

Wills Eye Health System

Annual Progress Report: 2009 Nonformula Grant

Reporting Period

June 1, 2010 – June 30, 2010

Formula Grant Overview

The Wills Eye Health System received \$3,598,366 in nonformula funds for the grant award period June 1, 2010 through May 31, 2014. Accomplishments for the reporting period are described below.

Research Project: Project Title and Purpose

Confronting Unequal Eye Care in Pennsylvania - The purpose of the research project is to increase access to eye care for older African Americans with diabetes and to provide research training and mentoring for minority students. We will conduct a randomized, placebo-controlled clinical trial to test the efficacy of Behavior Activation, which is a culturally relevant intervention, to increase rates of dilated fundus examinations in this population. We have also developed a research training and mentoring program to increase minority nursing and biomedical students' research skills.

Anticipated Duration of Project

6/1/2010 - 5/31/2014

Project Overview

The project's overarching goals are to increase older African Americans' access to eye care and to promote minority students' interest in pursuing research careers. Older African Americans with diabetes are more likely than Whites to develop and go blind from diabetic retinopathy (DR), which is a major complication of diabetes. To prevent and treat DR, dilated fundus examinations (DFE) are necessary. However, African Americans are less likely to have DFEs than Whites. To reduce this health disparity, we propose the following Specific Aims:

1. To conduct a randomized, placebo-controlled clinical trial to test the efficacy of Behavior Activation (BA) to increase rates of DFEs in older African Americans with diabetes. The control treatment is Supportive Therapy, which is a placebo condition that controls for the interpersonal attention that subjects randomized to active treatment will receive. Both interventions will be conducted in subjects' homes. We will enroll 206 older African Americans with diabetes who have not had a DFE in the past year and randomize 50% to each treatment group in this 6 month clinical trial. We hypothesize that 60% of subjects who receive Behavior Activation compared to 35% of subjects who receive Supportive Therapy will receive a DFE by 6 months. Secondary

outcomes include knowledge of the risk of diabetes complications, adherence to diabetes self-care recommendations, and depressive symptoms. We will also examine the long term efficacy of BA to increase annual DFE rates.

2. To develop a Minority Research Training and Mentoring Program at the Wills Eye Health System for undergraduate and graduate minority nursing and biomedical students to increase their research skills and promote their interest in pursuing research careers. To accomplish Aim 2, we will create a minority training program and summer research internship for up to four minority students per year.

Principal Investigator

Julia A. Haller, MD
Ophthalmologist-in-Chief
Wills Eye Health System
840 Walnut Street, 15th Floor
Philadelphia, PA 19107

Other Participating Researchers

Lisa Hark, PhD, RD, Ann Murchison, MD – employed by Wills Eye Health System
Barry Rovner, MD, Robin Casten, PhD, Laura Gitlin, PhD, Christine Arenson, MD, James Plumb, MD, MPH, Brooke Salzman, MD, Benjamin Leiby, PhD, Kathy Ashton, PhD, Brandon Johnson, MD, Neva White, BS – employed by Thomas Jefferson University
Rickie Brawer, PhD, MPH – employed by Thomas Jefferson University Hospital
Jeffrey Henderer, MD, Omesh Gupta, MD, David Barclay, MD – employed by Temple University School of Medicine

Expected Research Outcomes and Benefits

This research project will have both immediate and long-term outcomes. The immediate outcome is 2-fold. First, we will determine the efficacy of an innovative, culturally relevant intervention to increase rates of diabetic eye screening in older African Americans. We know that many patients in this population do not fully understand diabetic eye disease or how to access care to prevent it. Our research will demonstrate ways to increase their access, thereby reducing their risk for vision loss and blindness and a pervasive health disparity. The research project's second immediate impact is that we will increase the research skills of a cadre of undergraduate and graduate minority nursing and biomedical students through direct participation in our research projects and research training programs. We will accomplish this via a research training program that consists of a summer research internship and individual student mentoring. The ultimate goal is to promote minority nursing and biomedical students' interest in pursuing research careers as another step towards reducing health disparities.

The long-term impact of our work will be to prevent unnecessary suffering and disability in an underserved population at high risk for vision loss. If our efforts are successful, they will reduce costs associated with vision-related depression, falls, hip fractures, and nursing home placement.

Ultimately, the intervention that we are testing can serve as a broad-based, community health model for other medical conditions that disproportionately affect African-Americans such as asthma, hypertension, and prostate cancer, where treatment adherence is similarly low. In this way, our translational research project's impact extends well beyond the treatment of disorders of the eye. It will provide important new information to patients, clinicians, and policy makers about effective interventions that have the potential to save money using low cost, culturally relevant, community-based interventions.

Summary of Research Completed

This annual report covers project activities undertaken from June 1-31, 2010. Our activities have focused mainly on the development, completion, and submission of Institutional Review Board applications for review at Wills Eye Health System, Thomas Jefferson University, and Temple University for Aim 1. Additional activities related to Aim 1 (the clinical trial) include personnel recruitment and identification of hardware and software requirements. During June 2010 study staff begin the process of refining study materials such as the Manual of Procedures (MOP) and treatment manuals for both the active and control interventions. Final drafts of these documents will likely be completed by August 2010. During grant year 1, we also initiated Aim 2: The Minority Research Training and Mentoring Program.

IRB Applications

IRB approval from the applicant organization was granted on May 19, 2010. We are in the process of obtaining IRB approval from collaborating institutions, namely Thomas Jefferson University (TJU) and Temple University (TU). All documentation was submitted to the IRB at TJU, and we expect to receive formal approval shortly. The protocol to be submitted to the IRB at TU is now complete and we expect the board to review this study on June 27, 2010. Copies of IRB approvals from the subcontract sites will be submitted to the PA DOH as soon as they are available. In addition, we currently have an amendment to the protocol under review at Wills. The purpose of this amendment is to allow us to recruit patients to serve as practice subject for study staff (the BA interventionist, the ST interventionist, the study assessor) who are undergoing training. We will require that each study interventionist deliver their respective interventions to 5 practice patients, and that the study assessor administer study assessments to 10 practice patients.

Personnel Recruitment

We created job descriptions, identified candidates, interviewed prospective candidates, and hired the appropriate candidates for the research coordinator, research assistant, and the three community health educator positions.

Hardware and Software Requirements

In order to minimize human error for data entry, we are utilizing a computer software program, Teleform, which will convert data entered from the field by the Community Health Educator - Assessor into SPSS, which is our data analysis program. Additionally, we will use the web-

based server version of FileMaker Pro, which will enable us to have an online dynamic database that will be available for entering data by research personnel at our three sites. We have identified the appropriate laptops and computers that will be able to support these software programs.

Instrument and Protocol Development

We have identified instruments that will enable us to test our secondary and exploratory aims of the study. These instruments mainly include the Patient Health Questionnaire-9, used to assess depression; the Diabetes Self-Care Inventory-Revised questionnaire, used to assess patient adherence to diabetes self-care recommendations; and the Risk Perception Survey-Diabetes Mellitus, used to assess risk perception and risk knowledge of diabetes and its complications.

Additionally, we began developing the Manual of Procedures (MOP) which will outline all details of the clinical trial. The training manuals for both study interventions are in the process of being refined. We expect final drafts to be completed by August 2010.

Subcontractor communication

Subcontractor agreements were developed and sent to Thomas Jefferson University and Temple University's Office of Research Administration. These agreements will be completed and finalized following IRB approval from the respective institutions. Investigators from all collaborating institutions have been meeting on a regular basis to implement study start up activities.

The Minority Research Training and Mentoring Program (MRTMP)

We have selected two African-American students, one pre-health undergraduate (Jolecia Flournoy) and one graduate biomedical science student (Bianca Collymore) to begin the MRTMP. These students have attended lectures (see Table 1) aimed at the Jefferson CURE grant Minority Research Training Program organized by Scott Waldman, PhD and Elizabeth Rappaport, MD. These lectures are designed to help them learn about different aspects of conducting clinical and laboratory research. These students have been involved with all of the tasks described above during the development of the study period.

Table 1: MRTMP Lectures Attended at Jefferson Medical College			
Date	Time (hours)	Title	Speaker
June 8, 2010	1.0	Animal Care and Use	Judith Daviau, DVM
June 8, 2010	1.0	Environmental and Laboratory Safety	Sue Gotta, Biosafety Officer
June 15, 2010	1.0	Responsible Conduct of Research	John Flynn, PhD
June 15, 2010	1.0	Institutional Review Board (IRB), Human Subjects	Bruce Smith, MD, CIP
June 22, 2010	2.0	What is a Clinical Trial? Principles and Procedures of Studies Involving Human Subjects	Kathleen Ashton, PhD