

Temple University

Annual Progress Report: 2005 Nonformula Grant

Reporting Period

July 1, 2009 – May 31, 2010

Nonformula Grant Overview

Temple University received \$4,151,920 in nonformula funds for the grant award period June 1, 2006 through May 31, 2010. Accomplishments for the reporting period are described below.

Research Project: Project Title and Purpose

Treating Obesity and Its Consequences in Underserved Overweight Populations - We will investigate a cost-effective and sustainable approach to improve weight loss and insulin sensitivity among overweight and obese individuals. Based on our experience and success in telemedicine, this project will determine if a telemedicine system can help participants, who have undergone a conventional weight loss program, maintain their weight loss. Overweight and obese men and women will participate in a 16-week well-established diet and exercise weight loss program given at local churches and community centers. A one year weight loss maintenance program will follow, in which the subjects will be randomized into the “In-person” follow-up group or to a “telemedicine” group for one year. The latter will provide support through self-monitoring, education, supervised chat room, bulletin board and e-mail. We expect to see a greater reduction in weight and insulin resistance in the telemedicine group.

Duration of Project

6/1/2006 - 5/31/2010

Project Overview

Obesity has reached epidemic proportions with nearly two-thirds of the US population either overweight or obese. Ethnic minorities are disproportionately affected with 37% of African-American adults being obese. In Pennsylvania, the prevalence of obesity increased from 14.7% in 1991 to 24.0% in 2002, and annual medical expenditures attributable to obesity are estimated at \$4.2 billion; making Pennsylvania the 4th highest cost state in the country.

The goal of this project is to reduce weight and improve insulin sensitivity in overweight adults who live in medically underserved communities. Overweight and obese men and women (n=400) will participate in a 16-week behavioral weight management program that includes a low-fat diet and increased physical activity. To increase accessibility in our underserved population, the program will be given at local churches and community centers. After the 16-

week weight loss program, subjects will be randomly assigned to two different weight loss maintenance programs (In-person versus Telemedicine) for an additional one year.

Accordingly our specific aim is to compare, in 400 overweight and obese persons who have completed a 16-week behavioral weight loss program, the effects of “In-Person” contact with a supervised "Telemedicine" weight maintenance program on weight loss, body composition and insulin sensitivity (assessed by QUICKI). *Hypothesis:* We predict that those in the telemedicine group will experience greater reductions in body weight, body fat and greater improvements in insulin sensitivity than those in the in-person group. We expect these results will be due to greater changes in diet and physical activity, which will be mediated through greater participation in and adherence to treatment and telemedicine usage.

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Other Participating Researchers

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Christopher Still, DO - employed by Geisinger Medical Center
Timothy McConnell, PhD - employed by Bloomsburg University
Steven Hughes, PhD, Marilyn Guidry, MA, MPH - employed by Cheyney University
Ted Hoobler - employed by Insight Telehealth

Expected Research Outcomes and Benefits

Overall, we expect that this project will confirm the efficacy of a program that in underserved

populations can reduce the consequence of this obesity epidemic. We expect that our diet/exercise weight loss program with telemedicine maintenance will help the vast majority of participants to both lose and even more importantly maintain their weight loss. Associated with this weight reduction, we expect to see a 40% reduction in free fatty acid levels and a similar degree of improvement in insulin sensitivity.

Obesity is associated with serious health problems including type 2 diabetes, high blood pressure and elevated cholesterol levels, which are all risk factors for the development of accelerated atherosclerosis.

Modest weight loss and increases in physical activity have been demonstrated to reduce these risk factors. It has been estimated that a sustained 10% weight loss among obese individuals would reduce the expected lifetime incidence of heart disease and stroke by 12-38 cases per 1,000 and by 1-13 cases per 1,000, respectively. We expect that the majority of individuals who participate in this project will achieve and maintain a 10% weight loss and thus will experience a significant decrease in their risks for cardiovascular disease. As a result of the community involvement and training, which has been built into this project, we further expect the benefits of this program to continue to expand within the communities involved over the next several years.

Summary of Research Completed

Main Clinical Study - Phase 2 - Healthy Lifestyle Program

A goal of our project was to determine if telemedicine could be as effective as in person meetings in weight loss maintenance. After the initial weight loss Phase 1 program, the maintenance phase ran for one year. In the controls, the study participants attended 12 monthly meetings at local churches. Similar to Phase 1, these sessions were led by a group leader and co-leader who were trained in nutrition/dietetics and or other health-related field. In the telemedicine groups, the study participants received their educational material, food diaries, and SAFE form through the telemedicine website. They also monitored their weight, caloric intake, and physical activity through this telemedicine system. They sent and received messages to their group leader and other members in their group.

Table 1 compares the final values for the controls and telemedicine groups. There are no significant differences between the control and telemedicine groups at the final visit. Thus, one of the main goals of our study was confirmed that telemedicine was as effective as in-person meetings in weight loss maintenance.

At the completion of phase 2, some weight regain occurred in both groups. Most of the improvements in cardiovascular disease risk factors persist, but are no longer significantly different than baseline values. Of note, systolic blood pressure, total cholesterol, and LDL were significantly lower than baseline in the control group. Diastolic blood pressure and total cholesterol were significantly lower in the telemedicine group as compared to baseline values.

Factors Influencing Outcome

Attendance, Food Diaries, and SAFE Form

At both Geisinger and Temple, the participants were divided into 12 groups for the Phase 1 and Phase 2 programs. Weekly attendance, weights, food diary records, and SAFE form completion were recorded. The average attendance for the Geisinger groups was 79% and for the Temple groups was 72%.

We examined the impact of weekly attendance on weight loss. For every subject, their weekly attendance for the initial 12-week program was calculated as a percentage (6 meetings = 50%; 9 meetings = 75%, etc.). At each percentage attendance, the mean weight loss and standard error were calculated. Figure 1a plots this weekly attendance for the Phase 1 twelve-week program versus the final weight loss. There is a clear relationship between weekly attendance and the final weight loss. In general, those individuals who attended more sessions had a greater weight loss.

Figure 1b shows the relationship between food diary completion and weight loss. Similar to attendance, higher rates of keeping a weekly food diary were associated with larger weight loss.

Table 2 examines the impact of weekly food diaries in greater detail. Individuals with a low rate of keeping a weekly food diary (<50%) were compared with those individuals with a high rate of keeping a weekly food diary ($\geq 50\%$). At baseline, except for diastolic blood pressure (75.5 ± 9.7 in Low vs. 82.1 ± 7.4 in High) and triglycerides (89.3 ± 34.3 in Low vs. 125.7 ± 70.4 in High), there were no significant differences between the Low rate of weekly food diary group versus the High rate of weekly food diary group. At 12-weeks in the Low group, there were no significant changes in the measured parameters. In striking contrast, in the High group, almost every parameter improved; weight, waist circumference, BMI, and fat mass decreased. Systolic BP, Diastolic BP, total cholesterol, LDL, and blood glucose decreased. At the final visit in the Low group, there were no significant changes in the measured parameters, except for HDL which decreased (a negative impact). In the High group, most of the benefits were maintained at the final visit; weight, waist circumference, BMI, systolic BP, diastolic BP, total cholesterol, and LDL were significantly lower than the baseline values.

We examined whether the impact of weekly attendance, keeping food diaries, and completing the SAFE form on weight loss was similar for Geisinger and Temple participants. There is a clear relationship between weekly attendance, food diaries, and completing the SAFE form and the final weight loss. Geisinger and Temple participants were similar; those individuals who attended more sessions, kept food diaries, and completed the SAFE form had a greater weight loss.

Table 1. 12-Week and Final Values for Control and Telemedicine Subjects Who Finished Study

	<u>Controls (N=109)</u>		<u>Telemedicine (N=130)</u>	
	<u>12 weeks</u>	<u>Final</u>	<u>12 weeks</u>	<u>Final</u>
Age (yr)				
Height (in)				
Weight (lbs)	195.5 ± 33.6*	197.6 ± 35.2	197.3 ± 32.3*	201.3 ± 34.3
Waist circumference (in)	39.7 ± 4.9*	39.6 ± 5.1*	39.3 ± 5.3*	39.2 ± 5.1*
BMI (kg/m ²)	32.6 ± 5.1*	33.1 ± 5.3	32.6 ± 4.9*	33.4 ± 5.3
Fat Mass (%)	42.9 ± 9.9	42.4 ± 8.5	42.9 ± 8.0	42.7 ± 9.1
Systolic BP (mmHg)	121.6 ± 14.7*	122.6 ± 15.9*	121.4 ± 14.0*	122.2 ± 17.5
Diastolic BP (mmHg)	78.7 ± 10.2	78.3 ± 8.4	77.8 ± 8.9*	77.9 ± 9.5*
Chol (mg/dl)	196.5 ± 45.5	193.3 ± 37.0*	186.4 ± 41.1*	186.0 ± 37.4*
HDL (mg/dl)	52.4 ± 13.2	52.2 ± 14.9	50.5 ± 14.6	50.3 ± 13.4
LDL (mg/dl)	123.9 ± 37.2	121.6 ± 30.7*	118.7 ± 33.8	116.5 ± 33.1
Triglycerides (mg/dl)	110.2 ± 59.0	115.1 ± 66.8	105.0 ± 56.8	118.4 ± 89.5
Blood Glucose (mg/dl)	94.7 ± 11.8*	97.4 ± 14.8	93.8 ± 10.5*	97.9 ± 12.5
A1c (%)	5.9 ± 0.4	6.0 ± 0.5	5.9 ± 0.4	6.1 ± 0.4

Data are mean ±S.D.

* - significant difference compared to baseline at P < 0.05.

Table 2. 12-Week and Final Values for Individuals with High ($\geq 50\%$) Rates of Weekly Food Diaries vs. Individuals with Low ($< 50\%$) Rates of Weekly Food Diaries

	<u>Low (N=60)</u>		<u>High (N=179)</u>	
	<u>12 Weeks</u>	<u>Final</u>	<u>12 weeks</u>	<u>Final</u>
Age (yr)	51.7 \pm 12.1		50.3 \pm 10.7	
Height (in)	64.8 \pm 2.3		65.2 \pm 3.1	
Weight (lbs)	207.0 \pm 33.5 \dagger	208.5 \pm 33.6 \dagger	193.0 \pm 31.9*	196.7 \pm 34.7*
Waist circumference (in)	41.1 \pm 4.2 \dagger	41.3 \pm 4.5 \dagger	38.9 \pm 5.3*	38.8 \pm 5.1*
BMI (kg/m ²)	34.6 \pm 5.1 \dagger	34.9 \pm 5.1 \dagger	31.9 \pm 4.8*	32.7 \pm 5.3*
Fat Mass (%)	48.9 \pm 8.0	48.2 \pm 6.4	40.8 \pm 8.2*	40.6 \pm 8.7
Systolic BP (mmHg)	120.6 \pm 14.9	123.9 \pm 16.9	121.8 \pm 14.1*	121.9 \pm 16.7*
Diastolic BP (mmHg)	75.2 \pm 9.9 \dagger	76.4 \pm 7.6	79.2 \pm 9.2*	78.6 \pm 9.4*
Chol (mg/dl)	192.0 \pm 41.5	194.0 \pm 40.1	190.6 \pm 44.0*	187.9 \pm 36.3*
HDL (mg/dl)	54.4 \pm 14.3	52.2 \pm 13.3*	50.3 \pm 13.8	50.8 \pm 14.4
LDL (mg/dl)	123.2 \pm 31.0	127.5 \pm 35.7 \dagger	120.4 \pm 36.7	116.2 \pm 30.4*
Blood Glucose (mg/dl)	95.6 \pm 9.3	95.9 \pm 10.2	93.8 \pm 11.6*	98.2 \pm 14.5
A1c (%)	6.1 \pm 0.3 \dagger	6.1 \pm 0.4 \dagger	5.8 \pm 0.4	5.9 \pm 0.5

Data are mean \pm S.D.

\dagger - significant difference compared to High food record individuals at $P < 0.001$,

* - significant difference compared to baseline at $P < 0.05$.

