

Wills Eye Health System

Annual Progress Report: 2009 Nonformula Grant

Reporting Period

July 1, 2010 – June 30, 2011

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 Behavioral 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 Caucasians 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 Caucasians. 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 (ST), which is a placebo condition that controls for the interpersonal attention that subjects randomized to active treatment will receive. Both interventions are 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 to increase research skills and promote interest in pursuing research careers for undergraduate and graduate minority nursing and biomedical students. 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

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Other Participating Researchers

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Rickie Brawer, PhD, MPH; Brandon Johnson, MD; Neva White, MSN, CRNP, CDE (Thomas Jefferson University Hospital)
Jeffrey Henderer, MD (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 two-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 test a program to increase access to ophthalmology care, thereby reducing African Americans' risk for vision loss and blindness which is 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 with didactic and hands-on training as well as 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 loss and its complications (e.g. depression, falls and fall related injuries, and nursing home placements). 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 July 1, 2010 – June 30, 2011. Our activities have focused on finalizing and implementing the research protocol at Wills Eye Health System (WEHS), Thomas Jefferson University (TJU), and Temple University (TU) for Aim 1. These activities included training research staff on study protocols (including assessing and administering study interventions to 10 practice subjects), implementing subject recruitment procedures, and enrolling and randomizing 80 subjects into the trial. During grant year 2, we initiated a second and more formal didactic Minority Research Training and Mentoring Program which is a part of Aim 2.

Staff Trainings

Staff training for two assessors, one BA interventionist, and one ST interventionist began in August 2010. Training consisted of a series of didactics, followed by staff performing their designated responsibilities with practice subjects. IRB approval was obtained in July 2010 to enroll 10 practice subjects for training purposes (referred to as the practice sample). The practice sample was used to train study assessors on obtaining informed consent and administering the study assessments. Five practice subjects received BA and four received ST. These were administered by study interventionists for training purposes. All sessions with practice subjects (both assessment and intervention sessions) were audio taped and reviewed for training purposes by Drs. Casten and Hark. All audio tapes of practice sessions received extremely favorable ratings. Training was completed in October 2010.

Protocol Development and Amendments

The following amendments were made to the protocol for the clinical trial. All amendments have been approved by the Wills IRB and Temple IRB.

1. We added neuropsychological tests to the baseline and 6-month assessments. Older people with diabetes are likely to experience cognitive impairment. By collecting data on cognitive functioning, we will be able to determine the extent to which the intervention is effective for people with varying levels of cognitive impairment.
2. We added specific procedures for reporting adverse events to the IRB.
3. We developed recruitment flyers to advertise the study in local clinics.
4. We developed the following materials to minimize attrition: Retention letters for subjects who leave the study, confirmation letters to verify the date and time of the visit as well as a

photograph of the Community Health Educator, a Question-and-Answer Fact Sheet about the study protocol, a Results/FAQ Sheet about Hemoglobin A1C, a contact information for the two ophthalmologists in the study to schedule a DFE, and a Wrong Number Recruitment Letter mailed to those patients we have been unable to contact due to disconnected/wrong phone numbers.

5. We added a Jefferson Internal Medicine Associates (JIMA) diabetes care letter with the study recruitment letter to JIMA (JIMA) patients.
6. We amended the protocol to expand recruitment to senior/community centers, health fairs, and area churches. This amendment included supplementary materials to support expanded recruitment, including web advertisements and newsletter/newspaper advertisements.

Protocol Reapproval

The WEHS IRB reapproved the study for an additional year on April 14, 2011 and TU IRB reapproved the study for an additional year on May 18, 2011.

Recruitment

A total of 1,496 patients from TJU clinics and TU clinics met preliminary eligibility criteria (age ≥ 65 , African American, type 2 diabetes). Six hundred thirty-three (633) Jefferson patients and 863 Temple patients were identified through primary care practices and were sent recruitment letters via mail. Table 1 summarizes recruitment outcomes for both recruitment sites. As of June 30, 2011 39 Jefferson patients and 37 Temple patients have completed baseline assessments and have been randomized.

As we began exhausting our potential patient pool from the TJU and TU primary care clinics, we expanded recruitment efforts to community centers, health fairs, and churches. At these events/places, research staff informed interested attendees about the study and handed out recruitment flyers to those who were interested. Twenty-six (26) people expressed interest in the study. Of these, 10 did not meet preliminary eligibility criteria. Five agreed to participate and four have completed their baseline assessment and have been randomized. Recruitment outcomes for community outreach efforts are summarized in Table 1.

In total, 80 subjects have completed their baseline assessment and have been randomized to either the BA or ST intervention as of June 30, 2011. Baseline demographic statistics for the 80 randomized patients can be found in Table 2. Of those 80 subjects, four have dropped out of the study. One participant dropped out of the study due to disinterest; one participant was hospitalized for an extended period of time; one participant was placed in hospice care; one participant died before the 6-month follow-up assessment. Our current attrition rate (11%) is lower than initially anticipated (20%).

Forty-eight (48) subjects have completed their four treatment sessions. Of these subjects, 31 subjects have completed their 6-month follow-up assessment. Twenty-eight (28) subjects are currently receiving BA or ST interventions.

Outcomes Data

Our primary hypothesis for Aim 1 is that a greater proportion of subjects who receive BA will have a dilated eye examination by 6 months compared to subjects who received ST. The primary outcome measure is medical documentation of a DFE. During the 6-month follow-up assessment all subjects are asked if they obtained a DFE and verification will be obtained by reviewing medical records. Subjects who dropped from the study and are missing follow-up data at 6 months will be excluded from analysis.

Secondary hypotheses for Aim 1 include:

- a) subjects who receive BA will increase their risk perception and risk knowledge of diabetes and its complications to a greater extent compared to subjects who receive ST at 6 months;
- b) subjects who receive BA will increase their adherence to diabetes self-care recommendations to a greater extent compared to subjects who receive ST at 6 months;
- c) subjects who receive BA will have lower levels of depressive symptoms compared to subjects who receive ST at 6 months.

These secondary outcomes are measured by the Risk Perception Survey for Diabetes Mellitus (RPS-DM), the Diabetes Self Care Inventory – Revised (SCI-R), and the Patient Health Questionnaire (PHQ-9). The means for these secondary outcomes at baseline by treatment group can be found on Table 3.

One exploratory hypothesis for Aim 1 is that subjects who receive BA will have a larger reduction in A1C levels from baseline to 6 months compared to subjects who receive ST. A target A1C for individuals with diabetes is less than 7%. At baseline, 39 of the 73 (53.4%) subjects who had A1Cs tested had A1C levels above 7%. Table 4 shows the mean A1C levels for all subjects and by treatment group at baseline.

The Minority Research Training and Mentoring Program (MRTMP)

Six students were selected from a pool of 12 applicants to participate in the 9-week MRTMP that began June 13, 2011. In addition, two students asked to volunteer in order to participate in the program. The students come from a variety of backgrounds: one African-American medical student, one African-American nursing student, one African-American master's student, one Hispanic-American medical student, one African-American undergraduate, two Indian-American med students, and one Indian-American college graduate. We created a syllabus for the students, elements of which include: a lecture series (see Table 5) involving Co-Investigators on Aim 1 as well as outside faculty from Thomas Jefferson University, mentorship sessions with faculty members from the Wills Eye Health System as well as TJU, and copies of major grant protocols from the Wills Eye Health System Department of Research. The program's goal is to introduce minority students to clinical research by providing hands-on experience by having direct exposure to community epidemiological and public health research and clinical trials.

Table 1: Subject Recruitment Outcomes				
Recruitment Site	Jefferson	Temple	Community*	Total
Subjects meeting preliminary eligibility criteria*	633	863	16	1512
Subjects enrolled	39	37	4	80
Ineligible subjects	346	111	11	468
Subjects declined	107	11	0	118
Subjects with outcome pending	141	704	1	846
Reasons for Ineligibility				
Subjects report DFE	225	78	10	313
Deceased	24	22	0	46
Cognitive Impairment	43	8	1	52
Reports they do not have diabetes	20	0	0	20
Lives out of range	10	0	0	10
Other (too sick, hard of hearing)	24	3	0	27
Reasons for Refusal/Declining				
Not interested	80	8	0	88
No time	13	0	0	13
Other reasons	14	3	0	17
Outcome Pending				
Have not opted-in**	Not applicable	677	Not applicable	677
Wrong Address	0	15	0	15
Wrong Number	32	3	0	35
Wait to call	6	3	1	10
Left message	103	6	0	109

* Includes only persons who met preliminary eligibility criteria (age ≥ 65 y/o, African American, type 2 diabetes).

**At Temple University 159 patients opted-in to the study

Table 2: Baseline Demographic Characteristics by Treatment Group						
	<i>BA Subjects (n=40)</i>		<i>ST Subjects (n=40)</i>		<i>Total Subjects (n=80)</i>	
	n	%	n	%	n	%
Marital Status						
Married	12	30.0	10	25.0	22	27.5
Widowed	10	25.0	18	45.0	28	35.0
Divorced	10	25.0	8	20.0	18	22.5
Other	8	20.0	4	10.0	12	15.0
Gender						
Female	25	62.5	29	72.5	54	67.5
Male	15	37.5	11	27.5	26	32.5
Living Status						
Lives Alone	18	45.0	16	40.0	34	42.5
Age						
Age 65 to 74	28	70.0	26	65.0	54	67.5
Age 75 to 84	11	27.5	12	30.0	23	28.8
Age 85+	1	2.5	2	5.0	3	3.7
Education*						
< 12 years	16	41.0	15	37.5	31	38.8
≥ 12 years	23	57.5	25	62.5	48	60.0

* 1 BA Subject did not provide education.

Table 3: Secondary Outcomes at Baseline by Treatment Group						
	<i>BA Subjects (n=80)</i>		<i>ST Subjects (n=40)</i>		<i>Total Subjects (n=80)</i>	
	Missing	Mean (SD)	Missing	Mean (SD)	Missing	Mean (SD)
RPS-DM						
Risk Knowledge ¹	0	4.18 (1.02)	0	4.12 (0.94)	0	4.15 (1.02)
Perceived Personal Control ²	0	3.18 (0.60)	0	3.10 (0.50)	0	3.14 (0.55)
Worry ³	0	3.15 (0.67)	0	2.76 (0.66)	0	2.96 (0.69)
Optimistic Bias ⁴	0	2.21 (0.78)	1	2.15 (0.68)	2	2.19 (0.73)
Personal Disease Risk ⁵	0	2.86 (0.74)	0	2.99 (0.84)	0	2.92 (0.79)
Environmental Risk ⁶	0	2.19 (0.67)	0	2.21 (0.52)	0	2.20 (0.60)
SCI-R Scaled Score	0	52.89 (15.34)	0	51.53 (13.81)	0	52.21 (14.52)
PHQ-9 Total Score⁸	0	5.57 (4.49)	0	5.33 (4.98)	0	5.45 (4.71)

¹ Scores range from 0 to 5 with higher scores indicating greater knowledge of diabetes complications.

² Scores range from 1 to 4 with higher scores indicating more perceived control and less perceived risk over diabetes complications.

³ Scores range from 1 to 4 with higher scores indicating more worry.

⁴ Scores range from 1 to 4 with higher scores indicating more optimistic bias; lower scores indicating greater realism/pessimism.

⁵ Scores range from 1 to 5 with higher scores indicating greater perceived personal disease risk.

⁶ Scores range from 1 to 4 with higher scores indicating greater perceived environmental risk.

⁷ Scores range from 0 to 100 with higher scores indicating greater adherence to self-care recommendations.

⁸ Possible scores range from 0 to 27, with higher scores indicating worse depressive symptoms.

Table 4: A1C Data at Baseline by Treatment Group			
	<i>Baseline</i>		
	N	Missing*	Mean A1C % (SD)
All subjects	80	7	7.48 (1.62)
BA subjects	40	3	7.46 (1.74)
ST subjects	40	4	7.50 (1.52)

*Participants did not agree to have their A1C measured during the study.

Table 5: Minority Research Training and Mentoring Program Lecture Series		
<i>Date</i>	<i>Topic</i>	<i>Lecturer</i>
Tue. 6/14	What Is Clinical Research?	Dr. Robin Casten
Wed. 6/15	Vision and Public Health Research	Dr. Elaine Yuen
Thur. 6/16	Enhancing Grant Writing Skills	Dr. Lisa Hark
Tue. 6/21	Measurement and Data Collection	Dr. Robin Casten
Wed. 6/22	Designing Clinical Research Trials	Dr. Barry Rovner
Wed. 6/22	IRB Protocol	Dr. Anna Murchison
Thur. 6/23	What Are Populations and Samples?	Dr. Kathleen Ashton
Tue. 6/28	Obtaining Consent	David Weiss
Thur. 7/7	Research Ethics	Dr. Kathleen Ashton
Wed. 7/13	Statistics in Clinical Research	Dr. Ben Leiby
Thur. 7/21	Resume Writing Workshop	Dr. Lisa Hark
Thur. 7/28	Research Funding Opportunities for Students	Dr. Lisa Hark