Randomized Controlled Community-Based Nutrition and Exercise Intervention Improves Glycemia and Cardiovascular Risk Factors in Type 2 Diabetic Patients in Rural Costa Rica

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OBJECTIVE — The prevalence of type 2 diabetes, especially in developing countries, has grown over the past decades. We performed a controlled clinical study to determine whether a community-based, group-centered public health intervention addressing nutrition and exercise can ameliorate glycemic control and associated cardiovascular risk factors in type 2 diabetic patients in rural Costa Rica.

RESEARCH DESIGN AND METHODS — A total of 75 adults with type 2 diabetes, mean age 59 years, were randomly assigned to the intervention group or the control group. All participants received basic diabetes education. The subjects in the intervention group participated in 11 weekly nutrition classes (90 min each session). Subjects for whom exercise was deemed safe also participated in triweekly walking groups (60 min each session). Glycosylated hemoglobin, fasting plasma glucose, total cholesterol, triglycerides, HDL and LDL cholesterol, height, weight, BMI, and blood pressure were measured at baseline and the end of the study (after 12 weeks).

RESULTS — The intervention group lost 1.0 ± 2.2 kg compared with a weight gain in the control group of 0.4 ± 2.3 kg ($P = 0.028$). Fasting plasma glucose decreased 19 ± 55 mg/dl in the intervention group and increased 16 ± 78 mg/dl in the control group ($P = 0.048$). Glycosylated hemoglobin decreased $1.8 \pm 2.3\%$ in the intervention group and $0.4 \pm 2.3\%$ in the control group ($P = 0.028$).

CONCLUSIONS — Glycemic control of type 2 diabetic patients can be improved through community-based, group-centered public health interventions addressing nutrition and exercise. This pilot study provides an economically feasible model for programs that aim to improve the health status of people with type 2 diabetes.

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T ype 2 diabetes is a rapidly growing chronic health problem, the complications of which cause significant morbidity and mortality (1). Although type 2 diabetes has long affected developed countries, over the past decades, it has become an increasingly serious public health problem in developing countries. The prevalence of diabetes in Costa Rica, among people older than 20 years of age, was 4.6% in 1995 and is projected to reach 6.9% by 2025 (2,3). In 1995, worldwide prevalence of diabetes was 4.0% and U.S. prevalence was 7.4% (3,4). The epidemic increase in the prevalence of diabetes in developing countries has been linked to increased longevity and obesity and the adoption of Western diet and exercise patterns (4,5).

There is ample evidence that maintaining good glycemic control can decrease the rate of microvascular complications in patients with type 2 diabetes (6–8). Numerous studies have demonstrated salutary effects of dietary intervention and increased physical activity or exercise, supervised in a controlled environment, on hyperglycemia and other cardiovascular risk factors such as high cholesterol and hypertension (9–14). However, these interventions can only be offered to global populations of people with type 2 diabetes if the teaching of nutrition and exercise can be economically implemented in diverse cultures that often have very limited resources.

The prevalence of type 2 diabetes is increasing in Costa Rica, even in relatively poor, agrarian regions. The current pilot study was undertaken to determine whether a community-based, group-centered nutrition and exercise program could be conducted in rural Costa Rica and whether it would improve glycemic control and cardiovascular risk factors among type 2 diabetic patients.

RESEARCH DESIGN AND METHODS — This 12-week randomized controlled pilot study was conducted with type 2 diabetic volunteers from three small communities surrounding Grecia, Costa Rica–San Roque, Santa Gertrudis, and Rincón de Salas.

The Grecia region is located in the central valley of Costa Rica, 45 km from the capital, San José. The region consists

of a large town surrounded by farmland and six small towns with a total population of ~64,000 people. The population is evenly divided between Grecia center and the outlying rural areas. In 1998, 12% of Grecia's population was 45–65 years of age and 5% was aged >65 years. The literacy rate in the Grecia region is 94% due to universal public education; higher rates of illiteracy are common among older women from rural areas. Agriculture accounts for 43% of employment. Most primary healthcare, provided free of charge through the national health care system, is delivered in six primary clinics in the outlying small towns. These clinics are staffed by a multidisciplinary team: doctor, nurse, pharmacist, and health technician. The clinics are typically painted concrete buildings comprising five rooms. All records are kept in paper format. Fasting blood glucose levels are measured in patients with diabetes once every 3 months during their clinic visit. Most patients cannot afford to buy a device to check daily blood glucose levels.

Research subjects

Subjects in whom type 2 diabetes had been diagnosed, established through chart review and consultation with treating physicians, were recruited for the study. Diabetes was defined according to the 1997 American Diabetes Association diagnostic criteria as a fasting plasma glucose concentration ≥126 mg/dl (15). No potential volunteers were excluded. The subjects were recruited from several sources. A list of known diabetic patients from three small towns outside Grecia was generated by the San Francisco de Asís Hospital's informatics department. The social worker and health technician assigned to each community supplied a list of patients with diabetes. Individuals in the first two groups were specifically invited to attend informational meetings to explain what the study would entail. Additionally, publicity to recruit diabetic subjects was conducted in each of the three communities in cooperation with local health committees and included posters in public buildings and buses as well as announcements in churches, on a local radio station, and via a car-mounted megaphone.

The study protocol was approved by the ethics committee of the San Francisco de Asís Hospital in Grecia. All study sub-jects gave written and oral informed consent.

Interventions

A total of 75 subjects from three rural towns surrounding Grecia were randomly assigned to the intervention group or the control group using a randomization list. They were stratified according to the primary health clinic they attended. The subjects in both groups continued to receive standard medical care from their physicians. The physicians were informed that their patients were involved in the study, but assignments to the treatment groups were masked. For the duration of the 12-week study, the subjects' physicians were asked to refrain from nonessential changes in medication and dosage that might affect the study outcome measures. Any essential medication changes were implemented and then reported to the investigators. The subjects, nutrition educators, and walking group leaders could not be masked, owing to the nature of the intervention.

Before random assignment to the treatment groups, all volunteers received standard diabetes education in the form of a lecture that reviewed type 2 diabetes and its symptoms, treatment, and associated complications. After randomization, the subjects in the intervention group began the 12-week lifestyle intervention, and the subjects in the control group were informed that they would be offered a similar program at the end of the study.

The lifestyle intervention included 11 weekly nutrition classes (90 min each session) in centrally located community centers. The classes were taught by three nutritionists who were enrolled in a nutrition Master's degree program at the University of San José. They received instruction in the specific dietary curriculum that was used in the study and helped to refine it to conform to local customs. Each class was offered twice per week in each community to enhance attendance. The classes were limited to 15 individuals per class; subjects were encouraged to bring family members. The course focused on portion control for weight reduction and use of healthier food substitutes (electronic copies of the Spanish-language curriculum are available upon request from the corresponding author). Because the concept of counting calories is less common in Costa Rica, specific suggestions were made for por-tion control as opposed to total calories or grams of fat consumed. Examples of these suggestions include serving meals on a small plate to make the food appear bigger, avoiding eating a meal while watching television, and putting extra food away after serving oneself. Subjects were taught the basics of food groups; the difference between simple and complex carbohydrates and their relation to glycemic index and fiber content; the difference between saturated, unsaturated, and trans-saturated fats and their relation to cholesterol and atherosclerosis; sources of protein and the different fat content of each; hidden calories contained in beverages; and the micronutrient and fiber value of fruits and vegetables. The entire curriculum was presented in Spanish and was designed in a culturally and economically sensitive manner. Nutrition content was presented using demonstrations and other participatory activities. For example, during the session on fats, the nutritionists passed around a number of teaspoon-sized balls of lard equivalent to the saturated fat content in foods such as chicharrones (fried pork sausages). To harness the benefits of peer support, subjects set weekly goals for specific changes in their eating behaviors to decrease portion sizes and make healthier food choices. These goals were shared with the group at the end of class, and progress was reported at the beginning of the next class. Emphasis was placed on the importance of nutritional health for all family members, regardless of diabetes status. Each participant was given written handouts and a notebook to take notes and record food diaries. Those who were not able to read or write were assisted during the class and were encouraged to ask a family member for assistance at home. Each participant was also given a measuring cup and taught how to use it for portion control.

The subjects in the intervention group were invited to participate in 60-min walking group sessions three times per week for 12 weeks. Subjects who injected insulin and those who had open foot ulcers or clinically active coronary artery disease, who were considered by their physicians to be at risk, were excluded from the walking groups. Based on these criteria, only 20 of the 40 subjects in the intervention group were invited to participate in the walking groups. Another nine subjects did not participate in

Table 1—*Baseline characteristics of subjects in the intervention and control groups*

Characteristics	Intervention group	Control group
n	40	35
Sex (*n*)		
Men	7	9
Women	33	26
Age (years)	60 ± 10	57 ± 9
Weight (kg)	72.4 ± 14.6	71.9 ± 12.4
BMI (kg/m^2)	30.1 ± 5.1	29.0 ± 4.6
Fasting plasma glucose (mg/dl)	186 ± 103	171 ± 85
Glycosylated hemoglobin (%)	8.6 ± 3.7	8.6 ± 3.9
Serum lipids (mg/dl)		
Total cholesterol	247 ± 52	227 ± 47
HDL cholesterol	45 ± 12	42 ± 10
LDL cholesterol*	156 ± 47	144 ± 36
Triglycerides	288 ± 244	237 ± 215
Blood pressure (mmHg)		
Systolic	138 ± 19	134 ± 17
Diastolic	84 ± 10	82 ± 10
Use of hypoglycemic medications (%)†		
All classes	86	86
Sulfonylureas	62	57
Metformin	35	43
Insulin	32	26
Use of antihypertensive medications (%)†		
All classes	51	43
ACE inhibitors	22	14
β-adrenergic blockers	22	17
Calcium channel blockers	14	14
Other	22	11
Use of lipid-lowering medications (%)†		
All classes	33	18
Gemfibrozil	11	9
Lovastatin	22	9

Data are means ± SD unless otherwise indicated. LDL cholesterol = total cholesterol − (triglycerides/5 + HDL cholesterol). LDL cholesterol values were only calculated when triglycerides were < 400 mg/dl. For this reason, *n* = 67 for LDL cholesterol (intervention groups, *n* = 35; control groups, *n* = 32). †Baseline medications were established via chart review and physician consultation. Because three charts had incomplete or missing data, *n* = 72 (intervention groups, *n* = 37; control groups, *n* = 35). Numbers indicate percentages of all subjects taking the given class of medication within a treatment stratum.

the walking groups because of arthritis or lower back pain. Local volunteer community leaders organized and led the walking groups, and subjects were encouraged to invite their family members to participate. Although walking time was kept constant at 60 min, subjects were encouraged to increase their pace and distance over the duration of the program; a brisk workout was the goal. Subjects were instructed to wear socks and closed-toed shoes during the walking sessions and were taught to check their feet for ulcers or blisters. Leaders were trained in procedures for obtaining medical assistance in case of an emergency during the walking sessions.

Outcomes

Study subjects underwent measurement of weight, height, blood pressure, and glycosylated hemoglobin, fasting plasma glucose, serum total cholesterol, HDL cholesterol, and triglyceride levels at baseline and at the end of the study. LDL cholesterol was calculated using the Friedewald equation (16). The technicians who performed baseline and endpoint measurements, including height, weight, blood pressure, and laboratory analyses, were blinded to treatment group assignment.

At baseline and study end, if a subject was determined to have a previously un-

detected abnormal laboratory value or blood pressure, that subject was referred for medical follow-up in accordance with the Costa Rican health care system's guidelines.

Laboratory assessments

All assays were conducted at the central laboratory of the San Francisco de Asís Hospital using a Synchron Clinical System CX5CE (Beckman Coulter, Fullerton, CA). Glycosylated hemoglobin levels were determined by immunoassay (non-diabetic range 4.6–6.2%). Fasting plasma glucose, total cholesterol, HDL cholesterol, and triglyceride levels were determined by enzymatic assay (Beckman Coulter).

Statistical analysis

It was estimated that 56 subjects was a sufficient sample population, given a target absolute reduction in glycosylated hemoglobin of 1.5%, a standard deviation of the change in glycosylated hemoglobin of 2%, a two-sided α of 0.05, and a power of 0.8.

Two-sided homoscedastic *t* tests were used to analyze the differences between the intervention and control groups in changes from baseline to end-point measurements. All analyses were based on the intention-to-treat principle. EpiInfo 2000, Microsoft Excel XP with Microsoft Analysis ToolPak, and SAS software programs were used to perform all statistical analyses. All results are shown as means ± SD, unless noted otherwise.

RESULTS — All subjects began the program in January 2002. The baseline glycosylated hemoglobin was 8.6 ± 3.7% for the intervention group and 8.6 ± 3.9% for the control group. Baseline clinical and demographic characteristics did not differ significantly between the intervention and control groups and are shown in Table 1.

Of the 75 type 2 diabetic subjects who began the study, 61 subjects completed the program, as defined by attendance at the study-end measurement day. The primary reason for missing the study-end measurement day was conflict with subjects' schedules. The baseline characteristics of the 14 subjects who did not complete the program (7 intervention and 7 control subjects) did not differ significantly from the baseline characteristics of those subjects who completed the

Table 2—*Changes in clinical and metabolic variables from baseline to end-point measurements of subjects in the intervention and control groups*

Variable	Intervention group* (n = 33)	Control group* (n = 28)	CI	P†
Change in weight (kg)	−1.0 ± 2.2	0.4 ± 2.3	−2.48 to −0.15	0.028
Change in BMI (kg/m²)	−0.4 ± 0.9	0.2 ± 1.0	−1.06 to −0.08	0.022
Change in fasting plasma glucose (mg/dl)‡	−19 ± 55	16 ± 78	−71.1 to −0.28	0.048
Change in glycosylated hemoglobin (%)	−1.8 ± 2.3	−0.4 ± 2.3	−2.52 to −0.15	0.028
Change in serum lipids (mg/dl)				
Total cholesterol	−8 ± 36	1 ± 33	−27.05 to 8.67	0.31
HDL cholesterol	−5 ± 5	−3 ± 6	−4.05 to 1.95	0.49
LDL cholesterol§	5 ± 36	−1 ± 29	−12.43 to 24.02	0.53
Triglycerides	−48 ± 163	27 ± 176	−162.5 to 11.7	0.09
Change in blood pressure (mmHg)				
Systolic	−5 ± 23	−4 ± 16	−10.75 to 10.06	0.95
Diastolic	−7 ± 9	−3 ± 8	−8.57 to 0.24	0.06

Data are means ± SD. *A total of 14 subjects (7 intervention; 7 control) did not undergo end-point measurements; †*P* values were determined by a two-tailed, homoscedastic *t* test for the difference between the groups; ‡because not all subjects were fasting, the fasting plasma glucose could not be measured for all subjects and therefore, *n* = 57 for fasting plasma glucose (intervention group, *n* = 30; control group, *n* = 27); §LDL cholesterol value was calculated based on the following formula: LDL cholesterol = total cholesterol − (triglycerides/5 + HDL cholesterol). LDL cholesterol values were only calculated when triglycerides were < 400 mg/dl. For this reason, *n* = 53 for LDL cholesterol (intervention group, *n* = 29; control group, *n* = 24).

program (data not shown). Adherence to the intervention program was judged by attendance at the nutrition classes and exercise groups. Of the 33 subjects in the intervention group who completed the program, 20 subjects attended more than 70% of the nutrition classes and 9 subjects attended the walking groups an average of at least 60 min per week. None of the seven subjects from the intervention group who did not complete the program attended the walking groups an average of at least 60 min per week, and only one of these subjects attended more than 70% of the nutrition classes.

Over the 12-week study period, the mean BMI decreased 0.4 ± 0.9 kg/m² in the intervention group and increased 0.2 ± 1.0 kg/m² in the control group (P = 0.022). Weight decreased 1.0 ± 2.2 kg in the intervention group and increased 0.4 ± 2.3 kg in the control group (P = 0.028). Fasting plasma glucose decreased 19 ± 55 mg/dl in the intervention group and increased 16 ± 78 mg/dl in the control group (P = 0.048). Glycosylated hemoglobin decreased 1.8 ± 2.3% in the intervention group and decreased 0.4 ± 2.3% in the control group (P = 0.028). For the other measures, differences in changes between the intervention and

control groups from baseline to the end of the study were small and not statistically significant. The changes in measurements of the intervention and control groups are presented in Table 2.

One potential confounding factor in this study, in which effective blinding of the participants and health care providers was not possible, would be if more health care and/or medications were provided to the subjects in the intervention group. The mean frequency of clinic visits was almost identical between the intervention and control groups (1.03 ± 0.58 vs. 1 ± 0.59 visits, respectively). Similarly, the frequency of medication changes was not significantly different between the intervention and control groups for lipid, hypoglycemic, or antihypertensive therapies. Trends toward decreased medication usage in all three medication classes were observed in the intervention group. Changes in the number of subjects taking these medications are shown in Fig. 1.

CONCLUSIONS — This study provides evidence that a community-based nutrition and exercise intervention for type 2 diabetic patients, conducted in peer groups, can be effectively implemented in developing nations and that important health indicators significantly improve. In particular, BMI and glycemic levels decreased. The decreased glycosylated hemoglobin should translate into a reduced risk of microvascular complications (6–8). Moreover, the findings in this study can be viewed as conservative, for a scalable public health program, because all analyses were conducted according to the intention-to-treat principle, even though some subjects randomized to the intervention group did not partici-
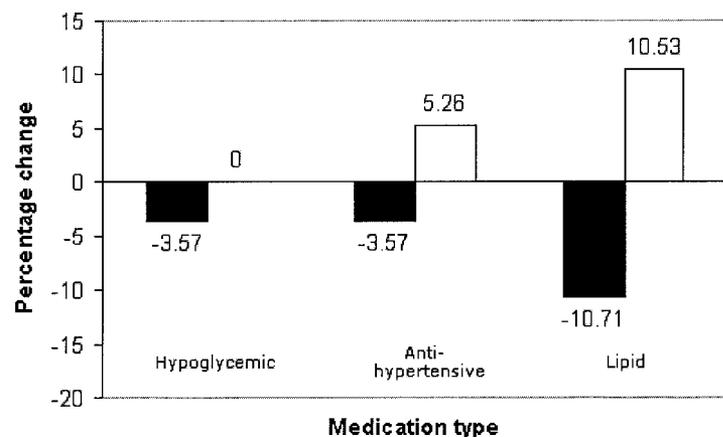

Figure 1—*Change in number of subjects (%), between baseline and study end, who were taking any medication (by class of medication). Solid boxes represent the intervention group; open boxes represent the control group. Because 14 subjects did not have an appointment during the period from 1 month before to 2 months after the end of the study, the total number of patients represented is 47 (intervention group, n = 28; control group, n = 19). Although the intervention group showed a tendency toward decreased medication use in all classes compared with the control group, none of the differences are statistically significant.*

pate in the nutrition classes and/or walking groups.

Of the subjects who completed the study, 82% were women. This gender imbalance is not uncommon in public health interventions or primary care clinic visits in Grecia. Among people aged >35 years in Grecia, 67% of all primary care clinic visits were for women during 2001 (17). For both clinic visits and this study, the gender imbalance is likely due to a variety of factors, including differences in work schedules and cultural norms.

Although we attempted to mask the treatment group assignments, we cannot be confident that the health care providers remained blinded to this information. Therefore, a potential exists for a differential application of therapy, such as frequency of clinic visits or prescription of medications. The standardized schedule of clinic visits for diabetic patients in Costa Rica under the national health care system (one visit every 3 months) provides some safeguard against this potential confounder. Moreover, there was no significant difference in medication use between groups. Furthermore, a greater percentage of the intervention group was taken off their lipid, hypoglycemic, and antihypertensive medications during the study (Fig. 1).

The 3-month study period was long enough to observe changes in some outcome measures but short enough to invite the criticism that these results are not sustainable. Although it is certainly difficult to maintain lifestyle changes, we are optimistic because of the community setting and peer reinforcement. Evidence of this includes the organization of walking groups for the poststudy round of the program, which was offered to subjects in the control group. Veteran participants have acted as recruiters and continue to walk with the control group members and other new participants since the completion of the study.

Several recent randomized, controlled trials have been successful in decreasing the rate of progression from glucose intolerance to type 2 diabetes through the provision of nutrition and exercise training in diverse communities (18–20). While providing an excellent demonstration of prevention of type 2 diabetes, most of these studies used resource-intensive, individualized nutrition and exercise counseling that was based predominately in academic centers. Re-

sults from other studies have begun to provide evidence that community-based nutrition and exercise interventions can significantly reduce risk factors for diabetic complications (21–23). The levels of improvement found in these other studies are similar to those found in our study. One of the most comprehensive of these studies is the randomized, controlled Starr County Border Health Initiative in a Mexican-American population of type 2 diabetic subjects in Texas (23), in which a 1.0% reduction in mean glycosylated hemoglobin levels of the intervention group was demonstrated at the 6-month measurement point (1.4% compared with the mean of the control group). An uncontrolled nutrition intervention conducted in El Guarco, Costa Rica also showed promising results, achieving a reduction in fasting blood glucose, glycosylated hemoglobin, and triglyceride levels (22). No randomized, controlled trials of community-based nutrition and exercise interventions with type 2 diabetic subjects, conducted in developing countries, were found via Medline searches for the following sets of terms: community nutrition exercise diabetes, community nutrition diabetes, and community exercise diabetes.

In many of the above-cited studies, the importance of family participation and the support structure provided by groups were emphasized. Health professionals often note that it is difficult to motivate lifestyle changes, specifically nutrition and exercise among type 2 diabetic patients. However, the current study, with its community emphasis, family involvement, and peer support, found both quantitative and qualitative evidence that changing lifestyle habits is achievable for type 2 diabetic patients. In addition to the subjects in the nutrition classes and walking groups, family members and friends, many with hypertension and high cholesterol, also attended.

The group structure allowed efficient teaching of nutritional information and an almost cost-free opportunity for exercise by harnessing the benefits of peer support and recruiting volunteer community walking group leaders. These qualities suggest that this program, and similar efforts cited above, may serve as scalable models for other communities and countries.

In conclusion, we have demonstrated, on a small scale, the feasibility of implementing an effective lifestyle modi-

fication program in rural Costa Rica. The program, initially conducted by nutritionists and members of the community, has the potential to be self-sustaining. Short-term benefits included improvement in weight and glycemia.

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