A Randomized Trial of an Intervention to Improve Self-Care Behaviors of African-American Women With Type 2 Diabetes

Impact on physical activity

THOMAS C. KEYSERLING, MD, MPH[1]
CARMEN D. SAMUEL-HODGE, PHD, RD[2]
ALICE S. AMMERMAN, DRPH, RD[2]
BARBARA E. AINSWORTH, PHD, MPH[3]
CARLOS F. HENRÍQUEZ-ROLDÁN, MS[4,5]
TOM A. ELASY, MD, MPH[6]
ANNE H. SKELLY, RN, PHD[7]
LARRY F. JOHNSTON, MA[8]
SHRIKANT I. BANGDIWALA, PHD[4]

OBJECTIVE — To determine whether a culturally appropriate clinic- and community-based intervention for African-American women with type 2 diabetes will increase moderate-intensity physical activity (PA).

RESEARCH DESIGN AND METHODS — In this randomized controlled trial conducted at seven practices in central North Carolina, 200 African-American women, ≥40 years of age with type 2 diabetes, were randomized to one of three treatment conditions: clinic and community (group A), clinic only (group B), or minimal intervention (group C). The clinic-based intervention (groups A and B) consisted of four monthly visits with a nutritionist who provided counseling to enhance PA and dietary intake that was tailored to baseline practices and attitudes; the community-based intervention (group A) consisted of three group sessions and 12 monthly phone calls from a peer counselor and was designed to provide social support and reinforce behavior change goals; and the minimal intervention (group C) consisted of educational pamphlets mailed to participants. The primary study outcome was the comparison of PA levels between groups assessed at 6 and 12 months by accelerometer, which was worn while awake for 7 days.

RESULTS — Totals of 175 (88%) and 167 (84%) participants completed PA assessment at 6 and 12 months, respectively. For comparison of PA, the *P* value for overall group effect was 0.014. Comparing group A with C, the difference in the average adjusted mean for PA was 44.1 kcal/day (95% CI 13.1–75.1, $P = 0.0055$). Comparing group B with C, the difference in the average adjusted mean was 33.1 kcal/day (95% CI 3.3–62.8, $P = 0.029$). The intervention was acceptable to participants: 88% were very satisfied with clinic-based counseling to enhance PA, and 86% indicated that the peer counselor's role in the program was important.

CONCLUSIONS — The intervention was associated with a modest enhancement of PA and was acceptable to participants.

Diabetes Care 25:1576–1583, 2002

From the [1]Department of Medicine, School of Medicine, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; the [2]Department of Nutrition, Schools of Medicine and Public Health, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; the [3]Department of Epidemiology and Biostatistics, Department of Exercise Science and Prevention Research Center, School of Public Health, University of South Carolina, Columbia, South Carolina; the [4]Department of Biostatistics, School of Public Health, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; the [5]Department of Statistics, University of Valparaíso, Valparaíso, Chile; the [6]Department of Medicine, School of Medicine, Vanderbilt University, Nashville, Tennessee; the [7]School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; and the [8]Center for Health Promotion and Disease Prevention, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina.

Address correspondence and reprint requests to Thomas C. Keyserling, MD, MPH, CB no. 8140, 1700 Airport Rd., University of North Carolina at Chapel Hill, Chapel Hill, NC 27599. E-mail: thomas_keyserling@med.unc.edu.

Received for publication 6 September 2001 and accepted in revised form 19 April 2002.

Abbreviations: CDA, community diabetes advisor; CHD, coronary heart disease; HPLC, high-performance liquid chromatography; PA, physical activity; PAA, PA assessment.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Type 2 diabetes is increasingly common and disproportionately affects minority populations in the U.S. (1). African-American women represent a very high risk group for this disease, with incidence and prevalence rates approximately twice as high as those for white women, and they are much more likely to develop microvascular complications (2,3). This increased morbidity among African-American women is due in part to poor glycemic and blood pressure control (4). The burden of suffering for patients with type 2 diabetes and the disparity in suffering between African-American and white women with this disease are not inevitable. There is substantial evidence that improving glycemic control decreases the risk of microvascular complications (5), lowering blood pressure decreases the risk of cardiovascular and microvascular disease (6), and decreasing blood lipids reduces the risk of coronary heart disease (CHD) (7).

Appropriate physical activity (PA) and dietary intake are fundamental to good glycemic (8,9), blood pressure (10), and blood lipid control (11) but are difficult to achieve in practice. Moreover, there is considerable evidence that available behavioral treatment programs for diabetes may be less effective for African-American women than for white women, perhaps due to an inadequate sociocultural match between intervention models and the needs of African-American women with diabetes (12–14) or possibly due to higher attrition rates with treatment programs (15). To facilitate improved management of PA and dietary behaviors, we developed an intervention program to meet the psychosocial, cultural, and economic needs of lower-income southern African-American women with type 2 diabetes. In this study, we report the impact of this intervention on PA during a 1-year follow-up period.

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

RESEARCH DESIGN AND METHODS

— This study was conducted at primary care practices in central North Carolina, including five community health centers, one staff model health maintenance organization, and the general medicine clinic at an academic health center. The study subjects were African-American women aged ≥40 years with type 2 diabetes, defined as diagnosis of diabetes at ≥20 years with no history of ketoacidosis. When computerized records were available (two sites), a list of patients meeting entry criteria was prepared for each primary care clinician, who then identified patients considered appropriate for the study. At the five sites without computerized records, clinicians invited patients to participate during routine visits. When referring a patient to the study, the primary care clinician indicated an intensity for the PA intervention; therefore, if a participant was randomized to an intervention group, she would receive PA counseling appropriate for underlying medical conditions. The categories for the PA intervention were moderate intensity (e.g., walking briskly, mopping, raking lawn), mild intensity (slow walking, stretching exercises), non–weight bearing activities (stretching exercises), or no PA.

Study design and intervention. The design of this study, a description of the intervention, and baseline characteristics of participants has been published elsewhere (16). The intervention, "A New Leaf. . . Choices for Healthy Living with Diabetes," was based on behavior change theory (17), extensive formative data collection (18–20), and prior testing in low-income and minority populations (21). It combined traditional clinic-based counseling with a coordinated community component using peer counselors (22) and included *1*) a PA component developed to increase moderate-intensity PA to a cumulative total of 30 min a day, *2*) a dietary component designed to decrease total and saturated fat intake and to improve control and distribution of carbohydrate intake, and *3*) a diabetes care component addressing various aspects of diabetes self-care.

The New Leaf Program was evaluated in a randomized trial with three treatment conditions (Fig. 1): clinic- and community-based intervention (group A), clinic intervention only (group B), and minimal intervention (group C). During the first 6 months, groups A and B received the clinic-based component, which included individual counseling visits at months 1, 2, 3, and 4. In addition, group A also received the community-based component, which consisted of two group sessions and monthly telephone calls from a peer counselor. During the second 6 months, group A participants continued to receive monthly phone calls from a peer counselor and attended one group session. Group C participants were mailed the following pamphlets published by the American Diabetes Association: *Staying Active, Healthy Eating,* and *What is Non-Insulin-Dependent Diabetes?* Study outcomes were assessed at 6 and 12 months of follow-up. Glycosylated hemoglobin and blood lipid results were sent to participants and their primary care clinician. The primary care clinicians were informed of participants' group assignment (so that clinician knowledge of group assignment would be consistent) and were instructed to reinforce educational information provided to participants by the study team, to monitor glycemic control, and to prescribe medications for diabetes according to their usual practices. The study protocol was approved by the institutional review board, University of North Carolina at Chapel Hill, and written informed consent was obtained from each participant. Enrollment was completed during a 1-year period.

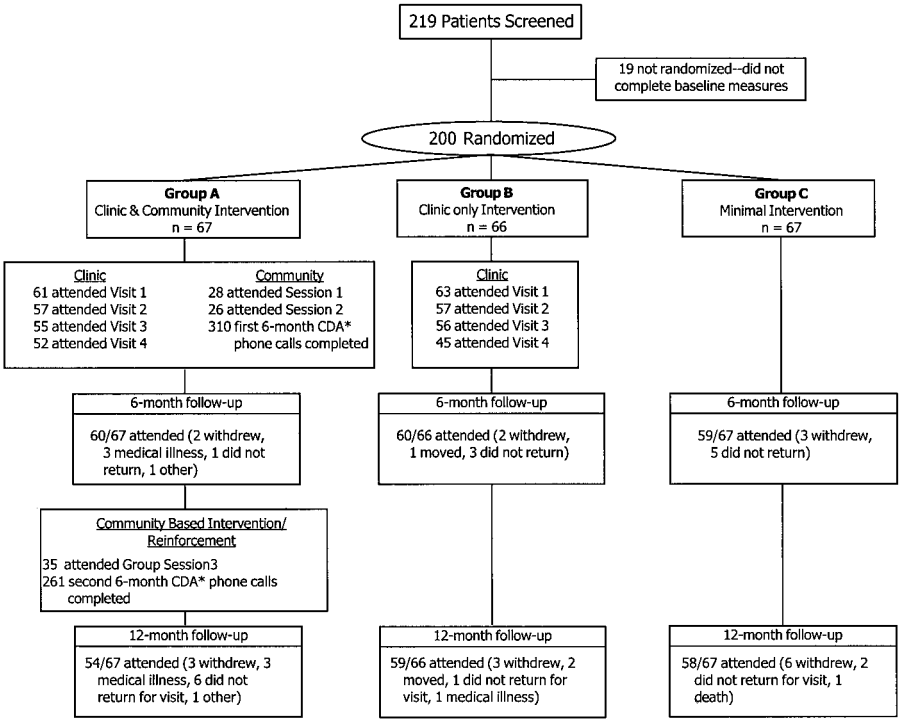

Figure 1—*Study participant flow diagram.*

The New Leaf PA intervention was based on guidelines from the Centers for Disease Control and Prevention and the American College of Sports Medicine, recommending daily accumulation of moderate PA instead of periodic intensive exercise periods (23). It was initiated and guided by a PA assessment (PAA), which facilitated individual tailoring of lifestyle change advice by directing counseling to behaviors in greatest need of change and barriers that may limit change. The PAA focused on both lifestyle and leisure-time activities relevant to older lower-income women and was designed to assess elements of both a sedentary and active lifestyle. The eight distinct categories of activity (or lack thereof) were: Work (pay or volunteer), Transportation, Household Chores, Child or Elder Care, Yard Work and Gardening, Church or Social Group Activities, Walking or Running (for exercise), and Structured Exercises or Sports. (At baseline, the correlation coefficient for the PAA and accelerometer assessments of activity was 0.36, $P < 0.0001$.) Participants were encouraged to increase the "minutes" (duration) of moderate or vigorous activities, or add "umph" (intensity)

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

to mild/sedentary activities (23). For those who could not perform ambulatory PA, chair exercises were recommended. In this study, a single nutritionist provided clinic-based counseling. During individual counseling sessions, the nutritionist negotiated with participants to select two to three PA and dietary goals to achieve before the next visit.

The community component of the New Leaf Program was facilitated by a community diabetes advisor (CDA), a nonprofessional peer counselor. Selection of the CDAs is described elsewhere (16); all were African-American women with type 2 diabetes. One CDA was recruited from each participating practice site and trained for her role in this study during four weekly 4-h sessions. The CDAs called participants on a monthly basis to provide social support and reinforce behavior change goals and assisted with group sessions, which were 90 min in length and designed to promote progress in readiness to change PA and diet behaviors and to provide social support.

Data collection and measures. During baseline and follow-up assessment visits at the participants' primary care clinic, research assistants administered questionnaires, outfitted participants with an activity monitor, and facilitated blood specimen collection. Additional data were collected during a series of three telephone calls after each of these visits.

PA was assessed by Caltrac accelerometer (Muscle Dynamics, Torrance, CA), a small electronic monitor that measures vertical accelerations and, when worn correctly at waist level over the hip, is considered to objectively measure PA energy expenditure (24). Participants were instructed to wear the Caltrac during waking hours for 1 week, except for when bathing or in water. If a participant wore the monitor for <4 h on a given day, it was considered a day not worn. A minimum of 4 days of monitoring was required for inclusion in the PA analysis. The average daily value for energy expenditure was calculated by dividing the monitor's reading for total kilocalories by the number of days worn. Daily energy expenditure attributed to PA (PA kcal/day) was calculated by subtracting the estimated resting energy expenditure (kcal/day) and thermic effect of food (kcal/day) from the Caltrac total kcal/day (25).

Dietary intake was assessed at baseline and 6-month follow-up by a series of three 24-h telephone-administered recalls using the Minnesota Nutrition Data System (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Glycosylated hemoglobin was assessed by automated affinity high-performance liquid chromatography (HPLC), determined on a Primus CLC-330 HPLC (Primus, Kansas City, MO) (26). Lipids were determined by automated enzymatic methods (HDL after dextran sulfate-Mg2+ separation [27]) at the University of North Carolina Hospitals' clinical laboratory, which participated in the Centers for Disease Control and Prevention lipid standardization program. Additional questionnaires were administered by telephone. Diabetes knowledge was assessed by a 15-item adaptation of the Diabetes Knowledge Scale (28); each correct answer contributed 1 point to the total score (maximum 15 points). The diabetes health status instrument (29) included two validated scales, Mental Well-Being and Social Well-Being, each with nine items.

Sample size, randomization, and statistical methods. Because no PA outcome data measured by accelerometer were available for our study population, the sample size for this study was based on anticipated dietary outcomes, as reported previously (16). For a two-sided comparison and a recruited sample size of 200, our power to detect a difference of 15% in a dietary risk score was 0.74. Randomization of individuals to treatment groups was stratified by clinic site. A statistical consultant prepared a site-specific allocation schedule (with randomly permuted blocks of size 3 and 6) from random numbers generated by a personal computer and prepared a set of sequentially numbered sealed envelopes containing study group assignments. Participants were assigned to a study group by a research assistant who opened the appropriate envelope after assessing eligibility and consent and after all baseline data were collected. For baseline comparisons, the χ^2 test for general associations was used for dichotomous variables, the extended Mantel-Haenszel statistic for mean scores of standardized midranks was used for ordinal variables, and one-way ANOVA was performed for continuous variables.

Change in PA was assessed by an overall comparison of adjusted means for PA kcal/day at both 6 and 12 months. For descriptive purposes, contrasts between treatment groups were also performed. Subjects with follow-up data were analyzed according to group assignment (intention to treat) (30) using mixed models (31). Treatment group and baseline value of the dependent variable were included in the model as fixed effects, and clinic was included as a random effect. To adjust the treatment comparison between groups, a set of variables was also included as fixed effects. This set included selected baseline characteristics deemed relevant to behavior change a priori (age, educational achievement, number of years with diabetes, BMI, living with spouse or someone like a spouse, taking oral medication for diabetes, and taking insulin). Because there was an observed difference by treatment group in the percent of participants living with a spouse or someone like a spouse and because there was concern for a possible effect modification of this variable on diabetes medication compliance, we evaluated interaction terms for these variables and included them in the final models if $P < 0.05$. The impact of the intervention was also assessed on a number of secondary outcomes considered relevant to the management of type 2 diabetes. SAS software (SAS Institute, Cary, NC) was used for analysis, all comparisons were two-sided, and $P < 0.05$ was considered significant.

RESULTS

Baseline characteristics of participants. Of 219 patients who met study-entry criteria (range of participants per practice 8–88), 200 completed baseline data collection and were randomized, 67 to group A, 66 to group B, and 67 to group C. Selected baseline characteristics are shown in Table 1. The mean age was 59 years. Participants had been diagnosed with diabetes an average of 10 years, almost one-third reported a total annual household income of <$10,000 per year, 24% had known CHD, 65% were hypertensive, and most were obese (mean BMI 36 kg/m^2). The mean cholesterol was 203 mg/dl (5.25 mmol/l), HDL cholesterol 51 mg/dl (1.31 mmol/l), and total glycosylated hemoglobin 11.1% (normal range for assay 5.5–7.8% vs. normal range for HbA_{1c} 4.8–6.0%).

For dietary intake, the mean for total energy was 1,299 kcal/day; the mean percent caloric intake from carbohydrate was 47.0%, from protein 19.5%, from total fat 34.3%, and from saturated fat 10.8%.

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

Table 1—*Baseline characteristics of participants by treatment group

Characteristic	Group A	Group B	Group C	*P*
N	67	66	67	
Mean age (years)	58.5	59.8	59.2	0.76
Mean diabetes duration (years)	10.8	10.7	9.9	0.84
Employed (%)	32.8	33.3	31.3	0.97
Mean educational achievement (years)	11.1	10.1	11.0	0.10
Living with spouse or someone like a spouse (%)	55.2	39.9	32.8	0.027
Total annual household income <$10,000 (%)	34.3	30.3	22.4	0.52
Taking oral medication for diabetes (%)	56.7	56.9	58.2	0.96
Taking insulin (%)	43.3	40.9	41.8	0.96
Taking oral medication and insulin (%)	11.9	7.6	9.0	0.68
Taking cholesterol lowering medication (%)	22.4	9.1	17.9	0.11
Known CHD (%)	22.4	15.1	32.8	0.054
Currently smoking cigarettes (%)	14.9	19.7	16.4	0.76
High blood pressure† (%)	62.7	65.1	67.2	0.86
Mean weight lb (kg)	209 (95.0)	202 (91.9)	210 (95.7)	0.55
Mean BMI (kg/m^2)	36.2	34.6	36.5	0.35
Mean cholesterol [mg/dl (mmol/l)]	198 (5.11)	205 (5.31)	207 (5.35)	0.41
Mean HDL [mg/dl (mmol/l)]	54 (1.39)	50 (1.29)	48 (1.25)	0.10
Diabetes knowledge score‡	9.0	8.6	9.4	0.29
Mean glycosylated hemoglobin (normal range for assay 5.5–7.8%)	10.8	11.1	11.3	0.51
Dietary intake				
Mean total kcal/day	1,327	1,283	1,287	0.77
Mean carbohydrate (% kcal)	46.4	47.5	47.2	0.79
Mean protein (% kcal)	19.6	19.2	19.7	0.82
Mean fat (% kcal)	34.7	34.1	34.0	0.84
PA				
Mean number of days accelerometer worn	6.8	6.8	6.7	0.64
Mean total kcal/day	2,053	2,041	2,056	0.97
Mean METs	1.21	1.22	1.21	0.80
Primary care clinicians' recommended intensity for PA intervention				
Moderate intensity (%)	73	59	55	0.12
Mild intensity (%)	23	29	36	0.23
Non–weight bearing (%)	5	12	9	0.28
No activity (%)	0	0	0	0

*Group A received the clinic- and community-based intervention, group B received the clinic-based intervention, and group C received the minimal intervention. †High blood pressure is defined as being treated by a physician for high blood pressure or taking medication to lower blood pressure. ‡Fifteen-item scale; each correct answer contributes 1 point.

Participants wore the Caltrac accelerometer an average of 6.8 days and were sedentary, with mean total daily energy expenditure of 2,050 kcal, energy expenditure attributed to PA of 325 kcal/day, and MET of 1.22. (A MET represents the ratio of the work metabolic rate to a standard resting metabolic rate, with 1 MET roughly equivalent to the resting metabolism while sitting quietly at rest.)

Intervention participation and follow-up. For participants in groups A and B, 124 (93%) returned for the first individual counseling visit (visit 1), 114 (86%) for visit 2, 111 (83%) for visit 3, and 97 (72%) for visit 4. The average duration of these visits was 68, 45, 41, and 45 min, respectively. For the community-based intervention, the average number of CDA phone calls per participant was 9.7 (571 calls to 59 participants—a participant had to complete the first clinic-based counseling session to be eligible for CDA phone calls and group sessions). Of the phone calls, 53% (n = 302) were 10–20 min in length, whereas 38% (n = 217) lasted <10 min. The first group session was attended by 28 of 48 (58%), the second by 26 of 53 (49%), and the third by 35 of 59 (59%) eligible participants. Attendance by site ranged from 27 to 89%, with better attendance at the smaller sites (≤6 participants assigned to group A). Of participants, 81% attended at least one session, 30% attended two sessions, and 19% attended three sessions (Fig. 1).

Follow-up for PA accelerometer assessment included 175 (88%) participants at 6 months and 167 (84%) at 12 months. Average wearing times for groups A, B, and C at 6 months were 6.8, 6.6, and 6.8 days, respectively (P = 0.28), and at 12 months were 6.7, 6.5, and 6.6 days (P = 0.32). Follow-up rates for 6-month dietary recalls were 94% for recall 1, 90% for recall 2, and 88% for recall 3; 162 (81%) participants had baseline and 6-month dietary recalls that met criteria for inclusion in the dietary analysis (16). Follow-up rates for glycosylated hemoglobin, blood lipids, and weight at 6 and 12 months were 90 and 85%, respectively.

A total of 21 (10%) participants did

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

Table 2—*Mean values for PA at baseline and follow-up* by treatment group and comparisons of adjusted means for PA during follow-up†*

	PA (kcal/day)‡					
	Group A		Group B		Group C	
	N	Mean (SE)	*N*	Mean (SE)	*N*	Mean (SE)
Baseline	59	342 (20.5)	60	336 (25.1)	62	321 (18.7)
6 months	56	339 (22.9)	58	344 (25.4)	58	289 (21.4)
12 months	53	364 (22.8)	56	322 (26.9)	56	297 (22.0)

	Comparisons of adjusted means for PA at 6 and 12 months§		
	Difference (SE)	95% CI	*P*
Group A vs. C	44.1 (15.8)	13.1 to 75.1	0.0055
Group B vs. C	33.1 (15.1)	3.3 to 62.8	0.029
Group A vs. B	11.0 (15.6)	−19.6 to 41.7	0.48

	Time-specific comparisons of adjusted means for PA		
	Difference (SE)	95% CI	*P*
Group A vs. C			
6 months	36.2 (21.6)	6.3 to 78.7	0.095
12 months	52.0 (22.0)	8.7 to 95.4	0.019
Group B vs. C			
6 months	44.5 (21.1)	3.0 to 86.0	0.036
12 months	21.7 (21.4)	−20.4 to 63.7	0.31
Group A vs. B			
6 months	−8.3 (21.4)	−50.3 to 33.8	0.70
12 months	30.4 (22.0)	−12.9 to 73.6	0.17

*Means are for participants with baseline and at least one follow-up measure. †Group A received the clinic- and community-based intervention, group B received the clinic-based intervention, and group C received the minimal intervention. Comparison of means are adjusted for the following variables: baseline value of PA, age, educational achievement, number of years with diabetes, BMI, living with a spouse or someone like a spouse, using oral medication for diabetes, use of insulin, and an interaction term for living with spouse or someone like a spouse and use of oral medication. ‡Kilocalories per day attributed to PA as assessed by accelerometer. §Overall group effect: $P = 0.014$.

not return for 6-month follow-up, and 29 (15%) did not return for 12-month follow-up. To assess possible differences between returnees and nonreturnees at 6- and 12-month follow-up, baseline variables were compared for these groups. Of 48 comparisons, the only significant differences between groups were number of years with diagnosed diabetes (5.9 years for nonreturnees and 11 years for returnees at 6-month follow-up, unadjusted $P = 0.026$) and percent of participants with known CHD (38% for nonreturnees and 21% for returnees at 12-month follow-up, unadjusted $P = 0.048$).

Change in PA. PA levels at baseline and follow-up, assessed as kcal/day by Caltrac accelerometer, are shown in Table 2 for participants with baseline and at least one follow-up measure. For the primary study outcome, the comparison of PA levels during 1 year of follow-up, the *P* value for the overall group effect was 0.014 (Table 2). Comparing group A with C, the average for the 6- and 12-month differences in adjusted means for PA was 44.1 kcal/day ($P = 0.0055$). Comparing group B with C, the average difference was 33.1 kcal/day ($P = 0.029$). Table 2 also shows time-specific outcomes for PA. Comparing group A with C, the difference approached statistical significance at 6 months ($P = 0.095$) and was significant at 12 months ($P = 0.019$). Comparing group B with C, the difference was statistically significant at 6 months ($P = 0.036$).

Change in other outcomes. The baseline and follow-up means for other outcomes are presented in Table 3. The percentage of calories from saturated fats, dietary cholesterol intake, and total energy intake decreased in all groups, but the comparisons of adjusted means at 6 months were not statistically significant, with *P* values for overall group effect of 0.98, 0.18, and 0.85, respectively. For glycosylated hemoglobin and total and HDL cholesterol, there were minimal changes during follow-up, with *P* values for overall group effect of 0.73, 0.51, and 0.15, respectively. From baseline to 12-month follow-up, weight increased modestly in all groups, with a *P* value for overall group effect of 0.52.

For the diabetes knowledge scale, from baseline to 12 months, there was an increase (indicating enhanced knowledge) of 1.6 points in group A, 1.2 points in group B, and 0.7 points in group C. The *P* value for the test of overall group effect at 6- and 12-month follow-up was 0.037. Diabetes-specific health status was assessed with two scales. For Mental Well-Being, from baseline to 12 months, the score increased (improved) by 4.5 points in group A, 1.8 in group B, and 2.8 in group C. The *P* values for the test of overall group effect and the comparison of group A with C at 6- and 12-month follow-up were not statistically significant (0.13 and 0.067, respectively). Changes in the Social Well-Being scale were small and not statistically significant.

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

Table 3—*Mean values for selected outcomes at baseline and follow-up* by treatment group†*

	Group A		Group B		Group C	
	N	Mean (SE)	*N*	Mean (SE)	*N*	Mean (SE)
Calories from saturated fat (%)						
Baseline	51	11.3 (0.5)	51	10.7 (0.4)	54	10.6 (0.3)
6 months	51	10.6 (0.4)	51	10.2 (0.4)	54	10.1 (0.4)
Dietary cholesterol (mg/day)						
Baseline	51	285 (19.4)	51	313 (21.7)	54	259 (17.5)
6 months	51	275 (19.9)	51	223 (16.7)	54	242 (19.3)
Total energy intake (kcal/day)						
Baseline	51	1342 (48.0)	51	1302 (47.0)	54	1313 (56.4)
6 months	51	1189 (49.1)	51	1214 (43.5)	54	1216 (47.6)
Glycosylated hemoglobin (normal range 5.5–7.8%)						
Baseline	60	10.7 (0.3)	62	11.0 (0.4)	61	11.3 (0.3)
6 months	60	10.7 (0.4)	60	11.1 (0.4)	58	11.5 (0.5)
12 months	54	10.8 (0.4)	59	10.9 (0.5)	57	10.7 (0.4)
Total cholesterol (mg/dl)						
Baseline	60	199 (4.5)	62	207 (5.5)	61	208 (5.9)
6 months	60	202 (5.1)	60	210 (5.8)	57	210 (7.2)
12 months	54	193 (4.5)	59	206 (6.0)	57	204 (6.2)
HDL cholesterol (mg/dl)						
Baseline	60	54 (2.0)	62	50 (1.6)	61	49 (1.9)
6 months	60	53 (2.1)	60	51 (1.8)	56	49 (2.0)
12 months	54	51 (1.9)	59	52 (1.8)	57	50 (2.2)
Weight (lb)						
Baseline	60	207 (5.5)	62	204 (6.2)	62	210 (5.7)
6 months	60	207 (5.7)	60	202 (6.3)	59	210 (5.8)
12 months	54	212 (5.8)	58	208 (6.7)	58	212 (6.2)
Diabetes knowledge scale‡						
Baseline	60	9.1 (0.3)	60	8.6 (0.4)	62	9.4 (0.4)
6 months	60	10.5 (0.4)	59	9.9 (0.3)	58	9.6 (0.4)
12 months	54	10.7 (0.3)	56	9.8 (0.3)	57	10.1 (0.4)
Diabetes health status: Mental Well-Being scale§						
Baseline	61	21.1 (0.8)	62	23.5 (0.9)	63	24.0 (0.9)
6 months	60	26.2 (0.8)	61	25.9 (0.9)	60	25.7 (1.0)
12 months	60	25.6 (0.9)	59	25.3 (1.0)	54	26.8 (1.0)
Diabetes health status: Social Well-Being scale§						
Baseline	61	27.5 (1.0)	62	27.5 (1.0)	63	29.3 (0.9)
6 months	60	29.0 (1.0)	61	28.8 (0.9)	60	30.0 (1.0)
12 months	60	28.5 (1.0)	59	28.3 (1.0)	54	29.5 (1.0)

*Means are for participants with baseline and at least one follow-up measure. †Group A received the clinic- and community-based intervention, group B received the clinic-based intervention, and group C received the minimal intervention. Comparison of means are adjusted for the following variables: baseline value of variable, age, educational achievement, number of years with diabetes, BMI, living with a spouse or someone like a spouse, using oral medication for diabetes, use of insulin, and an interaction term for living with spouse or someone like a spouse and use of oral medication (when interaction significant). ‡Fifteen-item scale; each correct answer contributes 1 point. §Nine-item scale; a higher score represents improved well-being.

Program acceptability. For clinic-based individual counseling, 94% of 117 respondents reported being very satisfied with the amount of information and help the nutritionist gave about diet, and 88% were very satisfied with the counseling provided to enhance PA, whereas 15% reported having some difficulty getting to the clinic for these visits. For the CDA component, 85% of 59 respondents felt the number of telephone calls was appropriate, 86% felt the role of CDAs in the program was important, and 83% strongly agreed that talking to someone else with diabetes was very helpful. Among the 48 participants who attended group sessions, all reported that they enjoyed the session(s) and 98% reported that they had learned a lot about diabetes.

CONCLUSIONS — The New Leaf intervention, which, over the course of 1 year, included 2–3 h of individual counseling, 4.5 h of group sessions, and 2 h of telephone contact, was associated with an enhancement of PA energy expenditure, as assessed by accelerometer, that was statistically significant ($P = 0.014$). A subgroup analysis comparing the full intervention to the minimal intervention at 6- and 12-month follow-up (average difference between groups 44.1 kcal/day, $P = 0.0055$) indicated group A participants were on average ~15% more active than group C participants and that this enhancement was achieved by reversing

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

the usual trend of decreasing PA over time (32), as experienced by groups B and C at 12-month follow-up. This study was not designed to detect a significant difference between groups A and B. However, the community component appeared to have a favorable effect on PA during the second 6 months of follow-up. With regard to dietary outcomes, participants in all groups reported reduced intake of saturated fat and cholesterol. However, because of the observed substantial under-reporting of dietary intake, we feel our dietary findings may not be valid. Improved dietary assessment methodology is needed for this population to better capture actual food intake and allow for evaluation of interventions.

The New Leaf Program had no material impact on blood lipids. Though weight loss was not an objective of this study, we were disappointed to observe that participants in all groups gained weight. In older patients with longstanding diabetes, insulin and oral medication use are the major determinants of blood glucose control (33). We believe the New Leaf Program had little effect on glycemic control because it did not specifically address diabetes medication adherence and did not emphasize self-monitoring of blood glucose. Other behavioral intervention studies have also shown no significant effect on glycemic control (34).

Both the clinic and community components of the New Leaf Intervention were acceptable to participants and were feasible in the context of a research study. Participation rates for individual counseling and telephone follow-up were high. Attendance at group sessions was modest at ~50%, but the sessions were very well received by those who were able to attend. Diabetes knowledge improved as a result of the intervention ($P = 0.037$). Our measures of diabetes-specific health status also improved during follow-up (except Social Well-Being for group C at 12 months), with the largest change observed in group A. For the Mental Well-Being score, the improvement approached statistical significance, suggesting that the group A intervention may actually enhance diabetes-specific health status.

We believe the Caltrac accelerometer provided a valid and reliable measure of the energy expenditure of participants in this study. A validation study of the Caltrac (24) reported a correlation of $r = 0.51$ for total PA energy expenditure, with detailed PA records kept over a 1-year duration. Thus, when worn correctly and for an appropriate period of time, the Caltrac is able to provide an objective estimate of usual daily PA levels in an adult population with predominantly sedentary activity habits. One limitation of this study is possible bias in PA measurement, which may have resulted from differences in actual Caltrac wearing time by treatment group. Although we cannot totally exclude this bias, there were no differences in reported wearing time between treatment groups. Additionally, it is possible that the actual PA energy expenditure was underestimated by the Caltrac, since it does not detect nonambulatory PA (e.g., arm swinging). However, this bias is consistent for all subjects and is a limitation in the use of vertically oriented accelerometers as a direct measure of PA.

In conclusion, the New Leaf Program was associated with a modest enhancement of PA compared with a minimal intervention. Whether this observed increase in PA will lead to improved health outcomes (35) is not known, and may depend largely on whether it is sustained over time. To our knowledge, this is the first study to develop a moderate-intensity PA intervention for older African-American women with type 2 diabetes and to assess its impact using accelerometer technology. Our findings suggest that a culturally appropriate clinic- and community-based intervention program, focused primarily on moderate-intensity activities and delivered in part by peer counselors, can enhance the activity of sedentary, overweight, African-American women with type 2 diabetes. Future research efforts should be aimed at confirming, enhancing, and sustaining the effect of this type of intervention in this high-risk population.

Acknowledgments— This study was supported in part by a cooperative agreement (U48/CCU409660) with the Centers for Disease Control and Prevention and through a memorandum of understanding with the National Institutes of Health.

Carlos F. Henríquez-Roldán is a PhD candidate at the University of North Carolina at Chapel Hill and is sponsored by a scholarship from "Beca Presidente de la República de Chile."

References

1. Brancati FL, Kao WH, Folsom AR, Watson RL, Szklo M: Incident type 2 diabetes mellitus in African-American and white adults: the Atherosclerosis Risk in Communities Study. *JAMA* 283:2253–2259, 2000
2. Carter JS, Pugh JA, Monterrosa A: Non-insulin-dependent diabetes mellitus in minorities in the United States. *Ann Intern Med* 125:221–232, 1996
3. Gu K, Cowie CC, Harris MI: Mortality in adults with and without diabetes in a national cohort of the U.S. population, 1971–1993. *Diabetes Care* 21:1138–1145, 1998
4. 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* 22:403–408, 1999
5. UK Prospective Diabetes Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 352:837–853, 1998
6. UK Prospective Diabetes Study Group: Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes (UKPDS 38). *BMJ* 317:703–713, 1998
7. Haffner SM: Management of dyslipidemia in adults with diabetes. *Diabetes Care* 21: 160–178, 1998
8. American Diabetes Association: Nutrition recommendations and principles for people with diabetes mellitus (Position Statement). *Diabetes Care* 23 (Suppl. 1):S43–S46, 2000
9. American Diabetes Association: Diabetes mellitus and exercise (Position Statement). *Diabetes Care* 23 (Suppl. 1):S50–S54, 2000
10. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Arch Intern Med* 157:2413–2446, 1997
11. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults: Summary of the second report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). *JAMA* 269:3015–3023, 1993
12. Gilliland SS, Carter JS, Perez GE, Two Feathers J, Kenui CK, Mau MK: Recommendations for development and adaptation of culturally competent community health interventions in minority popula-

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023

tions with type 2 diabetes mellitus. *Diabetes Spectrum* 11:166–174, 1998
13. Kumanyika S: Diabetes, diet and weight control among black Americans. *Diabetes Care and Education* 12:7–10, 1991
14. Murphy FG, Satterfield D, Anderson RM, Lyons AE: Diabetes educators as cultural translators. *Diabetes Educ* 19:113–118, 1993
15. Wierenga ME, Wuethrich KL: Diabetes program attrition: differences between two cultural groups. *Health Values* 19:12–21, 1995
16. Keyserling TC, Ammerman AS, Samuel-Hodge CD, Ingram AF, Skelly AH, Elasy TA, Johnston LF, Cole AS, Henriquez-Roldan CF: A diabetes management program for African American women with type 2 diabetes. *Diabetes Educ* 26:796–805, 2000
17. Eraker SA, Kirscht JP, Becker MH: Understanding and improving patient compliance. *Ann Intern Med* 100:258–268, 1984
18. Krueger RA: *Focus Groups: A Practical Guide for Applied Research*. Thousand Oaks, CA, Sage, 1994
19. Skelly AH, Samuel-Hodge C, Elasy T, Ammerman AS, Headen SW, Keyserling TC: Development and testing of culturally sensitive instruments for African American women with type 2 diabetes. *Diabetes Educ* 26:769–777, 2000
20. Samuel-Hodge CD, Headen SW, Skelly AH, Ingram AF, Keyserling TC, Jackson EJ, Ammerman AS, Elasy TA: Influences on day-to-day self-management of type 2 diabetes among African-American women: spirituality, the multi-caregiver role, and other social context factors. *Diabetes Care* 23:928–933, 2000
21. Keyserling TC, Ammerman AS, Davis CE, Chen Mok M, Garrett J, Simpson RA Jr: A randomized controlled trial of a physician-directed treatment program for low-income patients with high blood cholesterol: the Southeast Cholesterol Project. *Arch Fam Med* 6:135–145, 1997
22. North J: Diabetic contacts: an underused resource. *Diabet Med* 7:923–926, 1990
23. Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C, Buchner DM, Ettinger W, Heath GW, King AB, Kriska A, Leon AS, Marcus BH, Morris J, Paffenbarger RS Jr, Patrick K, Pollock ML, Rippe JM, Sallis J, Wilmore JH: Physical activity and public health: a recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *JAMA* 273:402–407, 1995
24. Richardson MT, Leon AS, Jacobs DR Jr, Ainsworth BE, Serfass R: Ability of the Caltrac accelerometer to assess daily physical activity levels. *J Cardiopulm Rehabil* 15:107–113, 1995
25. Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO: A new predictive equation for resting energy expenditure in healthy individuals. *Am J Clin Nutr* 51:241–247, 1990
26. Cefalu WT, Wang ZQ, Bell-Farrow A, Kiger FD, Izlar C: Glycohemoglobin measured by automated affinity HPLC correlates with both short-term and long-term antecedent glycemia. *Clin Chem* 40:1317–1321, 1994
27. Warnick GR, Benderson J, Albers JT: Dextran sulfate-Mg2+ precipitation procedure for quantitation of high density-lipoprotein cholesterol. *Clin Chem* 28:1379–1388, 1982
28. Dunn SM, Bryson JM, Hoskins PL, Alford JB, Handelsman DJ, Turtle JR: Development of the diabetes knowledge (DKN) scales: forms DKNA, DKNB and DKNC. *Diabetes Care* 7:36–41, 1984
29. Elasy TA, Samuel-Hodge CD, DeVellis RF, Skelly AH, Ammerman AS, Keyserling TC: Development of a health status measure for older African-American women with type 2 diabetes. *Diabetes Care* 23:325–329, 2000
30. Norleans MX: *Statistical Methods for Clinical Trials*. New York, Marcel Dekker, 2001
31. Littell RC, Milliken GA, Stroup WW, Wolfinger RD: *SAS System for Mixed Models*. Cary, NC, SAS Institute, 1996
32. Sidney S, Sternfeld B, Haskell WL, Quesenberry CP Jr, Crow RS, Thomas RJ: Seven-year change in graded exercise treadmill test performance in young adults in the CARDIA study. *Med Sci Sports Exerc* 30:427–433, 1998
33. Brown SA: Interventions to promote diabetes self-management: state of the science. *Diabetes Educ* 25 (Suppl. 6):52–61, 1999
34. Norris SL, Engelgau MM, Venkat Narayan KM: Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 24:561–587, 2001
35. Hu FB, Stampfer MJ, Solomon C, Liu S, Colditz GA, Speizer FE, Willett WC, Manson JE: Physical activity and risk for cardiovascular events in diabetic women. *Ann Intern Med* 134:96–105, 2001

Downloaded from http://diabetesjournals.org/care/article-pdf/25/9/1576/589972/dc0902001576.pdf by guest on 04 June 2023