

A Simple Meal Plan Emphasizing Healthy Food Choices Is as Effective as an Exchange-Based Meal Plan for Urban African Americans With Type 2 Diabetes

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OBJECTIVE — To compare a simple meal plan emphasizing healthy food choices with a traditional exchange-based meal plan in reducing HbA_{1c} levels in urban African Americans with type 2 diabetes.

RESEARCH DESIGN AND METHODS — A total of 648 patients with type 2 diabetes were randomized to receive instruction in either a healthy food choices meal plan (HFC) or an exchange-based meal plan (EXCH) to compare the impact on glycemic control, weight loss, serum lipids, and blood pressure at 6 months of follow-up. Dietary practices were assessed with food frequency questionnaires.

RESULTS — At presentation, the HFC and EXCH groups were comparable in age (52 years), sex (65% women), weight (94 kg), BMI (33.5), duration of diabetes (4.8 years), fasting plasma glucose (10.5 mmol/l), and HbA_{1c} (9.4%). Improvements in glycemic control over 6 months were significant ($P < 0.0001$) but similar in both groups: HbA_{1c} decreased from 9.7 to 7.8% with the HFC and from 9.6 to 7.7% with the EXCH. Improvements in HDL cholesterol and triglycerides were comparable in both groups, whereas other lipids and blood pressure were not altered. The HFC and EXCH groups exhibited similar improvement in dietary practices with respect to intake of fats and sugar sweetened foods. Among obese patients, average weight change, the percentage of patients losing weight, and the distribution of weight lost were comparable with the two approaches.

CONCLUSIONS — Medical nutrition therapy is effective in urban African Americans with type 2 diabetes. Either a meal plan emphasizing guidelines for healthy food choices or a low literacy exchange method is equally effective as a meal planning approach. Because the HFC meal plan may be easier to teach and easier for patients to understand, it may be preferable for low-literacy patient populations.

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Abbreviations: EXCH, exchange-based meal plan; HFC, healthy food choices meal plan.

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

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Minority groups have a high prevalence of type 2 diabetes (1–4). In the National Health and Nutrition Examination Survey III and BRFSS (Behavioral Risk Factor Surveillance System), the age-standardized prevalence of diabetes was 1.6-fold higher in African Americans than in Caucasians (5,6). The disproportionate frequency of diabetes in African Americans is especially impressive in women (4,7), even after correcting for the prevalence of obesity (4,8–10). The problem of diabetes for African Americans is particularly striking above the age of 45 years, when the prevalence of diabetes in African Americans is almost twice that in Caucasians (11); diabetes is present in 29% of African Americans 65–74 years of age (5). It is especially alarming that the frequency of altered metabolism is rising even in younger African Americans; recent studies found the prevalence of impaired glucose tolerance to be 20% in a group with an average age of 34 years (12) and 8.6% in girls between 5 and 10 years old (13).

Medical nutrition therapy is essential in preventing the development of diabetes (14–16), and medical nutrition therapy is well recognized as a cornerstone of management in patients who have diabetes. Medical nutrition therapy takes on even greater urgency in treatment of diabetes in high-risk populations such as African Americans in whom rates of complications are high (17–21) and metabolic control is poor (19,22). African Americans with diagnosed diabetes in National Health and Nutrition Examination Survey III had the lowest prevalence of normal HbA_{1c} and the highest prevalence of HbA_{1c} (>8%) compared with other ethnic groups, and African Americans with undiagnosed diabetes had the highest average HbA_{1c} as well (23).

Recognition of the relationship between dietary constituents and glucose tolerance (24) has contributed to the development of nutritional prescriptions,

such as the food exchange system, as strategies to restrict energy intake and provide macronutrient balance (25). However, patients may have trouble understanding meal plans based on the exchange system (26), and discussion groups in the Grady Health System in Atlanta have shown the exchange system to be difficult for this relatively low-literacy (27) patient population (28). Because of such potential barriers, some have recommended that a more simplified approach to dietary instruction, such as “eat less fat,” may be just as effective in the management of diabetes (29). Moreover, some studies suggest that the essential elements of successful medical nutrition therapy might lie in the food choices that are made—such as limitation of carbohydrates—rather than limitation of energy intake (29–32).

Given the difficulties obese African-American patients may face in implementing the recommendations of the exchange system, we asked whether a simpler meal plan that emphasizes “healthy food choices” (without emphasis on weight loss per se) would be as effective as a traditional exchange-based meal plan (emphasizing weight loss). To test this hypothesis, we conducted a randomized, controlled trial in the Grady Diabetes Clinic, comparing changes in HbA_{1c} as the primary outcome and changes in weight, serum lipids, and blood pressure as secondary outcomes.

RESEARCH DESIGN AND METHODS

Setting and study paradigm

The Grady Health System Diabetes Clinic serves an adult population (≥ 17 years of age) that is primarily urban and African American. A high proportion have incomes below the federal poverty line, lack health insurance, and have poor functional health literacy (27,33,34). Care is provided by a team that includes nurses, dietitians, podiatrists, and endocrinologists, and each patient’s initial visit includes an extensive evaluation and education focused on self-care. After the initial visit, patients are scheduled for return visits at 1, 2, and 4 weeks after the initial visit and then at 2, 4, and 6 months. All patients are routinely scheduled to see a dietitian at the initial visit and at visits at 1, 2, and 4 weeks with additional visits as needed; at each of these appointments,

patients receive individualized, one-on-one instruction in separate sessions. As described previously (33), all patients are managed with a stepped care protocol that emphasizes nonpharmacologic therapy during the first 2 months. During this period, antidiabetic pharmacologic agents are either discontinued or reduced in dose for patients who are not ketosis prone and do not have symptomatic hyperglycemia. If glycemic goals are not reached after 2 months, pharmacotherapy is reinstated or intensified.

Diabetes clinic patients were solicited for participation in the study if they had type 2 diabetes [classified according to accepted clinical criteria (33)], were able to understand spoken English, had no major complicating medical illnesses, and were judged to be capable of performing basic self-management skills. Patients were recruited at their initial visit and randomized according to the day of their initial visit (for logistical convenience) to receive instruction in either a simplified exchange-based meal plan (EXCH group) or a meal plan emphasizing healthy food choices without discussion about losing weight or limiting food intake (HFC group); details about dietary instruction are provided below. With the exception of instruction in meal planning, patients received all other management per the standard protocol of the diabetes clinic. The primary outcome was change in glycemic control (HbA_{1c}); secondary outcomes included changes in fat and sugar intake, BMI, lipids, and blood pressure. The study was reviewed and approved by the Emory University Institutional Review Board.

Comparison of meal planning approaches

The Diabetes Clinic dietitians were involved in all phases of design and implementation of the study. Instruction for each meal planning approach (EXCH or HFC) and advice regarding general physical activity involved the same dietitian time and the same personnel for each group. Approximately 1 h was spent on nutritional counseling at the initial visit and 30 min at each of three subsequent clinic visits. At each visit, individualized patient instruction was based on 24-h recalls to direct dietary reinforcement. Before enrolling participants in the study, a curriculum outline was developed, and training sessions were held. Training for

the dietitians involved practice sessions to ensure consistency in all aspects of patient instruction, which included planning menus, preparing foods, interpreting food labels, and making appropriate food choices.

Instructional materials used approximated the fifth and sixth grade reading level (J. Nurss, personal communication); median literacy for our patients has been estimated at the sixth grade level (K. Dobberstein, personal communication, 1993). In the EXCH group, low literacy educational material consisted of “Eating Healthy Foods” (American Diabetes Association, Inc. and The American Dietetic Association, copyright 1988). Patients were instructed in both food exchanges and portion sizes. Patients classified as obese ($>120\%$ of ideal body weight) were assigned meal plans that were 500 kcal below their estimated daily energy requirements, as calculated from the Harris-Benedict equation (35). In the HFC group, we used the same educational material but removed all content related to quantity of food (copyright permission obtained from the American Diabetes Association) and substituted the FDA Food Guide Pyramid, which was modified to group high-starch and high-protein foods as recommended for persons with diabetes. The modified food guide pyramid was glossy and in full color with line drawings of foods. Patients were instructed to limit use of sweets and fats, particularly saturated fat. Although food models were used, portion sizes were not discussed and weight loss was not emphasized.

Patients’ food usage was assessed at baseline and after 2 to 4 months of follow-up using questionnaires administered verbally. Use of fat-containing foods was assessed with a modification of the Kristal fat screener (36) and a revised version of Block et al.’s (37) 1989 food frequency scale that was modified for foods appropriate to this population. Use of sugar-sweetened foods was assessed with an instrument modeled after the fat screener. All scales were scored so that a higher score indicates a “healthier” meal plan (i.e., lower intake of the high fat or high sugar food item).

Laboratory analyses

Fasting plasma glucose was determined at each visit, HbA_{1c} at intervals of 2 months, and fasting lipids (secondary outcome) at baseline and between 4 and 6 months.

Table 1—Presenting characteristics of study population, including all subjects at baseline and those with laboratory studies available from return visits after 6 months of follow-up care

	EXCH Initial	HFC Initial	<i>P</i>	EXCH 6- month return	HFC 6- month return	<i>P</i>
Number	359	289		126	94	
Sex (F/M)	243/116	180/109	0.15*	92/34	67/27	0.78*
Race (%)			0.42*			0.42*
African American	90.3	89.6		85.7	89.4	
Caucasian	7.5	9.7		11.1	9.6	
Other	2.2	0.7		3.2	1.1	
Therapy (%)			0.87*			0.68*
Meal plan only	20.3	18		22.2	16.0	
Sulfonylurea	43.5	45.7		41.3	44.7	
Insulin	33.4	33.9		32.5	36.2	
Both	2.8	2.4		4	3.2	
Obese (%)	77	80.3	0.32*	69.8	79.8	0.09*
Age (years)	52 ± 0.7	52 ± 0.8	0.96	57.5 ± 1.0	55.2 ± 1.3	0.14
BMI (kg/m ²)	33.7 ± 0.5	33.2 ± 0.4	0.41	32.1 ± 0.7	32.9 ± 0.8	0.41
Duration (years)	4.8 ± 0.4	4.9 ± 0.4	0.95	6.2 ± 0.7	5.3 ± 0.8	0.39
Fasting glucose (mmol/l)	10.3 ± 0.23	10.7 ± 0.25	0.26	10.8 ± 0.4	10.3 ± 0.4	0.37
HbA _{1c} (%)	9.32 ± 0.1	9.57 ± 0.2	0.23	9.46 ± 0.20	9.69 ± 0.25	0.46
Blood pressure (mmHg)						
Systolic	127.5 ± 1.1	128.8 ± 1.1	0.43	130.3 ± 1.7	128.8 ± 1.8	0.56
Diastolic	77.7 ± 0.6	77.9 ± 0.6	0.79	77.9 ± 0.9	76.5 ± 0.9	0.29
LDL cholesterol (mmol/l)	3.62 ± 0.06	3.7 ± 0.07	0.26	3.85 ± 0.1	3.74 ± 0.12	0.46
HDL cholesterol (mmol/l)	1.11 ± 0.02	1.10 ± 0.02	0.61	1.12 ± 0.03	1.12 ± 0.03	0.9
Triglycerides (mmol/l)	1.75 ± 0.07	2.12 ± 0.15	0.14†	1.91 ± 0.17	1.89 ± 0.16	0.70†
C-peptide (mmol/l)	0.89 ± 0.08	0.90 ± 0.03	0.85	0.87 ± 0.04	0.90 ± 0.05	0.61

Data are means ± SEM or %. Comparisons are by unpaired Student's *t* test, except where indicated by * (χ^2) or † (Mann-Whitney *U* test).

HbA_{1c} was measured using an high-performance liquid chromatography method (Diamat; Biorad, Hercules, CA). Glucose analyses used a glucose oxidase method (APEC, Danvers, MA). Triglycerides were measured with a Hitachi 717 instrument using a lipase/glycerol kinase/glycerol-3-phosphate method. Total cholesterol was determined with the same instrumentation using a cholesterol esterase and cholesterol oxidase reaction from Boehringer Mannheim Diagnostics (Mannheim, Germany). HDL cholesterol was assessed by the same method after precipitation of LDL and VLDL cholesterol. LDL cholesterol was calculated using the Friedewald equation (38).

Statistical analysis

Data were analyzed using Statview II (Abacus Concepts, Berkeley, CA). Student's *t* test and Mann-Whitney *U* test were used to test differences in baseline characteristics. χ^2 analyses were used to compare categorical data. ANOVA with repeated measures was used for follow-up

data; only patients with values at every time point were included in these analyses. Spearman rank correlation analysis was used to test changes in triglyceride levels. Chronbach's α and logistic regressions were performed using STATA Statistical Software (Stata, College Station, TX).

RESULTS

Patient characteristics

Between August 1994 and August 1995, 648 patients with initial visits to the Grady Diabetes Clinic qualified and agreed to participate in the study; 359 were assigned to the EXCH group and 289 to the HFC group. A small number of patients later requested to switch from the HFC to the EXCH group for the purpose of weight management, but in all case subjects, data were analyzed on the basis of intention to treat.

The presenting population had a mean age of 52 years, 90% were African American, 65% were women, and 78%

were obese (>120% ideal weight, Table 1). The mean duration of diabetes was 4.8 years, the initial fasting plasma glucose 10.5 mmol/l, and HbA_{1c} 9.4%. There were no significant differences between the EXCH and HFC groups in age, ethnicity, gender, BMI, duration of diabetes, fasting glucose, or HbA_{1c}. The EXCH group had a higher follow-up rate at 2 months (59 vs. 51%, *P* = 0.03) but not at 6 months (48 vs. 52%, *P* > 0.2). Such follow-up rates are characteristic of this patient population and reflect barriers to care that are not unusual in patient groups that are confronted with poverty and low literacy (27,33,34). In both groups, the patients who returned for their 6-month visits had comparable demographic characteristics at baseline (see Table 1, "6-month return" groups).

On presentation, 19% of patients were being managed with meal plan alone, 44% were using sulfonylureas, 34% were using insulin only, and 3% were using sulfonylureas and insulin in combination (Table 1). The percentage of

patients managed with meal plan alone increased to 38% at 2 months (reflecting a vigorous trial of nonpharmacologic management for obese patients, see RESEARCH DESIGN AND METHODS) and then decreased gradually to 28% at 6 months. There was no difference in the distribution of therapies between the two groups at any time point (all χ^2 tests, $P > 0.15$).

Changes in fat and sugar intake

We used questionnaires to determine whether the EXCH versus HFC approaches to dietary instruction led to differences in eating patterns. Reliability of the modified Kristal fat screener in this population was comparable with that reported by Kristal et al. (39); Chronbach's α 's were generally 0.5 to 0.7 for initial evaluations with all of our questionnaires. At baseline, the EXCH and HFC groups had comparable fat intake as measured by the food frequency and Kristal fat screener. During follow-up, both groups decreased their fat intake ($P < 0.01$ for all but the HFC meal plan on the Kristal scale ($P = 0.07$)). Use of sugar-containing foods was comparable in the two groups initially ($P = 0.09$), and decreases were significant but similar in both groups ($P < 0.01$ for both changes). Change in food usage was not a significant predictor of change in HbA_{1c}, whether it was tested in univariate analysis or in a multiple regression model that included age, duration of diabetes, sex, ethnicity, BMI, and metabolic variables (data not shown).

Changes in HbA_{1c}

HbA_{1c} declined comparably for both groups over the 6 months of follow-up, dropping from 9.6 to 7.7% in the EXCH group and 9.7 to 7.8% in the HFC group ($P < 0.0001$ for both) (Fig. 1A). At 6 months, 41% of the EXCH group and 32% of the HFC group had achieved a HbA_{1c} of 7.0% or less ($P = 0.12$ between groups). Decreases in glucose levels were also comparable between the groups ($P > 0.5$, data not shown) with fasting glucose declining from 10.8 to 9.2 mmol/l for the EXCH group, and 9.9 to 9.0 mmol/l for the HFC group ($P < 0.0001$ for each change). In both groups, responses were similar for patients who were classified as lean or obese (data not shown).

Changes in weight

Results were evaluated for the 275 patients classified as obese (>120% of ideal

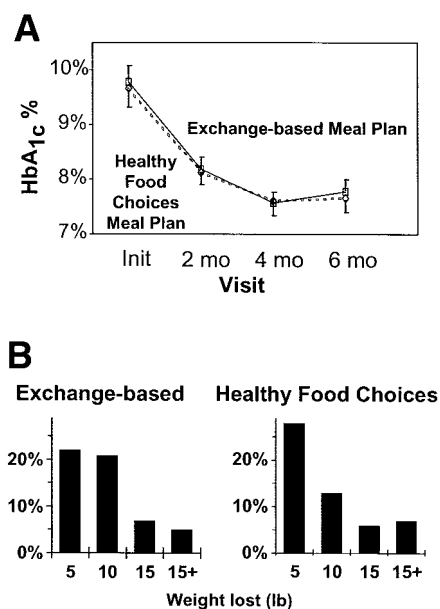


Figure 1—A: Changes in HbA_{1c} levels in patients on the EXCH and HFC. B: Percent of patients losing 0–5, 5–10, 10–15, or ≥ 15 lb (0–2.3, 2.3–4.5, 4.6–6.8, or ≥ 6.8 kg) by the 2-month follow-up visit.

weight) who returned for their 2-month follow-up appointment (158 EXCH and 117 HFC) and the 155 who returned for all three of their bi-monthly appointments (86 EXCH and 69 HFC). The EXCH and the HFC groups did not differ significantly in the percentage of patients who lost weight (53.2 vs. 53.0%, $P > 0.97$) or in the distribution of patients who lost 0–5, 5–10, 10–15, or >15 lb (0–2.3, 2.3–4.5, 4.5–6.8, or >6.8 kg, Fig. 1B). Both groups had small but significant average weight change at 6 months ($P = 0.02$ for both). The average weight of the EXCH group increased from 96.4 to 96.8 kg, and that of the HFC group declined from 95 to 94.1 kg; 59.7% of the EXCH and 45.1% of the HFC group gained weight ($P = 0.07$ between groups). Neither weight nor BMI was significantly different between the two groups at 6 months ($P = 0.15$). Changes in weight among the patients classified as obese were not significantly related to changes in fat or sugar usage or to dietary assignment group either by univariate analysis or in the multiple regression model. A small but significant increase in weight also occurred in patients classified as lean with the EXCH group gaining 2.3 kg and the HFC gaining 3.6 kg ($P < 0.0001$).

Lipids and blood pressure

Information on lipids was available for 638 patients at baseline and for 169 patients who had repeat measurements at the 4- or 6-month return visit. There was no systematic strategy to repeat lipid measurements or to institute or alter use of hypolipidemic agents. Neither total nor LDL cholesterol differed significantly between the groups on initial presentation, and values did not change significantly over time (all $P > 0.15$). HDL cholesterol increased slightly but significantly in both groups (from 1.09 to 1.15 mmol/l in EXCH and from 1.11 to 1.17 mmol/l in HFC; $P < 0.005$ for both). Average triglycerides dropped from 2.03 to 1.78 mmol/l in the EXCH group and from 2.92 to 2.38 mmol/l in the HFC group ($P < 0.001$ for both). Blood pressure did not differ significantly between the EXCH and HFC groups at initial presentation or after 6 months of follow-up (data not shown).

CONCLUSIONS— Medical nutrition therapy is essential in the management of type 2 diabetes. Moreover, effective medical nutrition therapy will be particularly important for populations such as that served by the Grady Health System in which diabetes and obesity are common, glycemic control on presentation is often poor (Table 1), and many patients already have diabetes complications (33,40,41). However, there has been relatively little examination of different nutritional approaches for urban populations enriched in minorities, the poor, and the underserved (25). In this setting, we found that instruction in meal planning based only on HFC was comparable with the EXCH system in impact on food selection, glycemic control, weight, lipids, and blood pressure. Although the additional benefits of weight loss should not be discounted (42,43), the data indicate that nutritional management for patients with type 2 diabetes does not need to be focused primarily on weight loss or to involve exchange approaches to have a beneficial impact on glycemic control. Since changes in lipids were small with both approaches, our findings also raise the possibility that neither the EXCH nor the HFC meal plan will constitute an effective first-line method for modifying these important cardiovascular risk factors in municipal populations; if LDL cholesterol abnormalities persist despite improve-

ments in glycemic control (44), patients may need earlier institution of hypolipidemic agents.

The lack of difference in outcomes between the EXCH and HFC approaches may be due to similarities in food usage; both groups had comparable fat and sugar intakes at baseline and reported significant but comparable reductions in fat and sugar intake at follow-up. It should be recognized that even though others have used similar approaches to evaluate dietary intake (36,45), such self-reports might not always be accurate reflections of actual dietary composition and energy intake (45–52). However, to the extent that the HFC approach produces comparable outcomes but is easier to understand and easier to teach than the EXCH approach, the HFC approach may be preferable for use in urban populations with low literacy such as that served by Grady (27).

One limitation of this study is that we did not assess patient satisfaction with either meal plan. However, patients reported anecdotally that the HFC meal plan was easy to understand, which contrasts with the difficulty patients may have with the EXCH meal plan (28). We also did not evaluate ease of use, but the dietitians reported anecdotally that the HFC meal plan was easier to teach. Although portion sizes were not discussed with patients in the HFC meal plan, it is possible that they were implied from demonstration of the food pyramid and use of food models. While the EXCH and HFC groups had comparable demographic characteristics and return rates, it remains possible that the substantial dropout rate led to some selection bias. However, a comparable dropout was recently reported for a diabetes education program that used a similar randomization scheme but was based in a suburban setting (53). Finally, it was not possible to obtain data on the cost of our interventions or on patient socioeconomic status, education, or literacy. However, demographic characteristics of the patients were otherwise similar between study groups and to what we have previously reported (33) with no obvious change in referral patterns.

Instruction in both meal plans, and the observed improvement in glucose control, occurred in the context of our general treatment program. Nonetheless, the reductions in HbA_{1c} under the HFC

meal plan can be seen as further support for the idea that emphasizing food choices, and not just energy intake, can be an important element in improving glycemic control. As a result of this study, providers in the Grady Diabetes Clinic continue to use the EXCH meal plan for those patients who desire a focus on food exchanges and portion sizes as a strategy to lose weight, but instruction in HFC without an emphasis on weight loss has become the standard approach to meal planning for all other patients.

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