

# University of Pennsylvania

## Annual Progress Report: 2005 Nonformula Grant

### Reporting Period

July 1, 2009 – May 31, 2010

### Nonformula Grant Overview

The University of Pennsylvania received \$2,000,000 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**

*Modeling Effective Obesity Treatment to Reduce Disparities through Primary Care* - The overall goal is to improve the treatment of obesity in adults in the general population, by conducting research with men and women recruited from primary care medical practices. The study will have a particular focus on African Americans and Latinos, who have higher than average prevalence of obesity and above-average difficulty in gaining access to or benefiting from obesity treatment programs. The research will examine the influence a Lifestyle Modification Program.

### Duration of Project

6/1/2006 - 5/31/2010

### Project Overview

Center of Excellence objectives are to:

- 1) Create an effective infrastructure at Penn for oversight and support of novel research on obesity treatment in primary care.
- 2) Assess the feasibility and effectiveness of a potentially sustainable approach to obesity treatment in urban primary care settings, with particular relevance to African American and Latino adults
- 3) Foster student and faculty training and career development in the field of obesity and health disparities research.

There is one research project, with the following specific aim, as follows:

Specific Aim 1. To demonstrate in a randomized controlled trial (of 240 participants) the effectiveness of a moderate-intensity Lifestyle Modification Program for the management of obesity in primary care practice, as compared with a low-intensity version of the same program.

## **Principal Investigator**

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## **Other Participating Researchers**

Andrea J. Apter, MD, MSc, Marjorie A. Bowman, MD, MPA, Russell A. Localio, JD, PhD, MPH, Knashawn H. Morales, ScD, David B. Sarwer, PhD, Thomas A. Wadden, PhD, Kelly Allison, Marion Vetter, MD, RD- employed by the University of Pennsylvania

Tina L. Harralson, PhD, Etienne Juarez Phipps, PhD - employed by Albert Einstein Healthcare Network/Jefferson University

Christopher Barnes, PhD, Shelly Weeks-Channel, PhD, Deivy Petrescu, PhD – employed by Cheyney University of Pennsylvania

## **Expected Research Outcomes and Benefits**

The Diabetes Prevention Program (DPP) weight loss program was effective in a diverse population when delivered by specially trained staff in a large, multi-site clinical research study. The proposed study will determine: a) how well programs adapted from the DPP lifestyle modification program can be delivered by staff in primary care practices; b) how many patients who enroll in the program remain in it over time and how they differ from those who drop out of the program; c) what the rate of initial weight loss is and how well that weight loss is maintained; d) which behavioral changes are associated with successful weight loss in this programmatic situation; and e) what the effects of the program are on other clinical factors such as waist circumference, blood pressure and quality of life.

Results of this study will be applicable to African Americans and Latinos as well as others and will, therefore, have potential relevance for reducing both the overall burden of obesity and related diseases and ethnic disparities.

## **Summary of Research Completed**

Background. To achieve the research aim, we conducted a randomized trial comparing two versions of a weight loss program conducted by primary care providers (PCP) and ancillary staff acting as Lifestyle Coaches (LC) with patients recruited from their own practices. The program is called *Think Health! A Personal Weight Management Program*, or “¡Vive Saludable! Un

*programa personalizado de control de peso*”. Participants assigned to *Basic* (a low intensity treatment) were offered brief counseling by their PCP every four months for up to 2 years, depending on date of enrollment. Those assigned to *Basic Plus* (a moderate intensity treatment) received the same frequency and duration of PCP counseling plus additional, more frequent counseling by an LC. Research activities during this fiscal year included the continuation of treatment implementation, data collection, closeout of all study participants and clinical sites, and a planned interim analyses of 1-year weight change.

Treatment Implementation: *Phase 1*, that is, the period for providing all participants with their first year of treatment, ended in December 2009—approximately one year after the latest randomization date. By the end of phase 1, 90% (234 of 261) of randomized participants initiated treatment, that is, had come to at least one visit with a PCP or LC. During their first 12 months post randomization, in *Basic*, 116 (85%) of 137 randomized participants initiated treatment (PCP visit) and in *Basic Plus*, 118 (95%) of the 124 randomized participants initiated treatment (PCP or LC visit). Attendance at Phase 1 study visits is shown in Table 1. As shown, 58% and 66% of *Basic* and *Basic Plus* participants attended at least 2 PCP visits, and about 40% in each treatment group attended at least 3 visits. In *Basic Plus*, 44% of participants attended at least 5 LC visits. *Phase 2* treatment lasted for up to an additional 12 months. The frequency of PCP visits remained the same as in Phase 1 (every 4 months). For *Basic Plus*, frequency of Lifestyle Coach Visits decreased from monthly to every other month. Two *Basic* and 1 *Basic Plus* participants who had not initiated treatment in Phase 1 attended at least one treatment visit in Phase 2, for a final treatment initiation rate of 91% (n=237 of 261). Overall completion of treatment visits is shown in Table 2, combining Phase 1 and Phase 2 attendance. The percentage of possible visits attended (rather than the number of visits attended) is shown to take into account that the total possible number of Phase 2 treatment visits differed according to the participant’s remaining time on study.

Periodic, computer-generated telephone prompts were added as adherence aids in Phase 2. As with Phase 2 treatment visits, the number of possible calls varied with duration of the participant’s remaining time on study. Completed calls were defined as those that were answered and lasted long enough for the participant to hear the message and also calls for which the message was left on an answering machine. Preliminary analyses of these data indicate that calls were attempted with 171 (66%) of the randomized participants. Calls were completed with 88% of those attempted (58% percent of randomized participants), with a maximum of 3 per person. The percent of those randomized receiving 0, 1, 2, and 3 calls were 41, 34, 18, and 7%, respectively, in *Basic*; in *Basic Plus* percents were similar: 37, 28, 24, and 11%, respective, with no difference by treatment group (chi-square (df=3)=3.15; p=.37).

#### Data Collection.

*Weight was recorded at all treatment visits.* The attendance data in Tables 1 and 2, therefore, also reflect data collection at treatment visits.

*One-year interim measurement visit.* Research staff attempted to complete an interim measurement visit for all participants at approximately 1-year post randomization, with the exception of the 14 participants who had withdrawn by this time: 7 (5%) from *Basic* and 7 (6%) from *Basic Plus*, leaving 247 participants (130 in *Basic* and 117 in *Basic Plus*). Weight, waist

and blood pressure measurements, physical activity assessment, current medications, and other questionnaire data were collected at this visit. Interim measurement visits were completed by 166 (67% of 247) participants: 90 (69% of 130) in Basic and 76 (65% of 117) in Basic Plus.

*Final measurement visit.* Research staff attempted a final measurement visit for all participants who had not withdrawn, during the final months of the study. These were phased to allow for feasibility of data collection while maximizing the duration of total follow up. At the time of study closeout 235 participants remained after a total of 26 formal withdrawals (14 (10%) from Basic and 12 (10%) from Basic Plus). Of these, 143 (61% of 235) completed a final measurement visit: 76 (62% of 123) in Basic and 67 (60% of 112) in Basic Plus.

*Additional weight measurement data.* Weight data recorded in medical charts were used for participants who had been inactive (no treatment visit for 6 months if in Basic and no treatment visit for 3 months if in Basic Plus—for whom visits were expected more frequently—or no measurement visit). As described for the interim weight change analyses, these medical record weights were used to supplement weight data from treatment visits or measurement visits.

### Closeout of Participants and Clinical Sites

*Participants.* Letters were sent to notify participants about the final measurement visit and the study closing date of May 31, 2010. A letter personally signed by the Principal Investigator was then mailed to all participants, except those who had formally withdrawn, during the first week in June. The letter thanked participants for their participation, indicated that overall study results would be sent to their primary care practice within a few months, and encouraged them to continue working with their PCP to manage their weight. Tips for weight loss maintenance were provided with a reminder to also periodically consult their study manual and physical activity guide.

*Clinical Sites:* Participating PCPs were periodically reminded of the study closeout date verbally by research staff when on site. They were offered the opportunity to receive master copies of the Think Health materials on a CD, for their further use, and asked to agree to an exit/debriefing interview. The exit interview with PCPs used a semi-structured interview to assess reasons for participating in the study, challenges associated with participation, opinions of the Think Health! program including suggestions for improvement, and perspectives about continuing to offer the Think Health program after the end of the study. The interviews were conducted by a University of Pennsylvania medical student who had not been directly involved with the clinical practices or the conduct of the study. Thirteen of the original fourteen participating PCPs were eligible for these exit interviews. (The PCP who was not interviewed went on family medical leave as of December 2009, at which time her study patients were reassigned to another PCP within that practice.) As of June 30<sup>th</sup>, 9 of the 13 PCP interviews had been completed.

*Analyses of 1-Year Weight Change.* Weight change is the primary study outcome. Only the 1-year interim weight change analysis was completed in time for this annual report. A specific data set was created to analyze the interim (1-year) weight change. For this analysis, weight measurements obtained within  $\pm 7$  weeks of the participant's anniversary date were used, giving preference to the weight taken at the interim measurement visit, then using an intervention or medical record weight within the  $\pm 7$  week window when there was no interim measurement visit or when it had occurred outside of the window (see Table 3). A comparison of

measurement visit weights with medical record weights available for a nearby date confirmed the validity of using medical record weights for this purpose. Based on this data set, weight data were available for 72% (n=187) of randomized participants for the interim analysis, with no difference in data availability by treatment group.

Participants assigned to Basic Plus had statistically significant weight loss at 1 year on average (mean; 95% confidence intervals [CI]) - 1.61 kg; -2.68, -0.53), whereas participants assigned to Basic did not (mean; 95% CI) -0.62 kg; -1.45, 0.20). The treatment group difference was not statistically significant: 0.98 kg; -0.36, 2.33); p=0.15. In Basic, 5% of participants lost 5% or more of their baseline weight compared to 7% in Basic Plus, however the difference was not statistically significant (Chi-square (df=1)=0.2265, p=0.63). Weight change appeared to be greater among participants who attended more study visits. This effect was clearest and statistically significantly only in Basic Plus and was observed for both PCP and LC visits, separately and combined (Figures 1-3). The association of weight change in Basic Plus with visit attendance is interdependent for the two types of visits; that is, Basic Plus participants who attended more LC visits also attended more PCP visits.

Training Activities. Three Cheyney University students participated in the project during this fiscal year. One, placed at Penn, conducted a mentored research project using Think Health data, entitled “*Participant Feedback In A Primary Care Weight Loss Study: Think Health!*” The other two students participated in journal club and survey development activities on the Cheyney campus under the supervision of Cheyney faculty collaborators. One Penn undergraduate student and one Penn medical student (who had also been previously involved while pre-med) also worked on the project during this year. The medical student was mentored in developing a proposal and securing internal funding to collect the exit interviews with PCPs. Cheyney faculty continued the Think Health! Lecture Series on the Cheyney campus, with two Cheyney faculty and three Penn or Einstein speakers. The Penn and Einstein speakers were collaborators on this project. Dr. Allison (Penn) and Drs. Phipps and Harralson (Einstein) gave lectures, respectively, entitled: “*Eating Disorders Related to Obesity*”, “*Human Subjects Protection and Research Ethics*”, and “*Importance of Exercise in Regulating Mood.*”

Summary. During this final year of the Think Health! Study, the first and second phases of treatment were completed, with good participant and clinician retention, and the study was closed out. Overall, 91% of those randomized initiated the treatment process by attending at least one treatment visit. Interim analyses of weight loss at 1 year post randomization, based on 72% of randomized participants, indicated a small, statistically significant mean weight change in the moderate-intensity but not the low-intensity condition; the treatment group difference was not statistically significant. A dose response of weight loss by attendance at treatment visits was observed, suggesting that the program was effective in proportion to the level of participation. Training activities involved Cheyney University and University of Pennsylvania undergraduate students and one Penn medical student. Penn and Einstein faculty gave lectures at Cheyney.

<b>Table 1. Distribution of Attendance (% of participants) at Phase 1 Treatment Visits<sup>a</sup></b>				
<b>Primary Care Clinician Visits</b>			<b>Lifestyle Coach Visits<sup>b</sup></b>	
<b># visits completed</b>	<b>Basic (n=137)</b>	<b>Basic Plus (n=124)</b>	<b># visits completed</b>	<b>Basic Plus (n=124)</b>
None	15%	5%	None	7%
1	26%	29%	1-4	48%
2	18%	25%		
3	20%	22%		
4 or more <sup>c</sup>	20%	19%	5-8	25%
			9-13	19%
	100%	100%		100%

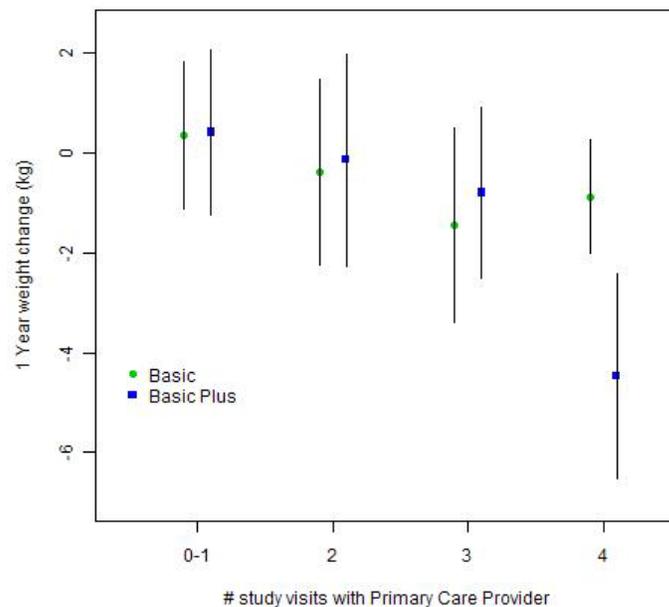
<sup>a</sup> Phase 1 treatment lasted for 12 months post randomization; for participants who withdrew, visits completed prior to the time of withdrawal were counted.  
<sup>b</sup> not applicable to Basic    <sup>c</sup> in some cases the 5<sup>th</sup> PCP visit occurred within the Phase 1 window

<b>Table 2. Distribution of Overall Attendance (% of participants) at Treatment Visits<sup>a</sup></b>			
<b>% of possible visits completed</b>	<b>Primary Care Clinician Visits</b>		<b>Lifestyle Coach Visits<sup>b</sup></b>
	<b>Basic (n=137)</b>	<b>Basic Plus (n=124)</b>	<b>Basic Plus (n=124)</b>
0%	15%	4%	6%
1% to 25% <sup>c</sup>	21%	22%	43%
26% to 50%	20%	35%	20%
51% to 75%	18%	10%	15%
76% to 100%	26%	29%	15%
	100%	100%	~100%

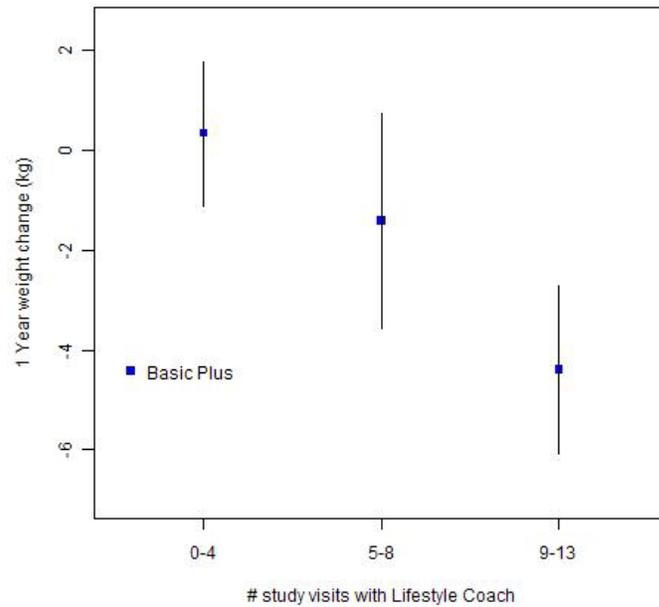
<sup>a</sup> Total treatment lasted for up to 24 months varying by date of randomization. Visit completion is, therefore, calculated with respect to percentage of possible visits attended before censoring; for participants who withdrew, possible visits are calculated for the time period prior to censoring.    <sup>b</sup> not applicable to Basic

**Table 3. Weight Data Availability for Interim (1-Year) Analysis**

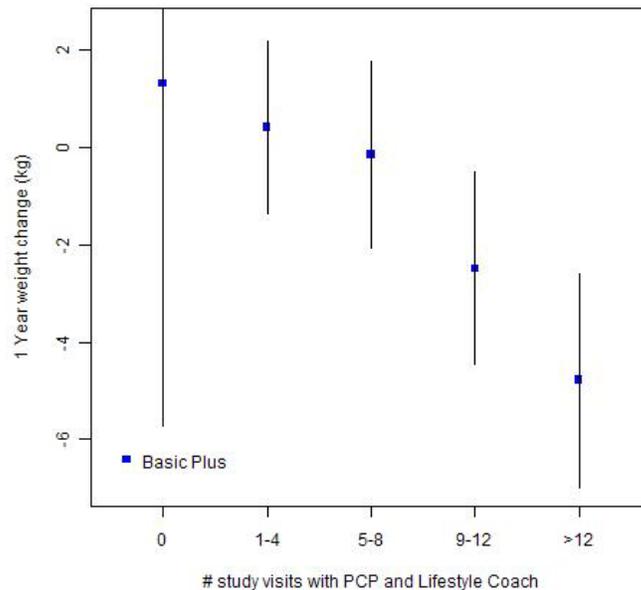
Variable	Basic (n=137)	Basic Plus (n=124)	All (n=261)
	n (%)	n(%)	n(%)
Completed interim data collection visit within $\pm$ 7 weeks of anniversary date	78 (57%)	64 (52%)	142 (54%)
Intervention or medical record weight within window	20 (15%)	25 (20%)	45 (17%)
<b>Subtotal: weight data used in interim analysis</b>	<b>98 (72%)</b>	<b>89 (72%)</b>	<b>187 (72%)</b>
Withdrew before annual visit <sup>a</sup>	7 ( 5%)	7 ( 6%)	14 ( 5%)
Other weight available, but not in window <sup>a</sup>	28 (20%)	28 (22%)	56 (21%)
Only available weight is baseline measurement <sup>a</sup>	4 ( 3%)	0 ( 0%)	4 ( 2%)
<b>Subtotal: weight data not used in interim analysis</b>	<b>39 (28%)</b>	<b>35 (28%)</b>	<b>74 (28%)</b>
<b>Total</b>	<b>137 (100%)</b>	<b>124 (100%)</b>	<b>261 (~100%)</b>
<sup>a</sup> not used for this interim analysis			



**Figure 1.** Mean (95% Confidence Intervals) of weight change at one year post randomization by number of year-one treatment visits with primary care clinician, by treatment assignment. Four was the number of possible visits for both the low- (Basic) and moderate- (Basic Plus) intensity treatment groups.



**Figure 2.** Mean (95% Confidence Intervals) of weight change at one year post randomization by number of year-one, monthly treatment visits with lifestyle coach for the moderate-intensity treatment group (Basic Plus). Thirteen was the maximum number of visits.



**Figure 3.** Mean (95% Confidence Intervals) of weight change at one year post randomization by number of total year-one, treatment visits for the moderate-intensity treatment group (Basic Plus). ~Seventeen year-one visits were possible (4 clinician visits plus ~13 lifestyle coach visits).