A Randomized Controlled Trial of Resistance Exercise Training to Improve Glycemic Control in Older Adults With Type 2 Diabetes

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OBJECTIVE — To determine the efficacy of high-intensity progressive resistance training (PRT) on glycemic control in older adults with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We performed a 16-week randomized controlled trial in 62 Latino older adults (40 women and 22 men; mean ± SE age 66 ± 8 years) with type 2 diabetes randomly assigned to supervised PRT or a control group. Glycemic control, metabolic syndrome abnormalities, body composition, and muscle glycogen stores were determined before and after the intervention.

RESULTS — Sixteen weeks of PRT (three times per week) resulted in reduced plasma glycosylated hemoglobin levels (from 8.7 ± 0.3 to 7.6 ± 0.2%), increased muscle glycogen stores (from 60.3 ± 3.9 to 79.1 ± 5.0 mmol glucose/kg muscle), and reduced the dose of prescribed diabetes medication in 72% of exercisers compared with the control group, $P = 0.004–0.05$. Control subjects showed no change in glycosylated hemoglobin, a reduction in muscle glycogen (from 61.4 ± 7.7 to 47.2 ± 6.7 mmol glucose/kg muscle), and a 42% increase in diabetes medications. PRT subjects versus control subjects also increased lean mass (+1.2 ± 0.2 vs. −0.1 ± 0.1 kg), reduced systolic blood pressure (–9.7 ± 1.6 vs. +7.7 ± 1.9 mmHg), and decreased trunk fat mass (−0.7 ± 0.1 vs. +0.8 ± 0.1 kg; $P = 0.01–0.05$).

CONCLUSIONS — PRT as an adjunct to standard of care is feasible and effective in improving glycemic control and some of the abnormalities associated with the metabolic syndrome among high-risk older adults with type 2 diabetes.

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More than 18% of the U.S. population 65 years of age and older have diabetes (1). According to the Third National Health and Nutrition Examination Survey (NHANES III), diabetes is becoming increasingly prevalent and undertreated in elderly people (2,3). Among Latinos, diabetes prevalence is double that of Caucasians (2). This is a concern given the disparate access and substandard health care among minorities (4), the rapid growth of the U.S. Latino population (5), and the economic cost and mortality associated with diabetes (6).

Epidemiological and intervention studies of endurance exercise training strongly support its efficacy for diabetes prevention and management (7). In contrast, research on the effects of resistance exercise on diabetes management is sparse. The resistance training modality used in some of these studies has been based on moderate-intensity and high-volume exercises (8–13). This type of exercise could have a significant aerobic component, which sedentary older adults may find difficult to tolerate. In contrast, high-intensity, low-volume resistance training may be a more tolerable exercise modality that additionally may increase muscle mass (14) and glucose uptake (15). Therefore, the purpose of this study was to determine the ability of high-intensity, low-volume progressive resistance training (PRT) to improve glycemic control and other metabolic abnormalities in a population of Latino older adults with poor glycemic control and no personal history of regular exercise.

RESEARCH DESIGN AND METHODS

Study population

A total of 62 community-dwelling Latino men and women >55 years of age with type 2 diabetes of at least 3 years' duration were randomized to 16 weeks of standard care (control group) or standard care plus PRT. The study took place in the General Clinic Research Center at New England Medical Center and the Jean Mayer USDA Human Nutrition Research Center on Aging (HNRCA) at Tufts University. Screening procedures included confirmation of diabetes diagnosis by a fasting plasma glucose ≥7.0 mmol/l or use of diabetic medications (16), physical examination, blood pressure, electrocardiogram, as well as blood hematology and chemistry. Exclusion criteria included myocardial infarction (within past 6 months) and any unstable chronic condition, including dementia, alcoholism, dialysis, retinal hem-

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Abbreviations: 1RM, one-repetition maximum testing; CV, coefficient of variation; HNRCA, Human Nutrition Research Center on Aging; NHANES, the Third National Health and Nutrition Examination Survey; PASE, Physical Activity Scale for the Elderly; PRT, progressive resistance training.

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

orrhage or detachment, or current participation in resistance training. Eligible subjects gave written informed consent in Spanish approved by the Human Investigation Review Committee at Tufts University.

Intervention

PRT group. Subjects exercised at the HNRCA three times per week. Each supervised session lasted ~45 min and included a 5-min warm-up (six chair stands and a 1-min brisk walk around the exercise facility), 35 min PRT using five pneumatic resistance training machines (chest and leg press, upper back, knee extension, and flexion; Keiser Sports Health Equipment, Fresno, CA), and a 5-min cool-down (flexibility and stretching exercises). Subjects performed three sets of eight repetitions on each machine per session. The PRT protocol was designed to provide progressive increases in intensity with periodic weeks of reduced intensity (~10% lower than current workload) during weeks 9 and 15, to minimize risk of injury and over-training (17) and to optimize results during midstudy and the final one-repetition maximum testing (1RM). Training intensities during weeks 1–8 were 60–80% of baseline 1RM, whereas intensities during weeks 10–14 were 70–80% of midstudy 1RM.

Postprandial blood glucose was monitored before and after exercise using a One Touch Glucometer (Lifescan, Johnson & Johnson, Milpitas, CA) (18). If blood glucose before exercise was <5.5 mmol/l in subjects receiving insulin or <6.6 mmol/l in non–insulin users, a snack with 25 g carbohydrate and 7 g protein was provided. Glucose monitoring log sheets were provided to subjects' primary care physicians for follow-up care. Subjects were advised regarding timing of diabetes medications and hypoglycemic signs and symptoms.

Control group. Control subjects received phone calls every other week and came to the HNRCA for testing during baseline and mid- and poststudy.

All study subjects continued their usual medical care, received Spanish-translated diabetes recommendations for self-management (19), and were not given dietary counseling other than to follow recommendations given by their health providers. Both groups were administered a weekly symptom checklist to document blood glucose self-monitoring, diabetes control, medical visits, medication changes, acute illness, and hospitalizations.

Outcome measures

Baseline measures were taken before randomization. Biochemical measurements were collected in a fasting state. Poststudy measures were carried out in a blinded fashion with the exception of muscle strength.

Glycemic and metabolic control. Plasma glycosylated hemoglobin concentration was the main outcome for gylcemic control followed by muscle glycogen stores. Glycosylated hemoglobin was analyzed using the GlycTest II assay (Pierce Chemical, Rockford, IL) with a coefficient of variation (CV) of 2%. Muscle glycogen stores were determined by hexokinase enzymatic and spectrophotometric analyses (Sigma Diagnostics, St. Louis, MO) with a CV of 5% (20). Muscle specimens were obtained in the nondominant vastus lateralis by percutaneous needle biopsy using a 5-mm Bergstrom needle (21) at baseline and 48 h after final strength testing.

Plasma glucose was determined by the hexokinase enzymatic method (Sigma Diagnostics). Serum cholesterol and triglycerides levels were measured by enzymatic assay in a Cobas Mira Analyzer (Roche Diagnostics Systems, Montclair, NJ) with a CV of 10%. Subjects' diabetic medication doses were recorded on the symptom checklist, and any changes made by their primary care physicians were recorded and confirmed by comparing the reported changes to the medication bottles and/or by direct communication with physicians.

Body composition. Body weight and height were measured to the nearest 0.1 kg and height to the nearest 0.25 cm, respectively. BMI was determined by body weight and height as kilograms per meters squared. Whole-body and regional lean and fat mass were determined by dual-X ray absorptiometry using a Hologic QDR2000 (Waltham, MA) scanner operating in array mode with software version 5.64A and a CV of 1.4 and 1.8% for total lean and fat mass, respectively (22). This method has been validated against multicompartment methods and compared with in vivo neutron inelastic scattering (23,24). Waist circumference was determined by standard technique (25).

Physical activity. Self-reported leisure and household activities in the previous 7 days were determined using the Physical Activity Scale for the Elderly (PASE, 10 items, score 0–400, higher scores reflect greater levels of physical activity). PRT was not included in the analysis. Construct validity was established by correlating PASE scores with resting heart rate ($r = -0.13$), grip strength ($r = 0.37$), static balance ($r = 0.33$), and the Sickness Impact Profile score ($r = -0.42$; $P < 0.05$) (26).

Muscle strength. 1RM was assessed twice on each machine at baseline (before randomization) and once during mid- (week 9) and poststudy (week 16). The highest of the two baseline 1RM values was used to set initial training loads and for analyses. Baseline and final muscle strength was calculated as the sum of 1RM measures for all machines used for training.

Dietary intake

Total energy and macronutrient intakes were assessed by a food frequency questionnaire adapted to the Latino population (27).

Statistical analysis

Statistical analysis was based on an intent-to-treat approach using SPSS 10.0 for Windows (SPSS, Evanston, IL). Results were considered statistically significant if the two-tailed P value was <0.05. Data are shown as mean and standard error (SE), except for non-normally distributed variables (serum triglycerides) for which group median and ranges are shown. The non-normally distributed variables were log-transformed, checked for normality after log transformation, and used as continuous log-transformed variables for analyses. Baseline comparisons were assessed by independent sample t test or χ^2 as appropriate. To test the significance of resistance training in predicting the study outcomes, ANCOVA of the absolute change (week 16 − week 0) in glycemic, metabolic, and physiological variables were carried out after adjusting for insulin use (the only variable different between groups at baseline), years of diabetes, sex, change in physical activity, and change in diabetes medication regimens. Group differences in the proportion of change in diabetic medication regimens were assessed by the χ^2 test.

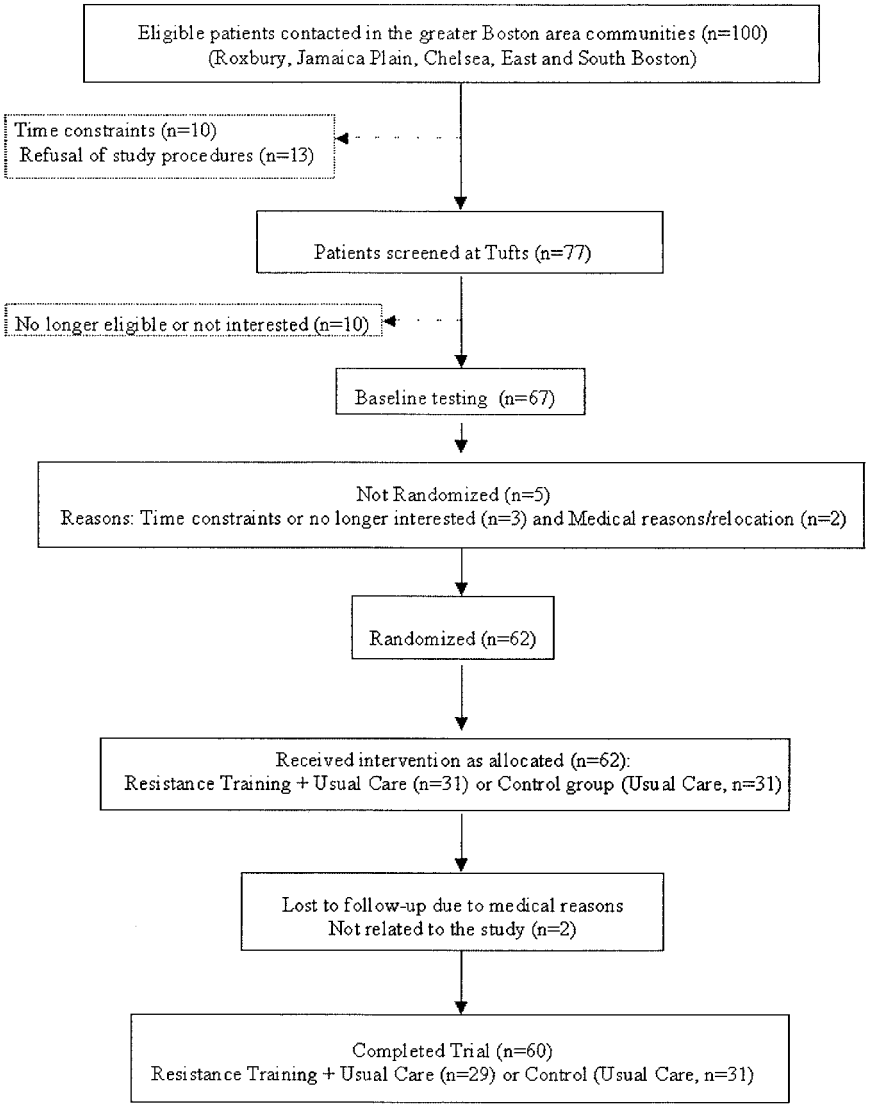

Figure 1—*Flow chart of subjects' enrollment.*

RESULTS

Subject characteristics

Sixty-two subjects were randomized and all but two completed the study (Fig. 1). The only difference between groups at baseline was that there was a higher proportion of prescribed insulin among control subjects (Table 1).

Compliance and adverse events

Compliance to PRT was 90 ± 10%. No exercise-related injuries were reported. Five hypoglycemic events were observed immediately postexercise, which resolved with administration of high-sugar snacks. Exercisers did not report hypoglycemia at home or during nontraining days. In contrast, subjects in the control group reported seven hypoglycemic events. Three incidents of chest pain were observed during training in subjects with coronary artery disease. Two subjects did not require treatment and were not precluded from continuing the exercise program. The other subject was taken to the emergency room and hospitalized for a week, during which myocardial infarction was ruled out. She resumed resistance training after 3 weeks as approved by her physician and had no further problems.

Glycemic and metabolic outcomes

As shown in Table 2, subjects in the PRT group, compared with control subjects, significantly improved plasma glycosylated hemoglobin levels (−12.6 ± 2 vs. +1.2 ± 1%, $P = 0.01$) and muscle glycogen stores (+31 ± 7 vs. −23 ± 6%, $P = 0.04$) after adjusting for insulin use, years of diabetes, sex, and the changes in physical activity and diabetes medications described below.

Fasting plasma glucose did not change between groups (Table 2). Diabetic medication regimens were reduced in 22 of the 31 (72%) subjects in the PRT group. The number of subjects per medication class who had a reduction in dose was as follows: 13 sulfonylureas, 7 biguanides, and 2 insulin. In addition, 21% of exercisers had no change, and 7% had an increase in diabetes medication doses. In contrast, subjects in the control group showed the opposite trend, with 13 of 31 (42%) subjects increasing and 3% decreasing the prescribed medications. For these, the number of subjects per given medication class were six for biguanides, four for sulfonylureas, and three for insulin, reflecting the worsening of glycemic control observed during the study period. These changes in medications were different between groups ($P = 0.03$). In all cases the subjects' primary care physicians carried out the modifications in prescribed diabetes medications.

Total, HDL, and LDL cholesterol levels did not change between groups (Table 2). There was a trend toward a reduction in serum triglyceride levels with PRT compared with control subjects ($P = 0.08$, Table 2). Finally, systolic blood pressure was significantly lowered in exercisers compared with control subjects ($P = 0.05$, Table 2).

Physiological outcomes

Body weight remained stable in both groups (Table 3). There was a mean gain in whole-body lean tissue mass of 1.2 kg with PRT compared with control subjects ($P = 0.04$). Similarly, regional lean tissue mass tended to increase with exercise ($P = 0.08$ for arms and trunk, $P = 0.07$ for the legs). Total, arm, and leg fat mass did not change between groups. Trunk fat mass was reduced by 0.7 kg with PRT compared with control subjects ($P = 0.01$). In the PRT group, the change in glycosylated hemoglobin correlated with the changes in lean tissue mass ($r = −0.35$, $P = 0.03$) and trunk fat ($r = 0.30$, $P = 0.02$).

Self-reported leisure and household physical activities outside of the PRT ses-

Table 1—*Baseline subject characteristics*

	PRT group	Control group
n	31	31
Age (years)	66 ± 2	66 ± 1
Sex (female/male)	21/10	19/12
BMI (kg/m^2)	30.9 ± 1.1	31.2 ± 1.0
Hispanic descent (%)		
Caribbean (Puerto Rico, Dominican, or Cuban)	90	84
Central American and Panamanian	7	10
South American	3	6
Education (years)	7 ± 1	6 ± 1
Diabetes duration (years)	8 ± 1	11 ± 1
Glycosylated hemoglobin (%)	8.7 ± 0.3	8.4 ± 0.3
Taking diabetes medication		
Insulin use	17 (5)	48 (15)*
Insulin dose prescription (Units)	78 ± 23	72 ± 10
Oral hypoglycemic use†		
Sulfonylureas	61 (19)	52 (16)
Biguanides	34 (10)	52 (15)
Troglitazone	10 (3)	10 (3)
Nonpharmacological diabetes treatment	10 (3)	4 (1)
Cholesterol-lowering medication	48 (14)	38 (11)
Blood pressure medications	83 (24)	79 (23)
Total number of medications	3.9 ± 0.3	3.1 ± 0.4
Hypertension ≥130/85 mmHg	48 (14)	69 (20)
Cardiovascular disease‡	55 (17)	64 (20)
Number of chronic conditions§	2.5 ± 0.2	2.9 ± 0.4
Current smoker	0 (0)	7 (2)

Data are means ± SE and % (*n*). *$P = 0.05$, different by group. Baseline comparisons between groups were assessed using independent sample *t* test comparisons for continuous and log-transformed variables, and χ^2 for categorical variables; †sulfonylureas: glyburide and glipizide; biguanides: metformin; troglitazone: Rezulin; ‡determined by history of coronary artery disease, stroke, or myocardial infarction or current use of medications to treat any of these conditions; §determined by self-report via health questionnaire and during physical examination.

sions increased among exercisers compared with control subjects ($P = 0.001$, Table 3). Mean physical activity was very low at baseline (113 kcal expended per week [23 min]) and rose (300 kcal expended per week [120 min]) after 16 weeks. Subjects in the PRT group were transported back and forth to the HNRCA by taxi to minimize increased physical activity associated with traveling.

Muscle strength

Mean training intensity was 70.2 ± 1.3% of 1RM (range 66–75%). Exercisers gained 33 ± 7% in whole-body muscle strength (from 389 ± 30 to 518 ± 48 kg) compared with a 15 ± 3% loss (351 ± 31 to 299 ± 30 kg) in control subjects ($P = 0.0001$). The change in glycosylated hemoglobin correlated with the change in muscle strength ($r = -0.45$, $P = 0.01$) with PRT.

Dietary intake

Dietary intake did not change as a result of the intervention. Energy intake was comparable in the PRT and control groups before (77.6 ± 4.9 vs. 83.9 ± 6.2 MJ · kg^{-1} · day^{-1}) and after the intervention (64.8 ± 4.0 vs. 75.3 ± 6.5 MJ · kg^{-1} · day^{-1}). There were no changes in the macronutrient composition within or between groups. Carbohydrate contributed ~50%, protein 18%, total fat 30%, and saturated fat 10% of total energy intake in both groups.

CONCLUSIONS — This study demonstrates for the first time that high-intensity PRT is effective in the management of diabetes in this high-risk population of Latino older adults with poor glycemic control. Resistance training significantly improved glycemic control, increased fat-free mass, reduced the requirement for diabetes medications, reduced abdominal adiposity and systolic blood pressure, and increased muscle strength and spontaneous physical activity.

At baseline, study subjects had poor glycemic control as shown by glycosylated hemoglobin concentrations at ~8.5%, similar to those reported among individuals with diabetes in the NHANES III study (2). Optimal glycemic control is difficult to achieve unless intensive pharmacological treatment is instituted (28, 29). In the present study, the proportion of subjects in the control group taking insulin was significantly higher than that of the exercise group. The improvement in glycemic control with resistance training, however, was independent of insulin use, years of diabetes, the change in diabetes medications, and the change in spontaneous physical activity. This suggests that resistance training may be beneficial as an adjunct to standard care in this patient population. This is particularly important in the case of individuals who may be noncompliant with medical recommendations (i.e., diabetes self-management and medications), and may receive substandard health care (4).

Subjects undergoing resistance training improved many of the abnormalities associated with the metabolic syndrome: namely glucose intolerance, hyperinsulinemia, abdominal adiposity, hypertension, and hypertriglyceridemia. Given the increased prevalence of the metabolic syndrome in the U.S. population over 60 years of age (30), an intervention that has the potential to improve metabolic syndrome abnormalities is promising, particularly among older individuals with undiagnosed diabetes who are more likely to have hypertension, obesity, and abdominal obesity than those without diabetes (31). Although we did not measure insulin sensitivity directly, others have shown improved insulin action with resistance training (32). The inverse associations between the change in glycosylated hemoglobin and lean mass or strength among exercisers suggests that resistance training reduces hyperglycemia by eliciting glucose uptake at the cellular level, in skeletal muscle, where the largest proportion of glucose uptake takes place (15). Our finding of an absolute mean reduction in glycosylated hemoglobin of 1.2% is twice that seen previously in diabetic subjects in response to moderately intense resistance training (9–11), suggest-

Table 2—*Biochemical and clinical parameters*

Dependent variable	PRT group	Control group	*P**
n	31	31	
Plasma glycosylated hemoglobin concentrations (%)			
Baseline	8.7 ± 0.3	8.4 ± 0.3	
Final	7.6 ± 0.2	8.3 ± 0.5	0.01
Muscle glycogen stores (mmol glucose/kg muscle) †			
Baseline	60.3 ± 3.9	61.4 ± 7.7	
Final	79.1 ± 5.0	47.2 ± 6.7	0.04
Fasting plasma glucose concentrations (mmol/l)			
Baseline	8.8 ± 0.5	9.7 ± 0.7	
Final	7.9 ± 0.4	8.9 ± 0.7	0.34
Serum triglyceride concentrations (mmol/l)			
Baseline (median)	1.52	1.45	
Range	(0.56–6.60)	(0.35–5.27)	
Final (median)	1.31	1.56	0.08
Range	(0.43–3.59)	(0.32–4.77)	
Total cholesterol concentrations (mmol/l)			
Baseline	4.97 ± 0.18	4.73 ± 0.18	
Final	4.81 ± 0.16	4.70 ± 0.18	0.59
HDL cholesterol concentrations (mmol/l)			
Baseline	1.18 ± 0.05	1.23 ± 0.07	
Final	1.25 ± 0.06	1.24 ± 0.07	0.46
LDL cholesterol concentrations (mmol/l)			
Baseline	2.94 ± 0.18	2.71 ± 0.15	
Final	2.70 ± 0.13	3.05 ± 0.15	0.13
Systolic blood pressure (mmHg)			
Baseline	145.2 ± 3.6	142.7 ± 4.1	
Final	135.5 ± 3.3	150.4 ± 3.9	0.05
Diastolic blood pressure (mmHg)			
Baseline	72.6 ± 1.1	71.1 ± 2.1	
Final	69.2 ± 1.2	70.8 ± 1.4	0.52
Heart rate (beats/min)			
Baseline	71 ± 3	72 ± 2	
Final	72 ± 1	71 ± 3	0.74

Data are means ± SE. *ANCOVA with the absolute change on each dependent variable (week 16 − week 0) adjusted for insulin use, years of diabetes, sex, and the changes in physical activity and in diabetes medication regimens; †10 subjects refused to have a muscle biopsy done—completed data are available for 26 exercisers and 24 control subjects.

ing that high-intensity resistance training may induce a stronger stimulus for glucose uptake. More research is needed to assess PRT alone or in combination with lifestyle interventions targeting diet and physical activity, such as that reported by Tuomilehto et al. (13). Although available evidence indicates that the effects of resistance exercise on glucose homeostasis and insulin action may be similar to those observed with endurance exercise (33), the fact that resistance training increases muscle mass suggests that the combination of the two exercise modalities may be additive.

There are some limitations to the present study. First, by design, control subjects received standard care only, and thus did not received the same contact time as exercisers. The statistically significant improvements in the biochemical and physiological parameters observed with resistance training against the worsening of parameters found among control subjects suggest that, for standard care, optimal glycemic control is difficult to achieve unless intensive pharmacological treatment is instituted (28,29). Second, we observed five hypoglycemic events in exercisers. While this number of events sounds high, it is similar to those reported with any other exercise intervention or with intensive pharmacological treatment (28,29). Third, although uncomplicated, the chest pain events observed during training underline the importance of adequate medical screening, exercise prescription, and supervision before the initiation of an exercise program. Fourth, we cannot make any inferences of the safety of high-intensity resistance training in regard to retinopathy status, as we did not measure this. Lastly, there may be a confounding effect of the changes observed in diabetes medication regimens and spontaneous physical activity. However, our results demonstrate that the improvement in glycemic and metabolic control was independent of these changes. The increase in physical activity observed among exercisers without any verbal encouragement was an added benefit of resistance training that has been shown in other populations as well (34–36). By the end of the study subjects in the PRT group were closer to meeting the Surgeon General's recommendations for physical activity (37). The potential for reducing diabetes medications by patients adopting a more physically active lifestyle is promising and deserves further investigation. A recently published study from the Diabetes Prevention Program does show that a lifestyle intervention aimed at reducing body weight and increasing habitual physical activity was more effective in delaying or preventing type 2 diabetes than the use of metformin alone in individuals at high risk for the disease (38).

In conclusion, appropriately prescribed and supervised high-intensity resistance training proved both feasible and effective among high-risk older adults with type 2 diabetes, resulting in improved gylcemic and metabolic control. More research is needed to determine the optimal intensity of resistance training resulting in maximal benefits while ensuring safety. Given the epidemic of diabetes in recent years, resistance training may be useful as an adjunct to standard medical care in the management of patients with diabetes.

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Any opinions, findings, conclusions, or rec-

Table 3—*Body composition and physical activity parameters*

Dependent variable	PRT group	Control group	*P**
n	31	31	
Body weight (kg)			
Baseline	79.3 ± 3.2	78.6 ± 3.1	
Final	79.5 ± 3.3	79.4 ± 2.9	0.89
Whole-body lean tissue mass (kg)			
Baseline	44.3 ± 1.7	44.9 ± 1.9	
Final	45.5 ± 1.9	44.8 ± 1.7	0.04
Arm lean tissue mass (kg)			
Baseline	4.0 ± 0.2	4.1 ± 0.2	
Final	4.4 ± 0.3	4.1 ± 0.2	0.08
Trunk lean tissue mass (kg)			
Baseline	21.9 ± 0.8	22.3 ± 0.9	
Final	22.4 ± 0.8	22.5 ± 0.9	0.08
Leg lean tissue mass (kg)			
Baseline	12.9 ± 0.6	12.7 ± 0.6	
Final	13.1 ± 0.6	12.8 ± 0.5	0.07
Whole-body fat mass (kg)			
Baseline	35.0 ± 2.2	33.7 ± 2.4	
Final	34.0 ± 2.3	34.6 ± 2.2	0.26
Arm fat mass (kg)			
Baseline	4.6 ± 0.4	4.5 ± 0.4	
Final	4.7 ± 0.4	4.6 ± 0.3	0.69
Trunk fat mass (kg)			
Baseline	18.8 ± 1.1	18.2 ± 1.3	
Final	18.1 ± 1.2	19.0 ± 1.1	0.01
Leg fat mass (kg)			
Baseline	10.6 ± 0.8	9.4 ± 0.7	
Final	10.6 ± 0.9	9.4 ± 0.7	0.41
Waist circumference (cm)			
Baseline	99.7 ± 2.3	100.1 ± 2.6	
Final	97.5 ± 2.3	102.0 ± 2.2	0.07
Leisure physical activity score			
Baseline	8.4 ± 1.9	12.8 ± 2.9	
Final	28.3 ± 0.9	7.2 ± 2.8	0.001
Household physical activity score			
Baseline	37.2 ± 4.8	32.4 ± 4.5	
Final	56.6 ± 5.8	26.2 ± 4.1	0.001

Data are means ± SE. Fat-free mass and total and trunk fat mass were determined by dual X-ray absorptiometry. Self-report past 7-day physical activity was assessed using PASE. *ANCOVA with the absolute change on each dependent variable (week 16 − week 0) adjusted for insulin use, years of diabetes, sex, and the changes in physical activity and in diabetes medication regimens. For physical activity the same covariates were used except for the change in physical activity.

ommendations expressed in this publication are those of the author(s) and do not necessarily represent the views of the U.S. Department of Agriculture or any of the funding sources. The results of this study have been presented in part at the American Diabetes Association annual meeting in Philadelphia in June 2001.

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