Translating the Diabetes Prevention Program Into an Urban Medically Underserved Community

A nonrandomized prospective intervention study

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OBJECTIVE — The objective of this study was to determine if a community-based modified Diabetes Prevention Program Group Lifestyle Balance (GLB) intervention, for individuals with metabolic syndrome, was effective in decreasing risk for type 2 diabetes and cardiovascular disease (CVD) in an urban medically underserved community, and subsequently to determine if improvements in clinical outcomes could be sustained in the short term.

RESEARCH DESIGN AND METHODS — This nonrandomized prospective intervention study used a one-group design to test the effectiveness of a community-based GLB intervention. Residents from 11 targeted neighborhoods were screened for metabolic syndrome ($n = 573$) and took part in a 12-week GLB intervention ($n = 88$) that addressed safe weight loss and physical activity.

RESULTS — A marked decline in weight (46.4% lost ≥5% and 26.1% lost ≥7%) was observed in individuals after completion of the intervention. Of these subjects, 87.5% ($n = 28$) and 66.7% ($n = 12$) sustained the 5% and 7% reduction, respectively, at the 6-month reassessment. Over one-third of the population (43.5%, $n = 30$) experienced improvements in one or more component of metabolic syndrome, and 73.3% ($n = 22$) sustained this improvement at the 6-month reassessment. Additional improvements occurred in waist circumference ($P < 0.009$) and blood pressure levels ($P = 0.04$) after adjustment for age, sex, race, mean number of GLB classes attended, and time.

CONCLUSIONS — Adults in an urban medically underserved community can decrease their risk for type 2 diabetes and CVD through participation in a GLB intervention, and short-term sustainability is feasible. Future research will include long-term follow-up of these subjects.

Diabetes Care **31:684–689, 2008**

Type 2 diabetes is a prevalent costly condition that disproportionately affects disadvantaged populations (1). Approximately 54 million American adults age ≥20 years had pre-diabetes in 2002, placing them at substantially increased risk for developing type 2 diabetes (2). Because the prevalence of type 2 diabetes in the U.S. is expected to more than double by the year 2050, reducing type 2 diabetes risk is a public health priority (3).

Obesity and sedentary lifestyle are risk factors for type 2 diabetes, since they interact multiplicatively in the development of the disease. Substantial evidence demonstrates that intensive lifestyle intervention (ILI) can reduce the incidence of type 2 diabetes in individuals at risk (4–6). The Diabetes Prevention Program (DPP) demonstrated a 58% reduction in incidence of type 2 diabetes in subjects who were randomized to the ILI group of the program (5). The ILI consisted of a structured diet and increased physical activity, without medication intervention. Significant reduction of incidence of type 2 diabetes occurred regardless of ethnicity, age, or sex. Moreover, the ILI was effective in reducing risk for cardiovascular disease (CVD) and components of the metabolic syndrome, while remaining cost-effective (7,8)

Although the DPP's intensive methodology was necessary to study the efficacy of lifestyle change in preventing type 2 diabetes, it is not easily replicated in community settings (9). Indeed, translation of this evidence into community settings remains limited. Therefore, our objective was to determine if a community-based modified DPP Group Lifestyle Balance (GLB) intervention, for individuals with metabolic syndrome, is effective in decreasing risk for type 2 diabetes and CVD in an urban medically underserved community, and subsequently to determine if improvements in clinical outcomes can be sustained in the short term.

RESEARCH DESIGN AND METHODS

This study was a nonrandomized prospective intervention study that used a one-group design to test the effectiveness of a community-based GLB intervention. Recruitment for the study began in April 2005 in 11 urban medically underserved neighborhoods near Pittsburgh, Pennsylvania. This is the primary service area of the community hospital and served as the study's base location.

The target community was a former hub of the steel industry that experienced industrial downsizing in the 1980s. This

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Received for publication 24 September 2007 and accepted in revised form 17 January 2008.

Published ahead of print at http://care.diabetesjournals.org on 5 February 2008. DOI: 10.2337/dc07-1869.

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Abbreviations: CVD, cardiovascular disease; DPP, Diabetes Prevention Program; GLB, Group Lifestyle Balance; ILI, intensive lifestyle intervention; LHC, lay health coach.

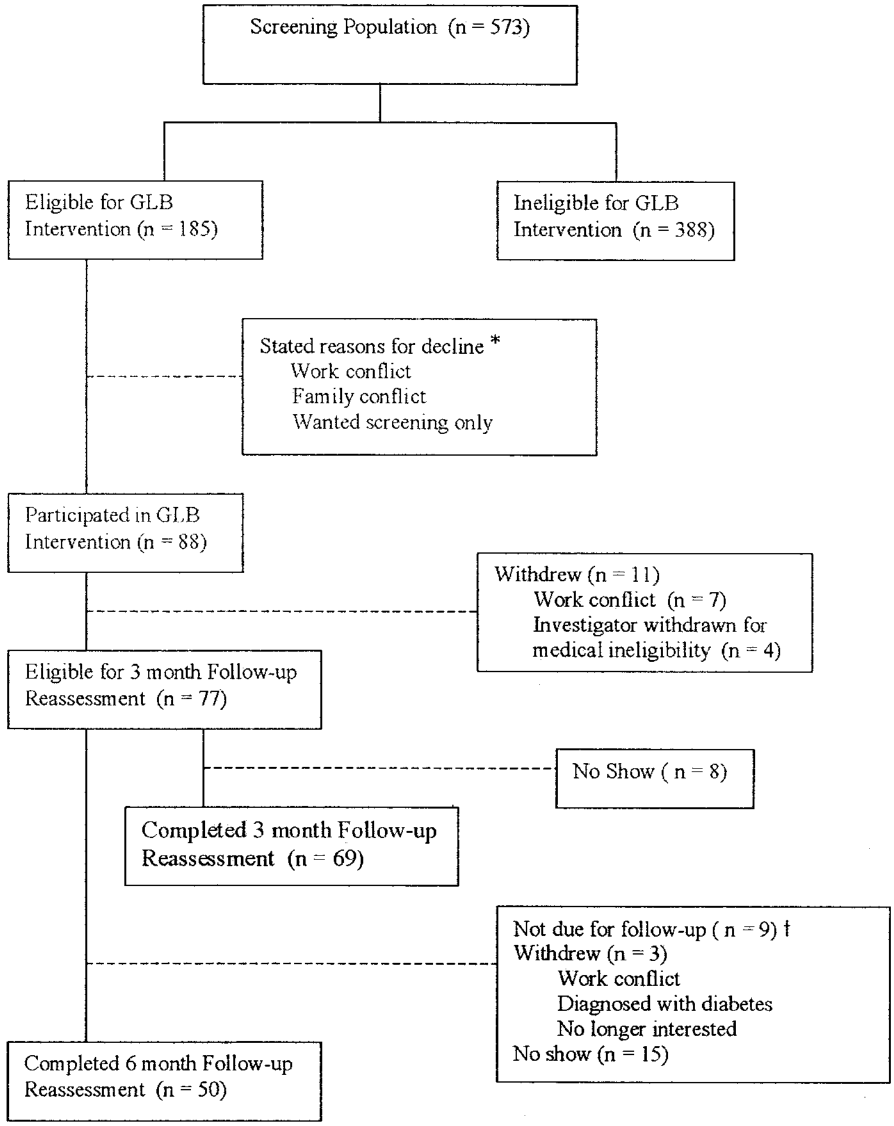

Figure 1—*Study design of a nonrandomized prospective GLB intervention study. *Per informal conversations between subjects and LHC. †One cohort had not reached 6-month mark at time of data analysis.*

led to increased rates of unemployment and out-migration of the young and more affluent, resulting in a predominately older socioeconomically depressed population with a high prevalence of chronic disease. Caucasians and African Americans are the predominate racial groups, with African Americans making up 36% of the community population compared with 13.1% in Allegheny county and 10.6% in Pennsylvania (U.S. Census Bureau, 2000 Census). The study was carried out in two phases: phase I, community-based screening to determine GLB intervention eligibility, and phase II, provision of the GLB intervention with 3- and 6-month reassessments. Follow-up remains ongoing. The study design is outlined in Fig. 1.

Phase I: community-based screening
Adults aged 18 years and older from the 11 targeted neighborhoods were eligible to be screened for metabolic syndrome. Recruitment involved posting flyers in churches, physician offices, worksites, and store fronts, as well as placing information in the local newspaper and on the local cable broadcast channel. People were not eligible for screening if they reported a diagnosis of diabetes or a current prescription for glucose-lowering medication, were pregnant, could not walk a quarter of a mile without stopping, had had bariatric surgery, were currently using weight-loss medications, or could not provide informed consent.

A total of 573 people attended one of 35 screenings during 2005–2006 to determine intervention eligibility. Screenings were offered at no cost in churches, worksites, and other community locations in the 11 neighborhoods. Eligible subjects had to have a BMI $\geq$25 kg/m^2, physician consent to exercise, and at least three of the five components of metabolic syndrome as defined by the National Cholesterol Education Program's Adult Treatment Panel III (10). Study staff (a registered dietitian, an exercise specialist, and two lay health coaches [LHC]) facilitated all screenings. The local hospital provided the phlebotomist and lab services. All staff were certified in standardized outcomes measurement consistent with the DPP.

After providing informed consent and completing a demographic questionnaire, participants had height, weight, waist circumference, and blood pressure measured according to standard protocol. Blood samples were collected after an 8-h fast to determine glucose, triglycerides, and HDL cholesterol levels. Triglycerides and HDL cholesterol were measured by enzymatic assays using the Dade Behring RXL. Blood glucose was measured by the hexokinase method using the Dade Behring RXL. Screening results were mailed to participants and their physicians. Eligible subjects (n = 185) were invited to participate in the GLB intervention (Fig. 1).

Phase II: modified GLB intervention
The original DPP ILI was developed at the University of Pittsburgh by the DPP Lifestyle Resource Core and has been described in detail elsewhere (9). Members of the DPP lifestyle team adapted the individual ILI to a group-based program, reconfiguring the 16 sessions into 12 sessions while maintaining key concepts. As in the original DPP ILI, the goals of the GLB intervention were to achieve and maintain a 7% weight loss and to progressively increase physical activity to 150 min/week of moderately intense physical activity. The modifications to the intervention were as follows: DPP intervention: 16 sessions over 24 weeks, individual counseling, food pyramid, fat intake, and brief introduction to pedometer; modified GLB: 12 weekly sessions over 12–14 weeks, group classes, healthy food choices, emphasis on fat intake and calories, and more emphasis on pedometer.

Two trained "preventionists" (one dietitian and one exercise specialist) were responsible for delivery of the GLB intervention, which took place in the 11 tar-

Table 1—*Baseline population characteristics of the GLB intervention population*

	% (*n*) or mean ± SD
Demographic	
Age (years)	54.0 ± 10.5
Race (% non-Hispanic white)	72.7 (64)
Female (%)	84.1 (74)
At least a high school diploma (% yes)	77.4 (68)
Poverty ≤200% (≤$41,300/year for household of four)	59.7 (37)
Family history of diabetes (% yes)	71.1 (63)
Class attendance (attended ≥75% of classes)	69.3 (61)
Weight (lb)	216.8 ± 40.7
Components of the metabolic syndrome*	
Abdominal obesity (≥102 cm in males, ≥88 cm in females)	93.2 (82)
Abnormal HDL cholesterol (<40 mg/dl in males, <50 mg/dl in females)	84.1 (74)
Hypertension (blood pressure ≥130/85 mmHg)	68.2 (60)
Triglycerides ≥150 mg/dl (% yes)	47.7 (42)
Glucose ≥100 mg/dl (% yes)	40.9 (36)

*National Cholesterol Education Program's Adult Treatment Panel III. $n = 88$.

geted neighborhoods and was held weekly for 12 weeks and lasted ~90 min. Group size ranged from 5 to 13 participants. The preventionists attended a 2-day training workshop, delivered by members of the original DPP lifestyle team that addressed how to properly deliver each of the 12 modified sessions. This workshop was conducted by the University of Pittsburgh's Diabetes Prevention Support Center. As part of the LHC training, the LHCs acted as participants in a GLB intervention to gain perspective on participant needs and concerns. LHCs communicated with participants and physician offices and identified barriers and solutions to promote program engagement and retention. They also aided in study logistics and shared relevant experiences to initiate class discussion. LHC performance was observed daily by professional staff.

Of the 185 eligible subjects, 88 enrolled in the intervention (Fig. 1). Each subject received a copy of the GLB handouts, a fat and calorie counter, self-monitoring books for keeping track of food and physical activity, a pedometer, measuring cups and spoons, a chart for recording weekly weights, and a free 6-month membership to the local YMCA. All subjects were asked to self-monitor food intake and physical activity throughout the 12-week intervention and were given feedback concerning progress.

GLB intervention measures. Anthropometric (height, weight, blood pressure, and waist circumference) and laboratory data (glucose, triglycerides, and HDL cholesterol) were subsequently collected at the 3- and 6-month reassessments. Participants and their physicians received copies of the results. A total of 69 participants provided 3-month data, yielding a response rate of 78.4%. There were 50 participants who provided 6-month data, with a response rate of 56.8%. Individuals who did not complete the intervention were significantly older, and a greater proportion was non-Caucasian in comparison to those who completed the intervention. There was no difference in education level between groups.

Study outcomes

There were two primary outcomes of the intervention: *1*) 5% or 7% weight loss from baseline to 3- and 6-month follow-up and *2*) improvement of at least one metabolic syndrome component from baseline to 3- and 6-month follow-up. Secondary outcomes were improvements in triglycerides, abdominal obesity, hypertension status, HDL cholesterol, and glucose levels. The University of Pittsburgh Institutional Review Board approved the study protocols, and all participants provided informed consent.

Analyses

Analyses and results presented in this report will focus on short-term (3- and 6-month) outcomes of the GLB intervention. A future report will examine long-term (≥18 months) outcomes. All analyses were conducted at the individual level. Analyses were not "intent to treat," since the study design was a nonrandomized intervention study. However, a last-response-carried-forward imputation was conducted to estimate the impact of attrition on the results. Six-month follow-up data were imputed for 19 individuals. Measures of central tendency (e.g., proportions, means, SDs, medians, etc.) were used for all descriptive analyses. Student's *t* tests and Pearson χ^2 tests were used to determine differences between the GLB intervention population ($n = 88$) and the screening population ($n = 573$). McNemar's test for discrete data were used to determine differences between baseline and 3- and 6-month reassessment in the intervention population. A χ^2 test for trend was used to determine unadjusted trends over time. To adjust for the effect of possible confounders and to examine the data in a continuous manner to allow for improvements to be observed even if metabolic syndrome criteria were not met, mixed modeling, using individual growth curve analysis, was used. Age centered at a mean age of 54.0 years, sex, race, mean number of intervention classes attended, and time were forced into all models. P values <0.1 were used to determine trends in the data. $P < 0.05$ were considered statistically significant. All analyses were conducted using SAS version 8.2 (SAS Institute, Cary, NC).

RESULTS — Baseline population characteristics of the 88 subjects who took part in the GLB intervention are presented in Table 1. The majority of subjects were female (84.1%), non-Hispanic white (72.7%), and an average of 54 years old. Approximately three-fourths of the population had at least a high school education (77.4%) and a family history of diabetes (71.1%). Nearly 60% of the study households had an annual income below 200% of the poverty level (<$41,300 for a family of four). Sixty-nine percent of subjects attended at least 75% of GLB classes. When comparing the GLB intervention population to the overall screening population to determine generalizability, no statistically significant differences were apparent (age: GLB [54.0 ± 10.5 years] vs. screening [53.7 ± 15.6], $P = 0.86$; sex: GLB [% female: 84.1] vs. screening [75.2], $P = 0.07$; race: GLB [% non-Hispanic white: 72.7] vs. screening [72.3], $P = 0.93$).

Table 1 also depicts the proportion of GLB subjects with each component of metabolic syndrome at baseline. Abdominal obesity was the most prevalent (93.2%), followed by abnormal HDL cholesterol (84.1%), hypertension (68.2%),

Table 2—*Change in the proportion of subjects meeting the criteria for components of the metabolic syndrome over time after the GLB intervention (baseline, 3-month, and 6-month reassessment)*

	Baseline	3-month reassessment	6-month reassessment	Unadjusted *P* for trend	Adjusted *P**
Abdominal obesity (≥102 cm in males, ≥88 cm in females)	90.0 (45)	82.0 (41)	68.0 (34)	0.006	0.009
Abnormal HDL cholesterol (<40 mg/dl in males, <50 mg/dl in females)	86.0 (43)	87.8 (43)	65.3 (32)	0.001	0.63
Hypertension (blood pressure ≥130/85 mmHg)	68.0 (34)	58.0 (29)	48.0 (24)	0.04	0.04
Triglycerides ≥150 mg/dl (% yes)	58.0 (29)	32.7 (16)	36.7 (18)	0.006	0.6
Glucose ≥100 mg/dl (% yes)	42.0 (21)	51.0 (25)	61.2 (30)	0.06	0.01

*Data presented are % (*n*) unless otherwise indicated. *n* = 50. All analyses are adjusted for age, sex, race, mean number of GLB classes attended, and time.

high triglyceride levels (47.7%), and increased glucose (40.9%).

Analysis of a 5% and 7% weight reduction was conducted on the 69 subjects who provided data at 3 months. In subjects who provided data at this time, 46.4% (32) lost at least 5% of their body weight, whereas 26.1% (18) lost at least 7%. A total of 87.5% (28) and 66.7% (12) of these subjects sustained the 5% and 7% reduction, respectively, at the 6-month reassessment. When improvement in metabolic syndrome components was examined, similar patterns were observed. Over one-third of the population (43.5%, *n* = 30) experienced improvements in one or more component of metabolic syndrome at 3 months, and 73.3% (22) of these subjects sustained this improvement at 6 months.

When change in the proportion of subjects who met individual metabolic syndrome criteria was examined over time, significant trends were observed (Table 2). Most notably, the proportion of subjects with abdominal obesity decreased significantly over time (baseline: 90% [45]; 3 months: 82% [41]; 6 months: 68% [34]; *P* for trend = 0.006). This significant reduction remained despite adjustment for age, sex, race, and the number of intervention classes attended (adjusted *P* = 0.009). A similar pattern was observed for subjects with hypertension (baseline: 68% [34]; 3 months: 58% [29]; 6 months: 48% [24]; *P* for trend = 0.04, adjusted *P* = 0.04). The proportion of subjects with triglyceride levels ≥150 mg/dl (baseline: 58% [29]; 3 months: 32.7% [16]; 6 months: 36.7% [18]; *P* for trend = 0.006, adjusted *P* = 0.6) and abnormal HDL cholesterol levels also improved over time (baseline: 86% [43]; 3 months: 87.8% [43]; 6 months: 65.3% [32], *P* for trend = 0.001, adjusted *P* = 0.63); however, after adjustment for age, sex, race, and class attendance, these significant associations were attenuated. In contrast to the other components of metabolic syndrome, the proportion of subjects with glucose ≥100 mg/dl increased over time (baseline: 42% [21]; 3 months: 51% [25]; 6 months: 61.2% [30], *P* for trend = 0.06, adjusted *P* = 0.01) (Table 2). Imputation analyses revealed the same pattern of significant results.

CONCLUSIONS — There are two principle findings from this nonrandomized prospective intervention study. Nearly half of subjects (*n* = 32) who participated in a 12-week GLB intervention lost at least 5% of their body weight, and ~1/3 (*n* = 18) lost at least 7%. A total of 87.5% (*n* = 28) and 66.7% (*n* = 12) of subjects sustained the 5% and 7% reductions, respectively, at the 6-month reassessment. Similar patterns were observed for improvements in metabolic syndrome parameters with over one-third (*n* = 30) of the population experiencing improvements in one or more component of metabolic syndrome, and 73.3% (*n* = 22) of subjects sustained this improvement at the 6-month reassessment. Additionally, significant improvements occurred in waist circumference, blood pressure, triglycerides, and HDL cholesterol levels.

To our knowledge, this is one of few reports to demonstrate the feasibility and effectiveness of translating the national DPP into an urban medically underserved community. Moreover, it is one of very few that demonstrated sustained weight loss and metabolic syndrome risk reduction in a community setting. Numerous studies reported initial weight loss and reduction in metabolic syndrome risk parameters immediately after a lifestyle intervention; however, they did not support the maintenance of health outcomes (11–13).

Translating the national DPP into the targeted community required an adaptation of the original DPP methodologies to better suit diverse populations, resources, and selected nonclinical screening sites. Our study used the presence of overweight (BMI ≥25 kg/m^2) and metabolic syndrome as a practical relatively low-cost proxy for determining type 2 diabetes and CVD risk and intervention eligibility in place of the oral glucose tolerance test (14–17). Fasting blood work was required, along with anthropometric measurements. Indeed, many programs avoid fasting blood work when recruiting for diabetes prevention programs and instead use anthropometric measurements, diabetes risk questionnaires, and knowledge and behavior surveys to determine diabetes and/or CVD risk (18–20). Measuring BMI and laboratory data enabled us to assess whether our intervention was indeed effective in reducing risk for type 2 diabetes and CVD among participants.

Another example of adapting the national DPP to the community setting is the use of LHCs in our study. The LHCs were members of the study community and fostered a comfortable and familiar atmosphere for participants. LHCs scheduled follow-up visits, encouraged participation, and provided any missed information. This may have contributed to high class attendance, since 77% of subjects completed the program. These completion and attendance rates compare positively to other community-based programs (11,20,21).

Sustainable weight loss is often the goal for interventions aimed at preventing or delaying type 2 diabetes and CVD (5,7,18,21). The weight loss goal in the national DPP was 7%; however, other studies have found a 5% loss to be clinically significant (11,20). Of those who lost at least 5% of their body weight at 3 months, a greater proportion was able to sustain this improvement than those who lost at least 7% of their body weight.

Lack of accuracy in self-reporting of food consumption and physical activity is commonly documented in weight loss studies (22). This study goes without exception. There was an overall resistance toward self-reporting both food consumption and activity levels. Calories and fat grams were often inaccurately documented, and portion sizes were usually not recorded. A similar pattern occurred when reporting minutes of activity. Although pedometers were introduced to help track daily activity, there was reluctance in using them. Common barriers included inaccuracy or inconvenience. Given these issues, these data were not considered. Nonetheless, participants verbally indicated minimal success achieving the physical activity goal of 150 min per week. Perhaps a method to obtain activity measures could include tracking the frequency of gym visits. Although it should be noted, despite the free YMCA membership, only 55 of the 88 participants obtained their membership. Reasons for not using the YMCA included perceived lack of time, distance, and apprehension toward a facility atmosphere.

Although food intake and physical activity data were not captured, subjects experienced improvements in weight and most parameters of metabolic syndrome after the intervention. Unexpectedly, the percentage of subjects with a glucose level ≥100 mg/dl rose at both the 3- and 6-month reassessments. Physical inactivity may explain this finding, since activity aids in the regulation of blood glucose in people without diabetes regardless of body mass (23). Improvement in blood glucose may be seen with further weight loss and increases in physical activity.

In conducting translational research, circumstances and environments are not "controllable," like efficacy-based research; therefore, limitations exist. For example, all subjects were volunteers able to attend morning screenings. This inherently introduced volunteer bias, since only those available in the morning could participate, and may have contributed to the small sample size of the cohort. Additionally, as with most community studies, males were underrepresented with 26% participation. Efforts to recruit more men may include the use of male LHCs and targeting traditional male professions. Modified strategies to avoid fasting blood work may enhance recruitment of both male and females in need of more flexible screening schedules.

Our study was underpowered to detect significant differences in the primary and secondary outcomes due to the small sample size. Initial sample size calculations estimated that 190 subjects would provide sufficient power to demonstrate valid changes in the proportion of subjects who decrease at least one parameter of metabolic syndrome. Therefore, it is possible these findings are subject to type II error where we failed to detect a difference when one truly existed. Thus, if there were improvements, we were unable to detect them. However, those findings that showed statistically significant differences represent true differences. As attrition may be perceived as a major limitation in our data, we performed last-response-carried-forward imputations for the 19 individuals who did provide 6-month follow-up data. The results remained unchanged with the same significant pattern as was seen in the non-imputed analyses. While imputation analyses allow adjustment for attrition, it must be noted that they provide an overestimation of the intervention effect.

These preliminary results suggest that adults in an urban medically underserved community can decrease their risk for type 2 diabetes and CVD through participation in a GLB intervention, and short-term sustainability is feasible. As a result, a local insurer became interested in this initiative. Discussions are underway for making primary prevention a billable and reimbursable service in the Pittsburgh area. Future analysis will include long-term follow-up of these subjects.

Acknowledgments— This research was sponsored by funding from the U.S. Air Force, administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, MD (award number W81XWH-04-2-003). Review of material does not imply Department of the Air Force endorsement of factual accuracy or opinion.

We acknowledge Rhonda Lee and Helen Tomasic for their efforts on this project. Additionally, we thank University of Pittsburgh Medical Center Braddock for their continued support throughout this effort. We also thank the YMCA of Greater Pittsburgh.

These data were presented in abstract format at the 2007 CDC Division of Diabetes Translation annual conference.

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