

Effect of a One Year Walking Program on Overweight Patients with Type 2 Diabetes Mellitus

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A. Introduction

The health, benefits of physical activity have been supported in many are studies. Regular exercise has been shown to be associated with a decrease in all cause mortality, weight loss, improved lipid profiles, decreased incidence and improved. glycemic control of Type 2 diabetes mellitus, decreased risk of coronary artery disease, reduction in blood pressure and improvement of symptom & of major depression. Despite this information the majority of the United States population is not physically active. A study done in 1997 found that only 15% of Americans performed the recommended amount of physical activity and 40% engaged in no leisure time activity at all.

America's inactivity is a cause for national concern. The surgeon general has declared that a sedentary lifestyle is hazardous to your health while the American Heart Association has added physical activity to their list of preventable factors for coronary artery disease. Healthy people 2010, a nationwide health promotion and disease prevention agenda, lists physical activity as it's number one leading health indicator.

Although physical inactivity is a problem for all American's, certain populations have been cited as being higher risk. The Centers for Disease Control and the Presidents Council on Physical Fitness and Sports, list Hispanics, people of lower income and lower educational status and adults of Northeastern states among those with lowest rates of physical activity. In addition the rates of sedentariness increase with age. This high risk sedentary minority populations typical of the community in the Washington Heights area of New York City that is served by the outpatient clinics of New York Presbyterian Hospital Columbia Campus.

The Nurses' Health Study and the Physicians Health Study both support the role of physical activity in the primary prevention of Type 2 diabetes, however, studies on the effect of exercise on glycemic control in type 2 diabetics have had heterogeneous results. The American Diabetes Association position statement sites the results of several long term studies which demonstrate a consistent beneficial effect of regular exercise training on glucose metabolism and insulin sensitivity. Reductions in glycosylated hemoglobin (HbA_{1C}) were, generally 10-20%. Improvements of HbA_{1C} of this magnitude were reported by Schneider et al. at 3 month follow-up after initiating an aerobic exercise program. Likewise, Mourier et al. found participation in a supervised exercise program to result in significant reduction of HbA_{1C} ($8.5 \pm 0.6\%$ to $6.2 \pm 0.2\%$, $p < 0.05$). Other studies, however, have reported dissimilar results Lehmann et.al reported no change in HbA_{1C} with regular aerobic exercise (although a deterioration in glycemic control was noted in the control group. Ligtenberg et al similarly did not observe an improvement in glycemic control with regular exercise. Despite this lack of clear-cut evidence for an improvement in glycemic control, regular exercise, along with diet, remain the mainstay of first line therapy for Type 2 diabetes mellitus.

The goal of this study is to determine if program of regular aerobic exercise in a Latino population of diabetics will result in improved glycemic control as measured by glycosylated hemoglobin. Implementation of a regular outpatient exercise program is often difficult. Barriers to exercise most frequently cited include cost, lack of access to facilities, lack of a safe environment in which to be active, lack of time, limited information on importance of exercise and noncompliance with long term programs. This study hopes to overcome many of these obstacles by providing a free program in a safe environment, transportation to and from the facility, information on the benefits of exercise and the program will be observed to enhance compliance.

B. Hypothesis

Participation in a one year observed exercise program will result in improvements of glycemic control and body mass index in previously sedentary overweight type 2 diabetics.

C. Methods

The study will be an interventional prospective study. Participants meeting inclusion criteria will be randomized to one of two treatment arms. The control group will be provided information on the importance of exercise and nutrition for diabetic patients. The information will be distributed by trained exercise physiologists and nutritionists who are blinded to treatment group. The intervention group will receive the same information as the controls plus enrollment in a group exercise program. Subjects will be followed for one year. The primary outcome being studied is glycosylated hemoglobin (HbA_{1C}) levels. Secondary outcome will be body mass index (BMI) and diabetic medication regimen. All blood analyses will be measured at the onset of the study, as well as at month 3, 6, 9 and 12 (given that glycohemoglobins circulate in RBCs whose life span is up to 120 days). All diabetic medications and dosages, will be recorded at each blood draw. BMI will also be recorded at these intervals. BMI will be calculated as weight (in kilograms) divided by height (in meter) squared.

D. Exercise Program

The exercise program will consist of group "healthwalking" sessions for one hour, three times a week. Healthwalking is a faster form of walking that also includes upper body movement. The sessions will take place at the Sports and Track Arena at the 168th Street Fort Washington Armory as part of the preexisting free "Walking Works Wonders" program sponsored by the Isabella Geriatric Center. Transportation will be provided for all participants to and from the Armory. At the start and finish of each day subjects will be required to sign attendance sheets to verify attendance.

E. Statistical Analysis

The difference in the change of HbA_{1C} and BMI between groups will be analyzed for statistical significance using the t-test.

Sample size

The ADA suggests an anticipated reduction in HbA_{1C} of 1-2%. Among the group of diabetics eligible for this study (HbA_{1C} in the range of 8-12) this would roughly correspond to a 1-2 point reduction. Given the heterogeneity of prior studies, the lower value, a reduction of 1 point will be used as the anticipated effect for power calculations. A consensus in the literature on the standard deviation was not available. Therefore, an estimated standard deviation was necessary. A value of 2 (twice the anticipated effect) was used to increase the likelihood that the study will be adequately powered.

Applying these numbers to the unpaired t-test results in: n(in each arm)=65. The preexisting walking program has capacity for 150 more participants, making the total of 150 patients a feasible goal.

F. Subjects

Participants will be recruited from the New York Presbyterian Columbia Campus outpatient clinics.

a. Inclusion Criteria:

- Age 50-75
- Hispanic ethnicity
- sedentary, at baseline (not performing regular aerobic exercise)

- overweight or obese (BMI 25-37)
- type 2 diabetes mellitus with HbA_{1c} 8-12

b. Exclusion Criteria:

- Require insulin
- history of heart disease or stroke
- severe asthma or COPD any condition preventing them from participating in a low to moderate intensity exercise program.

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