowerment approach to facilitating self-directed behavior change outlined in Table 2.

The educators provided short answers (to avoid turning answers into lectures) to technical/clinical questions, which facilitated a lively iterative process of questions and answers. Lifestyle and many self-management questions were used to initiate group problem-solving discussions.

Sessions 2–6 began with a group discussion of self-management experiments tried by the participants during the preceding week. After a discussion of the self-management experiments, questions were addressed that had not been answered at the previous session. For example, the intervention team might say, ''At the end of last week's session some of you said that you still had questions about nutrition. What are your questions?'' Because lectures were completely eliminated from this education program, we kept careful records to ensure all diabetes-related topics required by the national diabetes education standards were covered during the six-week program. Certified diabetes educators who were able to move fluidly from topic to topic based on patient needs and interests conducted the intervention. Emotional and behavioral issues related to each topic were addressed at the same time. The topics and content of each of the six sessions varied based on the individual needs and concerns of the participants. Intervention consistency was achieved by providing a consistent process (Tables 1 and 2) that allowed a truly patient-centered intervention.

Follow-up Interventions

The monthly support group follow-up sessions employed the same structure and process as the six-week group sessions. Patients who selected the phone follow-up intervention received an individually scheduled monthly phone call from a nurse. Using the empowerment behavior change model (Table 2), patients were engaged in a review/evaluation of their diabetes self-management, therapy, goal achievement, problems encountered, concerns, and current level of psychosocial adjustment. Patients were helped to formulate their own behavioral strategies based on the goals and priorities identified during their phone conversations with the nurse. Fifteen patients chose not to participate in either follow-up intervention (Figure 1). These patients were encouraged to remain in the study and provide six-month and one-year follow-up data. Seven of those patients provided data at six months, and five provided data at one year. These data were not analyzed separately because the numbers were too small to be representative.

Measures

Clinical measures were HbA1C, lipids, blood pressure, and weight. Patients also completed the Diabetes Care Profile (DCP),[18] the Diabetes Empowerment Scale Short-Form (DES-SF) (a measure of psychosocial self-efficacy),[19,20] as well as the ''Seriousness of Diabetes'' subscale of the Diabetes Attitude Scale-3.[21] Data were collected before and after the intervention and control periods and at six and twelve months. The orientation, education sessions, and data collection were conducted in community-based locations.

Statistical Methods

To determine differences between groups, we used chi-square tests for categorical distributions and Student *t* tests for continuous variables. Analysis of variance with repeated measures was used to test for concurrent differences over time and between groups. Analysis of variance with repeated measures was also used to investigate changes over time for all participants.

RESULTS

The study enrolled 239 participants; 125 were randomized to a six-session program, and 114 were randomized to the wait-listed control group. The experiment (Figure 1) was repeated

Table 3. Baseline information at enrollment (*N*=239)

Demographics	
Women	82%
African American	96%
Using insulin	34%
Mean age in years	61.0 ± 11.4
Mean years since diagnosis	8.5 ± 8.6
Currently married	31%
Completed high school	73%
Without insurance	12%
Clinical indices	
HbA1C	8.6% ± 2.2%
Serum cholesterol (mg/dL)	206.1 ± 45.0
Height (inches)	65.2 ± 4.1
Weight (pounds)	201.2 ± 45.5
Systolic blood pressure (mm Hg)	137.4 ± 26.0
Diastolic blood pressure (mm Hg)	77.4 ± 12.5
Testing own blood sugar	83%
Previously had some diabetes education	37%
Psychosocial indices	
Perceived understanding of diabetes*	2.68 ± 0.83
Diabetes empowerment scale†	3.89 ± 0.73
Attitude toward seriousness of diabetes†	4.03 ± 0.71
Positive attitude†	3.48 ± 0.91
Negative attitude†	3.30 ± 0.95

* Scale: 1=poor to 5=excellent.

† Scale: 1=strongly disagree to 5=strongly agree. For seriousness of diabetes (some) and for negative attitude (all) items reversed for scale mean in positive direction.

14 times over a four-year period from March 1999 until January 2002. The mean number of patients in each experiment (immediate intervention and wait-listed control groups combined) was seventeen. Over each of the six-week programs the mean number of classes attended was 5.07 (± 1.24); control and intervention patients did not differ in attendance rates. Table 3 shows mean values or percent distributions for demographic variables as well as selected laboratory, psychosocial, and health variables at baseline. The intervention and control patients did not differ significantly on any of these measures.

Table 4 compares between-group changes and within-group changes during the first six weeks for the control and intervention groups. In this time period, the only significant difference in change scores between the groups was patients' self-rated understanding of

Table 4. Between- and within-group pre/post changes during the first six weeks of each experiment

Variable	Group	*N*	Mean and SD at Baseline	Mean and SD at Six Weeks	Difference by Group by Time	Within-Group Difference Over Time
Hb A1C*	Intervention	117	8.74 ± 2.13	8.34 ± 1.91	ns	*P*<.001
	Control	108	8.41 ± 2.22	8.13 ± 2.08		*P*=.001
Serum cholesterol	Intervention	115	203.9 ± 44.5	189.5 ± 45.1	ns	*P*<.001
	Control	107	207.8 ± 43.0	197.4 ± 47.3		*P*=.011
Weight	Intervention	111	201.2 ± 44.3	199.7 ± 43.6	ns	*P*=.027
	Control	101	201.2 ± 46.8	201.4 ± 46.9		ns
Systolic blood pressure	Intervention	116	138.6 ± 27.3	140.1 ± 23.0	ns	ns
	Control	106	136.1 ± 23.9	136.6 ± 21.6		ns
Diastolic blood pressure	Intervention	114	77.4 ± 12.8	77.8 ± 15.3	ns	ns
	Control	106	77.4 ± 12.1	76.3 ± 12.2		ns
Perceived understanding of diabetes†	Intervention	106	2.73 ± 0.86	3.43 ± 0.73	*P*<.001	*P*<.001
	Control	86	2.58 ± 079	2.83 ± 0.82		*P*=.001
Diabetes empowerment scale‡	Intervention	106	3.94 ± 0.71	4.19 ± 0.58	ns	*P*=.001
	Control	86	3.81 ± 0.74	4.00 ± 0.72		*P*=.012
Attitude toward seriousness of diabetes‡	Intervention	106	4.05 ± 0.75	4.19 ± 0.68	ns	*P*=.049
	Control	86	3.98 ± 0.72	4.17 ± 0.66	ns	*P*=.007
Positive attitude‡	Intervention	105	3.60 ± 0.90	3.66 ± 0.91	ns	ns
	Control	85	3.29 ± 0.91	3.31 ± 0.84		ns
Negative attitude‡	Intervention	106	3.39 ± 1.00	3.60 ± 0.91	ns	*P*=.013
	Control	86	3.21 ± 0.91	3.40 ± 1.00		*P*=.023

* Abbreviation: Hb A1C is a measure of glycated hemoglobin.

† Scale: 1=poor to 5=excellent.

‡ Scale: 1=strongly disagree to 5=strongly agree. For seriousness of diabetes (some) and for negative attitude (all) items reversed for scale mean in positive direction.

Table 5. Pre/post comparisons for all patients who participated in the six-week education program (*N*=239 participants)

	N	Pre Class	Post Class	Statistical Significance of Overall Repeated Measures Comparison
Laboratory (Clinical) Variables				
HbA1C%	212	8.52 ± 2.15	8.23 ± 2.04	*P*>.000
Cholesterol (mg/dlL)	206	202.3 ± 45.8	191.1 ± 45.7	*P*>.000
HDL (mg/dL)*	205	53.1 ± 14.7	50.9 ± 13.4	*P*=.001
LDL (mg/dL)	194	116.4 ± 37.7	111.6 ± 38.7	*P*=.019
Triglycerides (mg/dL)	206	169.4 ± 92.1	153.9 ± 87.0	*P*=.005
Weight (lbs)	200	200.1 ± 46.3	198.4 ± 45.9	*P*>.000
Psychosocial Variables				
Mean of responses: patient's self-rated understanding of aspects of managing diabetes (13 questions)	183	2.76 ± 0.83	3.37 ± 0.72	*P*>.000
Mean of responses: diabetes empowerment scale (8 questions)	184	3.97 ± 0.72	4.16 ± 0.61	*P*=.001
Mean of responses: seriousness of diabetes, from diabetes attitude scale (7 questions)	184	4.10 ± 0.72	4.14 ± 0.70	ns
Mean of responses: positive attitude questions, diabetes care profile (5 questions)	180	3.49 ± 0.87	3.55 ± 0.90	ns
Mean of responses negative attitude questions (with scale reversed so that higher numbers show positive attitudes), diabetes care profile (6 questions)	182	3.39 ± 0.98	3.49 ± 0.94	ns

* Although lower values are more desirable for other blood lipid measures, for HDL cholesterol higher values are better.

managing diabetes. This variable was the mean score of a 13-item survey in which patients were asked to rate their understanding of various aspects of diabetes self-management (eg, diet, exercise, foot care) on a 1=poor to 5=excellent scale. Table 5 shows pre/post changes for all patients before and after they completed the six weekly group sessions. Overall, the results indicate significant changes in the desired directions for two out of five psychosocial measures and for all six laboratory values shown. Both groups had significant changes in the desired

Table 6. Repeated measures comparisons for patients who completed the program and provided data at all four points

	N	Point 1: Pre-Classes	Point 2: Post-Classes	Point 3: After Six Months	Point 4: After One Year	Statistical Significance of Overall Repeated Measures Comparison
Clinical indices						
HbA1C (%)*	176	8.41 ± 2.04	8.19 ± 1.98	8.04 ± 1.96	8.01 ± 1.87	*P*<.001
Serum cholesterol (mg/dL)	167	201.5 ± 46.8	187.7 ± 45.3	192.8 ± 47.0	199.2 ± 41.9	*P*<.001
High-density lipoprotein (mg/dL)†	166	53.1 ± 15.6	50.3 ± 13.6	53.1 ± 16.3	55.9 ± 15.4	*P*<.001
Low-density lipoprotein (mg/dL)	153	116.2 ± 37.6	110.0 ± 38.2	111.2 ± 39.7	114.9 ± 35.3	ns
Triglycerides (mg/dL)	167	168.9 ± 93.7	150.5 ± 84.7	152.4 ± 91.3	147.1 ± 83.6	*P*=.001
Weight (lbs)	152	201.1 ± 45.2	199.3 ± 44.9	199.7 ± 45.3	198.2 ± 43.9	*P*=.024
Systolic blood pressure (mm Hg)	174	138.1 ± 24.5	137.9 ± 20.9	135.8 ± 19.5	140.2 ± 23.3	ns
Diastolic blood pressure (mm Hg)	173	77.2 ± 12.5	76.5 ± 11.5	75.5 ± 11.6	76.1 ± 10.4	ns
Using insulin (%)	165	33.9 ± 47.5	35.2 ± 47.9	35.2 ± 47.9	37.0 ± 48.4	ns
Testing blood sugar (%)	154	83.8 ± 37.0	87.7 ± 33.0	91.6 ± 27.9	91.6 ± 27.9	*P*=.001
Psychosocial indices						
Perceived understanding of diabetes‡	160	2.79 ± 0.85	3.37 ± 0.74	3.34 ± 0.70	3.37 ± 0.74	*P*<.001
Diabetes empowerment scale§	161	3.97 ± 0.73	4.15 ± 0.62	4.09 ± 0.70	4.17 ± 0.64	*P*<.001
Attitude toward seriousness of diabetes§	162	4.10 ± 0.70	4.13 ± 0.69	4.21 ± 0.70	4.29 ± 0.64	*P*=.001
Positive attitude§	156	3.47 ± 0.86	3.53 ± 0.90	3.59 ± 0.94	3.69 ± 0.86	*P*=.013
Negative attitude§	161	3.42 ± 0.97	3.50 ± 0.95	3.58 ± 0.93	3.61 ± 1.01	*P*=.020

* Abbreviation: A1C is a measure of glycated hemoglobin.
† Although lower values are more desirable for other blood lipid measures, for HDL cholesterol higher values are better.
‡ Scale: 1=poor to 5=excellent.
§ Scale: 1=strongly disagree to 5=strongly agree. For seriousness of diabetes (some) and for negative attitude (all) items reversed for scale mean in positive direction.

All study participants showed a broad array of small-to-modest positive changes that were maintained for at least one year.

direction in HbA1C, serum cholesterol, and four psychosocial variables. Only the intervention group indicated a significant weight loss.

Table 6 shows psychosocial and laboratory measures at four timepoints: pre-test and post-test, at six months, and at one year. Although 203 patients provided one-year data they were included in Table 6 only if they had provided complete data for all four measurement periods. Over this extended time period, all psychosocial variables showed significant and sustained changes from the pre-test values. Most clinical values also showed improved levels that were maintained at one year. The LDL cholesterol level was an exception, as it initially fell but then rose to a level similar to the pre-test level. Mean blood pressure levels, which were in the normal range at baseline, remained unchanged during the study period. The correlation between one-year HbA1C values and the normalized number of support group sessions attended or phone contacts completed for patients in the follow-up conditions was .20 ($P<.005$).

CONCLUSIONS

The Primary Intervention

One statistically significant difference was seen in the change scores between the intervention group and the wait-listed control group after the initial intervention. Thus, the study was unable to show a benefit from participating in the six-week intervention sessions. The data (see Table 3) indicate that the finding of no difference in these change scores was due to the fact that both groups changed. All study participants showed a broad array of small-to-modest positive changes that were maintained for at least one year. We believe that both groups changed because of the combination of volunteer bias, study effects, and program impact. The reasons for our explanation for the study findings are presented below.

Volunteer Bias

The patients in this study were better insured and educated and exhibited better self-management, blood pressure, and glucose levels than those reported in similar studies. Several patients reported to us during enrollment and during the intervention sessions that they joined this study because they were concerned about their diabetes and were motivated to improve their diabetes self-management and blood glucose levels. We believe that they had made the decision to improve their diabetes self-management care and enrolled into the study as part of that commitment. The control group made the decision to improve their diabetes self-management during the control period. This explanation is supported by the fact that the only difference in the change scores between the controls and the intervention groups was the difference in perceived understanding of diabetes. Although both groups improved their diabetes self-management during the first six weeks of the study, only the intervention group was receiving diabetes education.

Study Effects

A separate MDRTC study, conducted during the same time period, indicated that providing study data to both the patients in the control group and their physicians had an interventional effect, especially when their metabolic values were out of the normal range.[22]

In that study, data were collected once each year and provided to all patients and their physicians, which contributed to a study effect whereby control group patients and/or their physicians made changes in their diabetes care. In our study, data were collected four or five times from each patient during the one-year study period. The study effects reported above would most likely be magnified by the increased frequency of providing patients in our study and their physicians data over the one-year study period.

Intervention Impact

As stated above, the study was unable to demonstrate a statistically significant impact of the intervention. Our conclusion that the intervention had an impact is supported by comments by participants and the results of a focus group with patients who had participated in the six weekly sessions. Furthermore, a significant number of positive pre/post changes, including HbA1C ($P<.001$) occurred during the six-week program (see Table 5).

Follow-up Period

After completion of the six weeks of group sessions, patients were invited to choose between attending a monthly support group or receiving monthly phone calls from a nurse. No between-group differences existed in HbA1C for the phone and support group follow-up conditions. As stated earlier, number of follow-up contacts was positively correlated with lower HbA1C values at one year. Three studies targeting African Americans[12,23,34] also reported improvements in blood glucose levels that were maintained over time (4–14 months) when follow-up support was provided.

In this study, the greatest number of positive parameter changes are shown in the one-year follow-up data. Table 6 shows that by one year most measures showed desirable changes, whether

made in the short-term and sustained throughout the year or augmented continuously in the positive direction over the year.

Summary

We believe that the best explanation for the findings is that we developed an effective intervention but employed a research design that did not allow us to ascertain the relative effect of the three forces (volunteer bias, study effects, and intervention impact) at work in this study. The most effective approach to minimizing the impact of volunteer bias and study effect is to assign patients to a usual-care or a wait-listed control group for a long period of time, eg, one year, during which neither patients nor their physicians would receive any study data. However, we have concerns about such an approach in our diabetes-related intervention research.[25] First, our research is primarily conducted among urban African Americans, many of whom are medically underserved and/or are not satisfied with the diabetes care available to them and are asking for help with their diabetes care. To address African-American concerns about medical research, we promised community leaders that we would design studies in which all participants had the potential to receive a direct benefit from their participation. Assigning patients to a usual-care control group for an extended period of time during which they do not receive any direct benefit would violate our commitment to the community. The challenge we now face is to incorporate what we have learned from this study into future research that is both rigorous and in accord with our commitments to the community.

ACKNOWLEDGMENTS

This study was supported by National Institutes of Health Grants R01 DK53994-01 and the Core(s) of the Michigan Diabetes Research and Training Center (NIH5P60 DK20572 from the National Institute of Diabetes and Digestive and Kidney Diseases.

REFERENCES

1. National Institute of Diabetes and Digestive and Kidney Diseases. *National Diabetes Statistics Fact Sheet: General Information and National Estimate on Diabetes in the United States, 2000*. Bethesda, Md: US Dept of Health and Human Services, National Institutes of Health; 2003.
2. Lipton RB, Liao Y, Cao G, Cooper RS, McGee D. Determinants of incident non-insulin-dependent diabetes mellitus among Blacks and Whites in a national sample. *Am J Epidemiol*. 1993;138:826–839.
3. Harris EL, Feldman S, Robinson CR, Sherman S, Georgopoulos A. Racial differences in the relationship between blood pressure and risk of retinopathy among individuals with NIDDM. *Diabetes Care*. 1993;16:748–754.
4. Harris EL, Sherman SH, Georgopoulos A. Black-White differences in risk of developing retinopathy among individuals with type 2 diabetes. *Diabetes Care*. 1999a;22:779–783.
5. Cowie CC, Port FK, Wolfe RA, Savage PJ, Moll PP, Hawthorne VM. Disparities in incidence of diabetic end-stage renal disease according to race and type of diabetes. *N Engl J Med*. 1989;321(16):1074–1079.
6. Harris MI, Eastman RC, Cowie CC, Flegal KM, Eberhardt MS. Racial and ethnic differences in glycemic control of adults with type 2 diabetes. *Diabetes Care*. 1999;22(3): 403–408.
7. National Diabetes Data Group. *Diabetes in America*. 2nd ed. Bethesda, Md: National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Disorders, 1995;chap 11, 30, 31. NIH Publications No. 95-1468.
8. Brown S. Interventions to promote diabetes self-management: state of the science. *Diabetes Educator*. 1999;25(suppl 6):52–61.
9. Norris SL, Engelgau MM, Narayan KMV. Effectiveness of self-management training in type 2 diabetes. *Diabetes Care*. 2001;24(3): 561–587.
10. Norris SL, Nichols PJ, Caspersen CJ, et al. Increasing diabetes self-management in community settings. A systematic review. *Am J Prev Med*. 2002;22(4S):39–66.
11. Padgett D, Mumford E, Hynes M, Carter R. Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *J Clin Epidemiol*. 1988;41: 1007–1030.
12. Agurs-Collins TD, Kumanyika SK, TenHave TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. *Diabetes Care*. 1997;20:1503–1511.
13. Hendricks LE, Hendricks RT. The effect of diabetes self-management education with frequent follow-up on the health outcomes of African-American men. *Diabetes Educator*. 2000;26:995–1002.
14. Keyserling TC, Ammerman AS, Samuel-Hodge CD, et al. A diabetes management program for African-American women with type 2 diabetes. *Diabetes Educator*. 2000;26:796–804.
15. Rimmer JH, Silverman K, Brauneschweig C, Quinn L, Liu Y. Feasibility of a health promotion intervention for a group of predominantly African-American women with type 2 diabetes. *Diabetes Educator*. 2002;28: 571–579.
16. Anderson RM, Barr PA, Edwards GJ, Funnell MM, Fitzgerald JT, Wisdom K. Using focus groups to identify psychosocial issues of urban Black individuals with diabetes. *Diabetes Educator*. 1996;22(1):28–33.
17. Sarkisian CA, Brown AAF, Norris CK, Wintz RI, Mangione CM. A systematic review of diabetes self-care interventions for older, African-American or Latino adults. *Diabetes Educator*. 2003;29:467–479.
18. Fitzgerald JT, Anderson RM, Gruppen LD, et al. The reliability of the diabetes care profile for African Americans. *Eval Health Professions*. 1998;21(1):52–65.
19. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care*. 2000;23(6):739–743.
20. Anderson RM, Fitzgerald JT, Gruppen LD, Funnell MM, Oh MS. The Diabetes Empowerment Scale-Short Form (DES-SF) [letter]. *Diabetes Care*. 2003;26:1641–1642.
21. Anderson RM, Fitzgerald JT, Funnell MM, Gruppen LD. The third version of the Diabetes Attitude Scale. *Diabetes Care*. 1998;21(9):1403–1407.
22. Hiss RG, Gillard ML, Armbruster BA, McClure LA. Comprehensive evaluation of community-based diabetic patients—effect of feedback to the patients and their physicians. A randomized controlled trial. *Diabetes Care*. 2001;24(4):690–694.
23. Jaber LA, Halapy H, Fernet M, Tummalapallis S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management. *Ann Pharmacother*. 1996;30:238–243.
24. Mazzuca SA, Moorman NH, Wheeler ML, et al. The Diabetes Education Study: a controlled trial of the effects of diabetes patient education. *Diabetes Care*. 1986;9(1): 1–10.
25. Anderson RM. Is it ethical to assign medically under-served African Americans to a usual-care control group in community-based interven-

tion research? *Diabetes Care*. 2005;28(7): 1817–1820.

AUTHOR CONTRIBUTIONS

Design and concept of study: Anderson, Funnell, Nwankwo
Acquisition of data: Anderson, Nwankwo, Gillard
Data analysis and interpretation: Anderson, Oh, Fitzgerald
Manuscript draft: Anderson, Funnell, Oh, Fitzgerald
Statistical expertise: Oh, Fitzgerald
Acquisition of funding: Anderson
Administrative, technical, or material assistance: Funnell, Gillard, Oh, Fitzgerald
Supervision: Anderson, Nwankwo, Fitzgerald