

Children’s Hospital of Philadelphia

Annual Progress Report: 2005 Nonformula Grant

Reporting Period

July 1, 2009 – May 31, 2010

Nonformula Grant Overview

The Children’s Hospital of Philadelphia received \$3,739,030.57 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

Primary Care Research Network for the Treatment of Adolescent Obesity - The “Primary Care Research Network for the Treatment of Adolescent Obesity” will establish infrastructure within the primary care setting to support programmatic research on weight loss for underserved adolescents, primarily urban African Americans and Latinos and rural Caucasians. Using primary care settings, to which many youths already have entry, may increase access for underserved adolescents to participate in obesity treatment and research. The primary project will be a randomized controlled study comparing a multi-family group Lifestyle Modification Program (LMP) of 23 sessions against Enhanced Usual Care (EUC) of 5 sessions for weight-loss reduction in adolescents. In collaboration with Lincoln University, the Network will develop a research training program for minority students and faculty.

Duration of Project

6/1/2006 - 5/31/2010

Project Overview

The broad objective is to establish a Center of Excellence for Research on Obesity at The Children’s Hospital of Philadelphia (CHOP) that will create a statewide, collaborative research network to develop and test effective treatments for reducing adolescent obesity and related medical co-morbidities in underserved populations. Collaborating institutions include Lincoln University (LU), GHS Health System (GHS), and the University of Pennsylvania (UPenn). Given the locations of these institutions, the investigators will focus on urban African Americans and Latinos and rural Caucasian adolescents. The novelty of this program will be the use of a family-based, lifestyle modification program within the pediatric primary care setting with interdisciplinary teams trained to treat obese adolescents. Specific aims are to: a) design, implement, and evaluate improved treatments for obese teenagers, b) conduct focus groups and treatment development projects to better understand the needs of these populations and c) train, minority students and faculty to become healthcare research professionals. The primary research

project will be a randomized clinical trial occurring at two sites: CHOP and GHS. In a four-year study, 156 adolescents (ages 13-17) will be randomized to either a one-year, 23 session, multi-family, group based Lifestyle Modification Program (LMP), or to a one-year, five-session Enhanced Usual Care (EUC). Both LMP and EUC will be tested as possible treatment protocols for primary care pediatric practice.

The primary aim is to compare the effectiveness of these two treatments in reducing body mass index (BMI) at 12 months. Secondary aims will compare impact of the treatments on reduction of risk factors related to cardiovascular disease and diabetes, including lipids, glucose and insulin, waist circumference, blood pressure, and measures of appetite. Training aims will be met through collaboration with Lincoln University to set up undergraduate summer internships, graduate assistantships, and faculty development. Other methods for achieving the objectives of the Center include: a) establishing a multidisciplinary advisory board consisting of parents, providers, and researchers; b) providing clinical training in obesity treatment for doctors, nurses, dietitians, and behavioral interventionists at our collaborating institutions (CHOP and GHS); c) making all protocols and materials culturally sensitive to the populations they serve; and d) carrying out treatment development activities to tailor the manuals for Latino youth and their families.

Principal Investigator

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Other Participating Researchers

The Children's Hospital of Philadelphia (CHOP) - Lorraine Katz, MD, , Babette Zemel, PhD, Victoria Vetter, MD, Nicholas Stettler, MD, MSCE, Chanelle Bishop-Gilyard, Psy. D., Melissa S. Xanthopoulos, Ph.D.

The Geisinger Health System (GHS) - Margaret Rukstalis, MD, William Cochran, MD
Lincoln University (LU) - Delroy Loudon, PhD, Denise Gaither-Hardy, MA, Michaille Rainey, MSW, LSW

University of Pennsylvania (UPenn) - Thomas Wadden, PhD., Reneé Moore, PhD; Janet Weiner, MPH, Leonard Davis Institute, The Wharton School of Business

Pennsylvania State University, Diane Mitchell, MS, RD

Janet Ohene-Frempong, MA, President of J O Frempong & Associates, Health Literacy Consultant
Study Monitor: - Stephanie Vander Veur, MPH, CCRC

Expected Research Outcomes and Benefits

Several outcomes and benefits are expected. First, a research infrastructure will be established

that can support ongoing programmatic research on adolescent obesity in underserved populations. This will include a focus on treatment, as well as biobehavioral, epidemiological, health services, and public policy research. Second, the study will be the largest, most rigorous effectiveness investigation of obesity treatment ever conducted for adolescents and the first major study to focus on minority and underserved youth. This will set a new standard for research in the field. Third, the clinical trial itself should yield empirically tested, culturally modified treatment manuals that can be further disseminated to other primary care settings. If the intervention is adopted by health care providers, it will broaden the numbers and reach of trained professionals equipped to treat the rising epidemic of adolescent obesity. Fourth, the research training program will develop a new cadre of investigators in obesity treatment research or related fields. The program aims to bring more minority students into the behavioral health research field, where they traditionally have low representation. Fifth, and maybe most important, adolescents and their parents should benefit from this program by adopting healthier lifestyles, losing weight, and reducing their risk for other obesity-related diseases.

Summary of Research Completed

Progress of the Randomized Clinical Trial (TEENS Study)

Implementation and Completion of the Clinical Intervention. The “TEENS” program acronym is defined as Thinking, Exercising, Eating, Nutrition, and Social support. All cohorts completed the primary randomized clinical trial (RCT) of the Group or Self-Guided Lifestyle Modification Program this year. At CHOP, Participants in Cohorts 1, 2, 3, and 4 were invited to attend follow-up booster session visits at Month 15. CHOP Cohorts 1, 2, and 3 were also extended the opportunity to attend a 6-month follow-up visit at month 18. Likewise, GHS held follow-up visits for Cohorts 1, 2, and 3 at Month 15, and held an additional follow-up at Month 18 for Cohorts 1 and 2.

The following visits were completed during this reporting period. At CHOP, Cohort 2 completed their Month 15 and Month 18 assessments. Cohort 3 completed their Month 12, Month 15, and Month 18 assessments. Cohort 4 completed their Month 6, Month 12, and Month 15 assessments. At the GHS site, Cohort 1 completed their Month 18 assessment. Cohort 2 completed their Month 15 and Month 18 assessments. Cohort 3 completed their month 6, Month 12, and Month 15 assessments. For details of the number of visits scheduled during this reporting period, see Table 1 (CHOP Visit Schedule) and Table 2 (GHS Visit Schedule). These visits included group and individual visits for the Group LMP condition and individual visits for the Self Guided LMP condition, phone counseling calls, and assessment visits.

Clinical team meetings and review of intervention protocols. Clinical team meetings took place 3 to 4 times a month at each clinical site for all clinical intervention staff to review clinical progress of all participants at each site as well as to promote consistency in the implementation of the interventions between sites. These meetings included clinical site PIs (Drs. Berkowitz and Rukstalis), interventionists, medical and nursing staff, and research staff. Dr. Berkowitz reviewed the conduct of the trial monthly with Dr. Thomas Wadden at University of Pennsylvania, who provided input regarding the conduct of the lifestyle modification program, its implementation, and retention strategies. Review of the intervention protocol, progress of

each participant, clinical and medical issues, retention, and assessments were reviewed. The research coordinators at both clinical sites communicated by phone conference and email to foster adherence to the assessment protocols and data collection procedures.

Medical Visits: There have been no study-related adverse events during this reporting period.

Retention: Retention for the primary analysis for the total sample (CHOP and GHS) during this reporting period was 65% and 67% for weeks 24 and 52, respectively.

Study Monitor: Monitoring visits for data quality and adherence to good clinical practice were conducted by an independent study monitor. Seven visits were made to the treatment sites during the reporting period and there were favorable findings at both sites.

Data Assessment and Collection: During this reporting period, anthropometric, blood pressure, behavioral and laboratory data were collected at the remaining major assessment periods (i.e. months 6 and 12) and anthropometric, blood pressure and behavioral measures were obtained at the follow-up assessment at month 18.

Exit interview. The exit interview was administered to all participants and their parent/caretaker at their last visit by study interventionists. This interview provided families with the opportunity to communicate additional information regarding program acceptability and will guide future treatment. If the participant and parent/caretaker wished further treatment, they were referred back to their primary healthcare provider (PCP) and provided a list of programs in the region.

Dietary Recall Data collected by Pennsylvania State University (PSU) Diet Assessment Center. Dietary intake was assessed from three 24-hour, multiple pass recalls collected by telephone on three random, unannounced days (1 weekend and 2 weekdays). Trained interviewers from the Penn State Diet Assessment Center (Department of Nutritional Sciences, Pennsylvania State University, University Park, PA) who were masked to participant research condition completed the assessments. During this reporting period, all assessment points (Baseline, Month 6, and Month 12) were collected and analyzed.

Data Management: During this period, the Microsoft Access database was completed. Research coordinators at CHOP were responsible for data entry and cleaning, in conjunction with the data manager and staff from BAC. Two students from Lincoln University assisted in data entry at the CHOP site. Two additional students from University of Pennsylvania were also hired and trained in data entry. Data entry progressed in accordance with the planned goals and schedule.

Data analysis and manuscript development meetings. During this period, the study statistician collaborated with the investigators and research staff in the data management process and conducted analyses on the primary and secondary aims of the RCT.

Latino Pilot Lifestyle Modification Program: The JOVEN Latino Pilot Project*

*Joven is the Spanish word for youth.

As planned, a pilot study was conducted to develop a lifestyle modification program for the treatment of obese Latino adolescents and their parent/caretaker. The following describe the

development of program materials, recruitment of a clinical site, recruitment and training of bilingual staff, and recruitment and treatment of Latino adolescents and their parents/caregivers.

Planning Phase Completed: Investigators from CHOP and GHS completed the design and received IRB approval for the 4-month pilot study of the group lifestyle modification program for eligible Latino adolescents (ages 12-16 with BMI ≥ 28 kg/m²) and their parents. This pilot tested the feasibility and acceptability of materials of the Group family-based lifestyle modification program. This program consisted of 12 sessions for weight management in Latino adolescents. At least one participating parent was involved.

Research Infrastructure development: a new clinical research site, the Geisinger Primary Care Intervention Site at Milton, PA. The JOVEN-Latino Intervention was conducted using the waiting, examination and conference rooms at Milton-Geisinger Clinic, where 20-30% of the primary care patients speak Spanish. Bilingual medical staff, lifestyle interventionists, and research staff were trained in the conduct of the intervention. Weekly clinical meetings were held to review recruitment, the intervention protocol, progress of all participants, assessments, and the conduct of the study intervention. Data collection included assessments at baseline and month 4 of the participants' weight, height, waist circumference, as well as the psychosocial, and laboratory measures similar to the TEENS Study. (This pilot study will allow further potential research applications to be developed to include Latino youth in research.)

Spanish Language Lifestyle Modification Program Materials Development. Adolescent and parent intervention manuals were adapted from the TEENS manual (from the primary RCT) for the 12 sessions (4 months) of the JOVEN-Latino Pilot program. The Spanish translation of treatment manuals, informed consent, assent, and parent permission materials was reviewed and approved by three bilingual physicians at GHS and then certified by a local certification company, Lexiteria (Pennsylvania).

Recruitment and conduct of the intervention: Seven Latino adolescents and one participating parent or other family member of each adolescent were recruited using advertisements and brochures with English and Spanish translated descriptions of the study. At baseline and at week 16, assessments of weight, height, body mass index (BMI), laboratory measures (fasting lipids, glucose, insulin, and HOMA), blood pressure and pulse rate, and progress noted at visits were recorded in the electronic health record (EPIC) and were made available to Geisinger healthcare providers. On average, the adolescents were severely obese with a BMI of M (SD) 35.3 (3.5) kg/m² at 15.6 years of age.

Revised Timeline: Originally the investigators had planned to pilot about 30 families. This goal was not reached, due to the time demands of the TEENS Study, the RCT. Factors that contributed to the delay in pilot start up included: the development of Spanish materials, the selection of an appropriate primary care site, and recruiting and training of staff – all required additional time.

Attendance: The majority of the group sessions were multi-lingual and multi-generational. Adolescents attended the sessions with one or two parents, siblings, or other family members (aunt and/or grandparent). Seven adolescents attended the first 6 sessions and 6 out of 8 missed

one of the twelve sessions. One teen had an appendectomy (missed 1 session, not study related) and one missed the last session related to school field trip. All adolescents and parents/caretakers completed the pilot study.

Abstracts during this period: Analyses completed during the reporting period culminated into three abstracts presented at the annual scientific meeting of The Obesity Society (TOS) in October 2009.

1. Bishop-Gilyard, C., Cronquist, J., Gehrman, C., Liepinis, N., Xanthopoulos, M., Sarwer, D., Wadden, T., Berkowitz, R. *Meal Preparation Involvement Among in a Lifestyle Modification Program*. Presented at the 27th annual scientific meeting of The Obesity Society, Washington, DC, October 2009.
2. Quinlan, N. P., Rukstalis, M. R., Diewald, L. K., Hoffer, K., Berkowitz, R. I., & Faith, M. S. (2009). *Electronic Health Record (EHR) recruitment for early childhood overweight intervention research*. Presented at the 27th annual scientific meeting of The Obesity Society, Washington, DC, October 2009.
3. Xanthopoulos MS, Khouri LM, Usas JC, Rezet BE. Clinician management of pediatric obesity: A survey of knowledge, attitudes, practices, and barriers. Poster Session. The Obesity Society. Washington, D.C., October 2009.

Publication Plan: The Executive Committee met to identify publication plans for the data set. During the reporting period, manuscripts were accepted or submitted:

1. Body Mass Index Measurement and Obesity Prevalence in Ten U.S. Health Plans. Arterburn D, Alexander G, Calvi J, Coleman L, Gillman M, Novotny R, Rukstalis M, Stevens V, Taveras E, Sherwood N. Accepted in *Clinical Medicine & Research*.
2. Maintenance of Weight Loss in Adolescents: Current Status and Future Directions Meghan L. Butryn, Ph.D., Thomas A. Wadden, Ph.D., Margaret R. Rukstalis, M.D., Chanelle Bishop-Gilyard, Psy.D., Melissa S. Xanthopoulos, Ph.D, Delroy Loudon, Ph.D., Robert I. Berkowitz, M.D. Accepted in *Journal of Obesity*.

Leveraged Funds and Grants Submitted: During this reporting period, a number of proposals were submitted and projects funded resulting in additional funds leveraged from the current grant. These projects include:

NIH (NHLBI) K23 application: “Weight loss treatment for obstructive sleep apnea syndrome in obese adolescents.” (NHLBI. Received a score of 38 in May 2010; pending council review).

- Melissa Xanthopoulos, Ph.D., CHOP pediatric psychologist on this study (mentored by Carole Marcus, M.D. at CHOP, and PA DOH study PIs. Robert Berkowitz, M.D. (CHOP), and Thomas Wadden, Ph.D. (UPenn)

NIH(NIDDK)/R01 “Behavioral and Pharmacological Therapy of Adolescent Obesity” (submitted July 2009). Reviewed and did not receive a fundable score, October 2010

- Robert. Berkowitz, M.D. (CHOP) PI, Thomas Wadden, Ph.D., Co-PI (UPenn).

NIH (NHLBI/NICHD)/U01 “Combined behavioral and pharmacologic intervention for severe

obesity in adolescents.” This application combines the family based lifestyle modification program with other forms of treatment, including use of meal replacements and pharmacotherapy in a RCT. Submitted October 2009; received a potentially fundable score (26), however was not funded due to budgetary constraints at NHLBI.

- Dr Berkowitz (at CHOP), Dr. Wadden (at UPenn), and Drs. Williamson and Martin from the Pennington Biomedical Research Center/Louisiana State University.

Infrastructure Development

During this reporting period, the following developments improved the research infrastructure for the investigators and the network:

1. The Latino pilot study, the JOVEN project, recruited a new primary care site for the pilot study of Latino youth, developed materials, hired and trained bilingual staff, developed intervention materials in Spanish, and collected outcome data. This site (Milton-Geisinger Clinic) adds a potential site for future clinical trials.
2. Geisinger Health System laboratories created a HIPPA compliant, electronic data management transfer system. Laboratory data were provided electronically by the GHS clinical laboratory for the randomized clinical trial and were sent directly to the UPenn/CHOP’s data management and statistical team.
3. In addition to the presentation described above, further dissemination capacity was developed by the network. Collaboration was developed with the Dissemination Group at the Leonard Davis Institute (LDI) of the Wharton School of Business at the University of Pennsylvania to provide the investigators with a new structure for dissemination of the results of the primary study.
4. A data management system was developed for the study at the University of Pennsylvania’s Center for Clinical Epidemiology and Biostatistics (CCEB) between CHOP, GHS, and UPenn. This data management system has set up a structure which has facilitated current analyses and will assist with future analyses for our multi-site trials planned for the network.

Rural Research Infrastructure at Geisinger. Investigators from both CHOP and GHS treatment sites used Geisinger Laboratories for assessment of insulin, glucose, lipid profile, liver function tests and other secondary metabolic parameters associated with obesity related co-morbid medical problems. CHOP investigators had web access to real time laboratory reports, and de-identified data from both sites were sent electronically with study ID numbers to the CHOP data management unit.

Research Activities by Lincoln University (LU) faculty: The LU investigators participated with the other investigators regarding the conduct of the RCT, including meetings regarding data analyses. Further, LU faculty expanded their own research in obesity. The prevalence of obesity is increasing among all Americans but has reached epidemic proportions among African Americans. The need to assess and develop prevention, intervention and treatment programs for obese adolescents, particularly those attending colleges and universities, is essential given the co-

morbidity factors associated with obesity. Therefore, during this reporting period, research at Lincoln University has focused on knowledge of nutritional content, food selection patterns, and caloric intake of African American college students. LU researchers used survey methodology to evaluate several modalities of student information sources. During this period, data were collected regarding food selection as it related to visual cues (whether a picture was present or not). Six food components (sodium, cholesterol, fat, protein, fiber, carbohydrates and calories) were included in this study. Over 1300 students participated in these research projects. Results for all studies are forthcoming. The goals of these studies were to generate information on knowledge, attitudes and practices (KAP) of college students and to develop a database of information as it pertains to an African American college population at an Historically Black College and University (HBCU).

Cross Site Meeting: The fifth Cross-Site Meeting of the study was held on November 9, 2009 at Lincoln University. The main goal of the meeting was to review the progress of the RCT (the TEENS study) with the Lincoln team, both clinical sites (CHOP and GHS), UPenn researchers, and the advisory board members. Another aim of the meeting was to visit the Lincoln University site and receive updates about the preliminary findings in their research projects. Dr. Delroy Loudon and Ms. Denise Gaither Hardy reviewed their studies of surveys of Lincoln University students' dietary choices and choices available to them in the cafeterias. In addition, they reviewed the Lincoln University faculty's interest in obesity research and the university's effort to measure BMI and to provide health promotion programs to the students. Further, there was an interventionist training regarding the implementation of the lifestyle modification program and a review of common clinical situations, role-playing how best to support the adolescents and parents/caregivers during the program. Thirty interventionists and research staff from CHOP, GHS, Lincoln University, and UPenn attended the meeting. In addition, members of the advisory committee were in attendance.

Table 1. Participant Visit Schedule at CHOP

Chop Visit Schedule, July 1, 2009-May 31, 2010				
	Cohorts			
	1	2	3	4
Participants who started treatment	18	19	29	26
Group Condition-Clinic Meetings:				
Group Sessions			3	8
Individual Family Meetings			1	3
Group Check-In Phone Calls			3	7
Self-Guided Condition-Clinic Meetings:				
Self-Guided Sessions			1	3
Phone Meetings with Health Coach				1
Major Assessments:				
Baseline				
Month 6				X
Month 12			X	X
Follow-up Visits:				
Month 15		X	X	X
Month 18		X	X	
Total Number of Scheduled Contacts:				
Group		2	6	12
Self-Guided		2	3	4
Phone Meetings in Self-Guided and Group Conditions			3	8

Table 2. Participant Visit Schedule at GHS

GHS Visit Schedule, July 1, 2009-May 31, 2010			
	Cohorts		
	1	2	3
Participants who started treatment	24	25	28
Group Condition-Clinic Meetings:			
Group Sessions			5
Individual Family Meetings			3
Group Check-In Phone Calls			7
Self-Guided Condition-Clinic Meetings:			
Self-Guided Sessions			3
Phone Meetings with Health Coach			1
Major Assessments:			
Baseline			
Month 6			X
Month 12			X
Follow-up Visits:			
Month 15		X	X
Month 18	X	X	
Total Number of Scheduled Contacts:			
Group	1	2	9
Self-Guided	1	2	4
Phone Meetings in Self-Guided and Group Conditions			8